

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2021

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number 001-04321

**CONTEXT THERAPEUTICS INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State of other jurisdiction of incorporation or organization)

**86-3738787**  
(I.R.S. Employer Identification Number)

**2001 Market Street, Suite 3915, Unit #15**  
**Philadelphia, Pennsylvania 19103**  
(Address of principal executive offices, including zip)  
(267) 225-7416  
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock, par value \$0.001 per share	CNTX	The NASDAQ Stock Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports); and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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.

Indicated by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

As of June 30, 2021 (the last business day of the registrant's most recently completed second fiscal quarter), the registrant's common stock was not listed on any exchange or over-the-counter market. The registrant's common stock began trading on the Nasdaq Stock Market on October 20, 2021. Therefore, the registrant is unable to calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of June 30, 2021.

As of March 18, 2022, the registrant had 15,966,053 shares of common stock, \$0.001 par value per share, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive Proxy Statement for its 2022 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K are incorporated by reference in Part III, Items 10-14 of this Annual Report on Form 10-K.

EXPLANATORY NOTE

On April 23, 2021, we completed a reverse triangular merger, resulting in Context Therapeutics Inc. becoming the sole holder of 100% of the membership interests in Context Therapeutics LLC. In connection with the merger, all of the common units, preferred units and all options, warrants or other rights to purchase common or preferred units of Context Therapeutics LLC converted into common stock, preferred stock and all options, warrants or other rights to purchase common or preferred stock of Context Therapeutics Inc. (the "reorganization").

---

---

---

## TABLE OF CONTENTS

<a href="#">Note Regarding Forward-Looking Statements</a>	<a href="#">ii</a>
<a href="#">Risk Factor Summary</a>	<a href="#">iv</a>
<a href="#">Market, Industry and Other Data</a>	<a href="#">v</a>
<a href="#">Part I</a>	
<a href="#">Item 1. Business</a>	<a href="#">1</a>
<a href="#">Item 1A. Risk Factors</a>	<a href="#">36</a>
<a href="#">Item 1B. Unresolved Staff Comments</a>	<a href="#">70</a>
<a href="#">Item 2. Properties</a>	<a href="#">70</a>
<a href="#">Item 3. Legal Proceedings</a>	<a href="#">70</a>
<a href="#">Item 4. Mine Safety Disclosures</a>	<a href="#">70</a>
<a href="#">Part II</a>	
<a href="#">Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</a>	<a href="#">71</a>
<a href="#">Item 6. [Reserved]</a>	<a href="#">71</a>
<a href="#">Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	<a href="#">72</a>
<a href="#">Item 7A. Quantitative and Qualitative Disclosures About Market Risk</a>	<a href="#">80</a>
<a href="#">Item 8. Financial Statements and Supplementary Data</a>	<a href="#">81</a>
<a href="#">Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosures</a>	<a href="#">105</a>
<a href="#">Item 9A. Controls and Procedures</a>	<a href="#">105</a>
<a href="#">Item 9B. Other Information</a>	<a href="#">106</a>
<a href="#">Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections</a>	<a href="#">106</a>
<a href="#">Part III</a>	
<a href="#">Item 10. Directors, Executive Officers and Corporate Governance</a>	<a href="#">107</a>
<a href="#">Item 11. Executive Compensation</a>	<a href="#">107</a>
<a href="#">Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</a>	<a href="#">107</a>
<a href="#">Item 13. Certain Relationships and Related Transactions, and Director Independence</a>	<a href="#">107</a>
<a href="#">Item 14. Principal Accounting Fees and Services</a>	<a href="#">107</a>
<a href="#">Part IV</a>	
<a href="#">Item 15. Exhibits, Financial Statement Schedules</a>	<a href="#">108</a>
<a href="#">Item 16. Form 10-K Summary</a>	<a href="#">111</a>
<a href="#">Signatures</a>	<a href="#">112</a>

Unless the context otherwise requires, all references in this Form 10-K to "Context," "Company," "we," "us," and "our" refer to Context Therapeutics Inc. and its subsidiaries.

### Trademark Notice

This Form 10-K contains references to our trademarks and to trademarks belonging to other entities. Context Therapeutics® is a registered trademark of Context in the United States. All other trademarks, trade names and service marks appearing in this Form 10-K are the property of their respective owners. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

## NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Form 10-K contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on our management’s beliefs and assumptions and on information currently available to us. All statements other than statements of historical facts are forward-looking statements. The forward-looking statements are contained principally in, but not limited to, the sections entitled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business.” These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- the timing of preliminary results for our ongoing investigator-sponsored trials;
- the timing, progress and results of preclinical studies and clinical trials for ONA-XR, CLDN6 bsAb, and other product candidates we may develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- the timing, scope and likelihood of U.S. and foreign regulatory filings and approvals, including timing of Investigational New Drug applications and final FDA approval of ONA-XR, CLDN6 bsAb and any other future product candidates;
- our ability to develop and advance ONA-XR, CLDN6 bsAb, and any other future product candidates, and successfully complete, clinical studies;
- our manufacturing, commercialization, and marketing capabilities, implementations thereof, and strategy;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus, sales strategy, and our ability to grow a sales team;
- the impact of the COVID-19 pandemic on our business and operations, including clinical trials, manufacturing suppliers, collaborators, use of contract research organizations and employees;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the size of the market opportunity for our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- our expectations regarding the approval and use of our product candidates in combination with other drugs;
- our competitive position and the success of competing therapies that are or may become available;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our plans relating to the further development of our product candidates, including additional indications we may pursue;
- existing regulations and regulatory developments in the United States, Europe and other jurisdictions;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering ONA-XR, CLDN6 bsAb, and other product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual

property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;

- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;
- our ability to obtain, and negotiate favorable terms of, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- the pricing and reimbursement of ONA-XR, CLDN6 bsAb and other product candidates we may develop, if approved;
- the rate and degree of market acceptance and clinical utility of ONA-XR, CLDN6 bsAb and other product candidates we may develop;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our current plans to seek additional capital in the future through equity and/or debt financings, partnerships, collaborations, or other sources and the availability of such future sources of capital;
- our financial performance;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- the impact of laws and regulations;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act;
- our anticipated use of our existing cash and cash equivalents; and
- other risks and uncertainties, including those listed under the caption “Risk Factors”.

In some cases, you can identify forward-looking statements by terms such as “may,” “could,” “will,” “should,” “would,” “expect,” “plan,” “intend,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “project” or “continue” or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the heading “Risk Factors” and elsewhere in this Form 10-K. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance.

This Form 10-K also contains certain data and information which we obtained from various government and private publications. Although we believe that the publications and reports are reliable, we have not independently verified the data. Statistical data in these publications includes projections that are based on a number of assumptions. If any one or more of the assumptions underlying the market data is later found to be incorrect, actual results may differ from the projections based on these assumptions.

The forward-looking statements made in this Form 10-K relate only to events or information as of the date on which the statements are made in this Form 10-K. Although we are a public company and have ongoing disclosure obligations under United States federal securities laws, we do not intend to update or otherwise revise the forward-looking statements in this Form 10-K, whether as a result of new information, future events or otherwise.

## RISK FACTOR SUMMARY

The risk factors summarized below could materially harm our business, operating results and/or financial condition, impair our future prospects and/or cause the price of our common stock to decline. For more information, see “Item 1A. Risk Factors” in this Annual Report on Form 10-K for the year ended December 31, 2021. Material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, the following:

### **Risks Related to Our Business and Industry**

- We have never been profitable and may never achieve or maintain profitability.
- If we are unable to raise substantial additional capital on acceptable terms, or at all, we may be forced to delay, reduce or eliminate some or all of our research programs, product development activities and commercialization efforts.
- We have a limited operating history, which makes it difficult to evaluate our current business and future prospects and may increase the risk of your investment.
- We may expend our limited resources pursuing particular research programs or product candidates that may be less successful or profitable than other programs or product candidates.
- Our business may be adversely affected by the ongoing coronavirus pandemic.

### **Risks Related to our Product Candidates**

- Our business is dependent on the successful development, regulatory approval and commercialization of our therapeutic product candidates, ONA-XR and CLDN6xCD3 bsAb, which are in the early stages of development.
- Results of preclinical studies, early clinical trials or analyses may not be indicative of results obtained in later trials.
- Interim “top-line” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- Our product candidates may cause serious adverse events or undesirable side effects, which may delay or prevent marketing approval, or, if approved, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.
- The success of our business depends primarily upon our ability to identify, develop and commercialize products using our proprietary technologies.

### **Risks Related to Our Organization, Structure and Operations**

- Our reliance on a central team consisting of a limited number of employees and consultants who provide various administrative, research and development, and other services across our organization presents operational challenges that may adversely affect our business.
- Our future success depends on our ability to retain our executive officers, and other key executives and to attract, retain and motivate qualified personnel.

### **Risks Related to Our Reliance on Third Parties**

- We expect to depend on collaborations with third parties for certain research, development and commercialization activities, and to rely on third parties to conduct, supervise and monitor our clinical trials and some aspects of our research and preclinical testing, as well as for the manufacturing process of product candidates. If any such collaborations or services by such third parties are not successful or not performed in a satisfactory manner, it may harm our business and prospects, and we may not be able to obtain regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed.
- If we are unable to obtain sufficient quantities of raw materials and supplies, at acceptable prices and on a timely basis, it could harm our business.

### **Risks Related to Government Regulation**

- The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

- We expect that CLDN6xCD3 bsAb will be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated.
- The FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.
- Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.
- Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.
- Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates, if approved, profitably.

**Risks Related to Intellectual Property**

- Patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our business position.
- Our ability to compete effectively in our markets may decline if we do not adequately protect our proprietary rights, and our proprietary rights do not necessarily address all potential threats to our competitive advantages.
- If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.
- We may not be able to protect our intellectual property rights throughout the world.
- Third parties may assert claims against us alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to defend or enforce our patents, either of which could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of product candidates, prohibit our use of proprietary technology or sale of potential products or put our patents and other proprietary rights at risk.

**Risks Related to the Market for Our Common Stock**

- Our common stock may be volatile or may decline regardless of our operating performance.
- We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to advance or complete the development and commercialization of our product candidates.
- We may issue additional debt and equity securities, which are senior to our common stock as to distributions and in liquidation, which could materially adversely affect the market price of our common stock.
- We may fail to maintain effective internal control over financial reporting and effective disclosure controls and procedures. If we fail to remediate any material weaknesses, we may not be able to report our financial results accurately or to prevent fraud, which could materially adversely affect the market price of our common stock.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

**MARKET, INDUSTRY AND OTHER DATA**

This Annual Report on Form 10-K contains estimates, projections, market research and other information concerning our industry, our business, markets for our product candidates, the size of those markets, and the prevalence of certain medical conditions. Unless otherwise expressly stated, we obtain this information from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources as well as from our own internal estimates and research and from publications, research, surveys and studies conducted by third parties on our behalf. Information that is based on estimates, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are reflected in this information. As a result, you are cautioned not to give undue weight to such information.

## PART I.

### Item 1. Business

#### Overview

We are a clinical-stage biopharmaceutical company dedicated to improving the lives of women living with cancer.

Profound advancements in oncology drug development have expanded the treatment options available to women with cancer, yet therapeutic resistance and relapse continue to limit the efficacy and duration of such treatments. Collectively, our founders and management team have decades of experience identifying and characterizing the mechanisms that drive cancer initiation and subsequent relapse in women with cancer and who have been associated with the development of products such as Kisqali (ribociclib), Arimidex (anastrozole), and Afinitor (everolimus) to treat such cancers.

Our development team is advancing a pipeline of innovative therapies with a primary focus on treating female cancers. Our first program and lead product candidate, onapristone extended release (“ONA-XR”), builds upon a foundation of successful drug development by our management team and advisors in the field of female hormone-dependent cancers. ONA-XR is a selective and potentially potent antagonist of the progesterone receptor (PR), a receptor that is activated by the hormone progesterone and that has been linked to resistance to multiple classes of cancer therapeutics, including anti-estrogen therapies, that are prescribed to treat female hormone-dependent cancers. In 2020, we initiated a Phase 2 investigator-sponsored trial in collaboration with Jefferson Health to evaluate ONA-XR in combination with Arimidex (anastrozole) in PR+ endometrial cancer and preliminary data is expected in mid-2022. Also, in 2020 we initiated a Phase 0 trial of ONA-XR in a window of opportunity study in primary breast cancer, and we reported preliminary data at the San Antonio Breast Cancer Symposium in December 2021. In 2021, a Phase 1b/2 investigator-sponsored trial was initiated in collaboration with Memorial Sloan Kettering Cancer Center (MSK) to evaluate ONA-XR in combination with Ibrance (palbociclib) and Femara (letrozole) in first line (1L) metastatic breast cancer patients with biochemically recurrent disease, defined as circulating tumor DNA (ctDNA) positive. This is potentially a new clinical opportunity for the estimated 20% of 1L patients who are at high risk of early disease progression on Ibrance plus Femara combination therapy and Phase 1b data is expected in mid-2022. In 2021, the first stage of a Phase 2 investigator-sponsored trial initiated by MSK to evaluate ONA-XR in recurrent granulosa cell tumors (GCT) of the ovary was completed. In July 2021, MSK initiated the second stage of this trial evaluating ONA-XR in combination with Arimidex, and preliminary data is expected in the second half of 2022. Also in 2021, a Phase 2 investigator-sponsored trial was initiated in collaboration with Wisconsin Oncology Network (WON) to evaluate ONA-XR in combination with Faslodex (fulvestrant) in second line (2L) or third line (3L) metastatic breast cancer. This trial is intended to evaluate potential ONA-XR plus Faslodex drug synergy after treatment failure of CDK4/6 and/or PIK3 $\alpha$  inhibitors, and preliminary data is expected in the second half of 2022. In 2022, WON intends to initiate a sub-study of its Phase 2 trial in 2L/3L metastatic breast cancer that will evaluate the uptake of radiolabeled progesterone (F-FFNP) via PET imaging in breast tumors. Our second program, CLDN6xCD3 bsAb, is an anti-CD3 x anti-Claudin 6 (CLDN6) antigen bispecific monoclonal antibody (bsAbs) that is intended to redirect T-cell-mediated lysis toward malignant cells expressing CLDN6. CLDN6 is a tight junction membrane protein target expressed in multiple cancers, including ovarian and endometrial tumors, and absent from healthy adult tissues. We expect to select a candidate to support IND-enabling studies for CLDN6xCD3 bsAb in the second half of 2022. Beyond these two product candidates, we continue to evaluate opportunities to expand our pipeline. We believe our team and capabilities uniquely position us to be a leader in developing novel therapies to address female cancers.



Context retains worldwide development and commercialization rights for ONA-XR outside of Greater China and retains full worldwide development and commercialization rights to certain CLDN6 antibody patents in the field of bispecific antibodies. Our product candidates are shown in the table below:

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				• Phase 1b data Mid 2022	
	2L/3L ER+,PR+,HER2- Post-CDK4/6 inhibitor	Phase 2 Trial				• Preliminary data 2H 2022	
Ovarian Cancer	Recurrent PR+ Granulosa Cell	Phase 2 Trial				• Preliminary data 2H 2022	☑
Endometrial Cancer	Recurrent PR+ Endometrioid	Phase 2 Trial				• Preliminary data Mid 2022	
<b>CLDN6xCD3 bispecific antibody</b>							
	Ovarian & Endometrial Cancer					• IND enabling studies 2H 2022	

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

## Our Product Pipeline and Development

### ***PR antagonist program: ONA-XR***

Currently, there are no approved therapies that selectively target progesterone receptor positive (PR+) cancers. Preclinical and clinical data suggest that onapristone extended release (ONA-XR) has anticancer activity by inhibiting PR binding to chromatin, downregulating cancer stem cell mobilization and blocking immune evasion. ONA-XR is currently being evaluated in three Phase 2 trials, and one Phase 1b/2 trial in women with primary or metastatic breast, ovarian, and endometrial cancers. These trials are intended to establish safety, pharmacokinetics, pharmacodynamics, and anti-tumor activity at the recommended Phase 2 dose of ONA-XR to guide potential advancement in Phase 3 development in 2023.

To help inform which patients may be most suitable for treatment with ONA-XR, we are evaluating multiple biomarker assays, including tools to monitor activated progesterone receptor as well as a PR gene activation signature that measures PR signaling activity, both of which are being utilized in our ongoing clinical trials and may be used for patient selection in future clinical trials. We expect to report preliminary data from two of our ongoing trials in mid-2022 and from the other two trials in the second half of 2022.

### ***CLDN6xCD3 bispecific antibody program***

Our second program, CLDN6xCD3 bsAb, is an anti-CD3 x anti-Claudin 6 (CLDN6xCD3) antigen bispecific monoclonal antibody (bsAbs) that is intended to redirect T-cell-mediated lysis toward malignant cells expressing CLDN6. CLDN6 is a tight junction membrane protein target expressed in ovarian and endometrial tumors and absent from healthy adult tissues. The structural complexity of CLDN6 and its similarity to proteins expressed on healthy tissue, particularly Claudin 9 (CLDN9), have limited its exploitation for targeted oncology therapies. Several pharmaceutical companies are developing anti-CLDN6 antibodies and/or bispecific antibodies. We expect to select a candidate to support IND-enabling studies for CLDN6xCD3 bsAb in the second half of 2022.

### ***Other preclinical programs***

In addition to our product candidates, we are leveraging our knowledge in female cancers to pursue discovery stage research programs. We continue to evaluate new opportunities to expand our pipeline in female cancers.

### **Our Management Team**

We have assembled a management team to develop novel products to treat female cancers. Members of our management team have experience leading organizations that have advanced multiple oncology therapeutics from early-stage research to clinical trials, and ultimately to regulatory approval and commercialization. Our team's select accomplishments include:

- Our Chief Executive Officer co-founded Context in 2015 and was previously a venture capitalist at Osage University Partners, where he led multiple oncology investments for the firm that resulted in successful public offerings or acquisitions.
- Our Chief Financial Officer previously served as Chief Financial Officer of Millendo Therapeutics, a publicly-traded biopharmaceutical company. Prior to Millendo, our CFO served as Director of Technical Accounting at PAREXEL International and began her career as an auditor at Ernst & Young.
- Our Chief Legal Officer previously served as Vice President, Deputy General Counsel and Assistant Corporate Secretary of OptiNose, a publicly-traded specialty pharmaceutical company. Prior to OptiNose, he served as Associate General Counsel of Teva Pharmaceuticals, a global pharmaceuticals company.
- Our Chief Medical Officer previously held the same position at H3 Biomedicine, where he led the early phase development for an oral selective estrogen receptor covalent antagonist (SERCA). During his career, he has either led or supported global drug development programs for several novel oncology drugs, including Kisqali (ribociclib), Arimidex (anastrozole), and Afinitor (everolimus), resulting in successful global registrations.
- Our management team has been involved in several multimillion-dollar strategic transactions, including as part of the leadership teams at Celgene, and Novartis.

We are supported by our advisors who are leading experts in female cancers. Our arrangements with these individuals do not entitle us to any of their existing or future intellectual property derived from their independent research or research with other third parties beyond what has previously been licensed to us.

### **Strategy**

Our goal is to develop and commercialize innovative and differentiated oncology products that address significant unmet medical needs in the field of female cancer, with a primary focus on the hormone-dependent subcategory. The key components of our strategy to achieve this goal include:

- ***Leveraging the insights, experience, and networks of our management team and advisors.*** Our management team and advisors have extensive experience identifying, developing, and commercializing innovative cancer therapeutics aimed at novel targets, including Kisqali, Arimidex, and Afinitor. We are using this broad oncology experience together with our internal search and development capabilities to build a diverse pipeline of therapies targeting multiple cancer resistance mechanisms. For example, our first program and lead product candidate, ONA-XR, while acquired from Armo Therapeutics, builds on academic work originally conducted by the laboratory of our scientific advisor, Dr. Carol Lange.
- ***Focusing on product candidates that can be first or second in market based on current competition.*** We believe that being first or second in market provides a unique advantage that later competitors may not be able to overcome. Based on the current competitors that are developing similar product candidates, we believe that we have the opportunity to be the first anti-progestin approved for PR+ cancer and one of the early market participants with our CLDN6xCD3 bsAb.

- Completing clinical development and obtaining regulatory approval for ONA-XR for the treatment of breast, ovarian, and endometrial cancer.** The PR signaling pathway has been implicated in resistance to anti-estrogen therapies in female hormone-dependent cancers, including breast, ovarian, and endometrial cancer. Our clinical development effort for ONA-XR, a selective and potentially potent small molecule antagonist of PR, will initially focus on indications where there is evidence suggesting PR-mediated signaling contributes to resistance and disease progression. In 2020, we initiated a Phase 2 investigator-sponsored trial in collaboration with Jefferson Health to evaluate ONA-XR in combination with Arimidex (anastrozole) in PR+ endometrial cancer and preliminary data is expected in mid-2022. Also, in 2020 we initiated a Phase 0 trial of ONA-XR in a window of opportunity study in primary breast cancer, and we reported preliminary data at the San Antonio Breast Cancer Symposium in December 2021. In 2021, a Phase 1b/2 investigator-sponsored trial was initiated in collaboration with Memorial Sloan Kettering Cancer Center (MSK) to evaluate ONA-XR in combination with Ibrance (palbociclib) and Femara (letrozole) in first line (1L) metastatic breast cancer patients with biochemically recurrent disease, defined as circulating tumor DNA (ctDNA) positive. This is potentially a new clinical opportunity for the estimated 20% of 1L patients who are at high risk of early disease progression on Ibrance plus Femara combination therapy and Phase 1b data is expected in mid-2022. In 2021, the first stage of a Phase 2 investigator-sponsored trial initiated by MSK to evaluate ONA-XR in recurrent granulosa cell tumors (GCT) of the ovary was completed. In July 2021, MSK initiated the second stage of this trial evaluating ONA-XR in combination with Arimidex, and preliminary data is expected in the second half of 2022. Also in 2021, a Phase 2 investigator-sponsored trial was initiated in collaboration with Wisconsin Oncology Network (WON) to evaluate ONA-XR in combination with Faslodex (fulvestrant) in second line (2L) or third line (3L) metastatic breast cancer. This trial is intended to evaluate potential ONA-XR plus Faslodex drug synergy after treatment failure of CDK4/6 and/or PIK3 $\alpha$  inhibitors, and preliminary data is expected in the second half of 2022. In 2022, WON intends to initiate a sub-study of its Phase 2 trial in 2L/3L metastatic breast cancer that will evaluate the uptake of radiolabeled progesterone (F-FFNP) via PET imaging in breast tumors.
- Advancing our second program, CLDN6xCD3 bsAb, as rapidly as reasonably possible through preclinical and clinical development.** Our second program, CLDN6xCD3 bsAb, is an anti-CD3 x anti-Claudin 6 (CLDN6xCD3) antigen bispecific monoclonal antibody (bsAbs) that is intended to redirect T-cell-mediated lysis toward malignant cells expressing CLDN6. CLDN6 is a membrane protein target expressed in multiple female cancers, including ovarian and endometrial, and absent from healthy adult tissues. We expect to select a candidate to support IND-enabling studies for CLDN6xCD3 bsAb in the second half of 2022.
- Evaluating opportunities to accelerate development timelines and enhance the commercial potential of our programs in collaboration with third parties, including through the potential out-licensing of our product candidates.** We have established collaborations and intend to continue evaluating opportunities to work with partners that meaningfully enhance our capabilities with respect to the development and commercialization of our product candidates, which may entail the potential out-licensing of the development and commercialization of our product candidates to larger pharmaceutical organizations, including our lead product candidate ONA-XR. For example, we entered into a manufacturing and development agreement with Tyligand Bioscience (Shanghai) Limited for ONA-XR that is intended to enhance our ability to meet drug manufacturing demands and expand our clinical trial footprint into Greater China. It is also possible that similar arrangements for ONA-XR could be sought for other geographic footprints. In addition, we intend to commercialize our product candidates in key markets either alone or with partners in order to maximize the worldwide commercial potential of our programs.
- In-licensing or acquiring additional drug candidates to build a fully integrated company focused on female cancers.** We believe that accessing external innovation and expertise is important to our success and plan to leverage our leadership team's prior business development experience as we evaluate potential in-licensing and acquisition opportunities to further expand our portfolio. For example, CLDN6xCD3 bsAb was licensed from Integral Molecular, Inc. ("Integral"), a company where our management and advisors

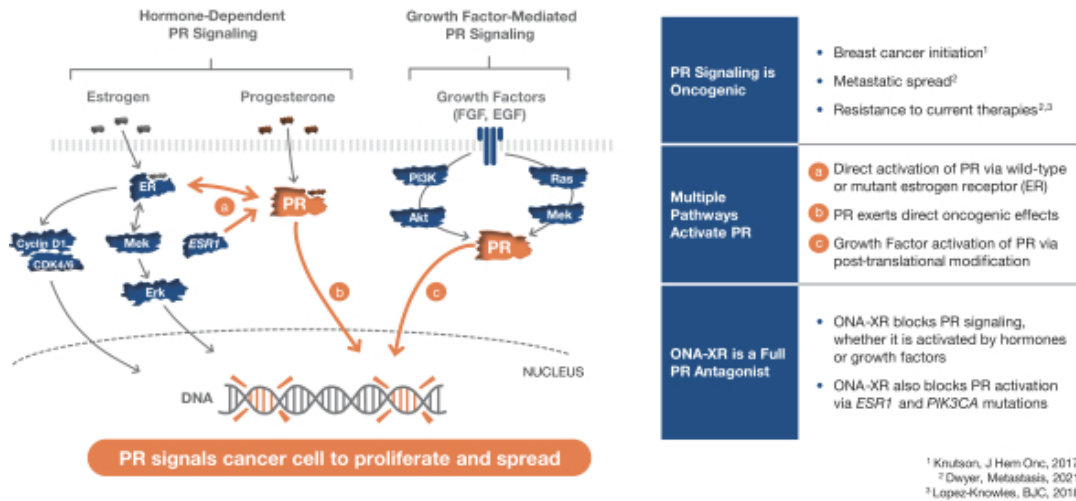
have long-standing relationships. We aim to be the partner of choice for academic groups and companies in the field of female cancers.

**Our focus on female hormone-dependent cancer**

Up to 70% of women with breast, ovarian, and endometrial cancer have hormone-dependent cancer. The hormones estrogen and progesterone drive cancer progression in those patients, but anti-estrogens are the only antihormonal therapy that is FDA approved and available to clinicians. Therefore, treatment of those patients to date has consisted of anti-estrogens alone or in combination with drugs that enhance the antitumor activity of anti-estrogens, including inhibitors of CDK4/6 or PI3K $\alpha$ . Given the broad use of anti-estrogens, anti-estrogen resistance is now a major clinical challenge. Treatment options for anti-estrogen resistance are limited, provide modest therapeutic benefit, and are associated with side effects.

Estrogen and progesterone are master regulators of normal female sex organ development and function, acting via estrogen receptors (“ER”) and progesterone receptors (“PR”). Mechanistically, published data suggest that in hormone-dependent cancers, ER and PR are often hyperactive, constantly pushing breast, ovary, and endometrial tissues to grow, divide, and metastasize. One such strategy to block this hormone-mediated growth is to administer anti-estrogen therapy (fulvestrant, letrozole, anastrozole, or tamoxifen), which may be used in combination with inhibitors of CDK4/6 or PI3K $\alpha$  to enhance anti-estrogen mediated effects. However, the cancer cells respond to this selective pressure of ER inhibition by further activating progesterone signaling as a compensatory mechanism, along with other resistance mechanisms that can further activate PR, including ER ligand binding mutations (*ESR1*), growth factor signaling, and enrichment of cancer stem cells. Over time, it is believed that all patients become resistant to anti-estrogens due to direct or indirect compensatory signaling mediated by the PR and other factors. These findings suggest that progesterone receptor and proteins that regulate PR could represent promising drug targets to address anti-estrogen resistance.

**Overview of antiestrogen resistance mechanisms**



<sup>1</sup> Knutson, J Hem Onc, 2017  
<sup>2</sup> Dwyer, Metastasis, 2021  
<sup>3</sup> Lopez-Knowles, BJC, 2018

We are building a portfolio of novel agents targeting multiple anti-estrogen resistance mechanisms by leveraging our specialized expertise in hormone-dependent cancers.

**PR antagonist program: ONA-XR**

Published data suggest that the PR signaling pathway is implicated in resistance to anti-estrogen therapies in female hormone-dependent cancer, including breast, ovarian, and endometrial cancer. Our clinical development effort for ONA-XR, a selective and potentially potent small molecule antagonist of PR, will initially focus on indications where there is evidence suggesting PR-mediated signaling contributes to resistance and disease progression. In 2020, we initiated a Phase 2 investigator-sponsored trial in collaboration with Jefferson Health to

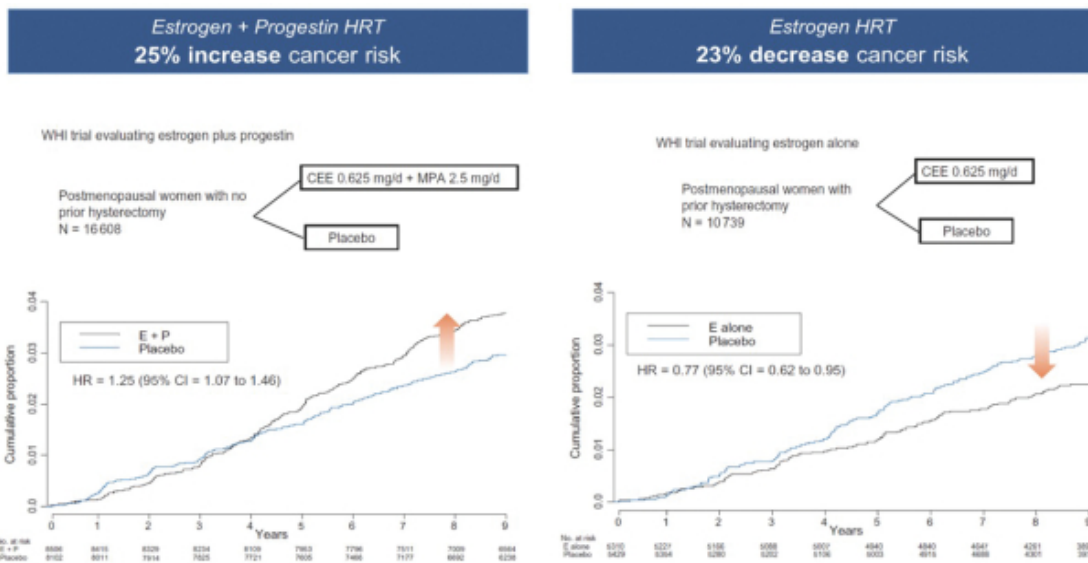
evaluate ONA-XR in combination with Arimidex (anastrozole) in PR+ endometrial cancer and preliminary data is expected in mid-2022. Also, in 2020 we initiated a Phase 0 trial of ONA-XR in a window of opportunity study in primary breast cancer, and we reported preliminary data at the San Antonio Breast Cancer Symposium in December 2021. In 2021, a Phase 1b/2 investigator-sponsored trial was initiated in collaboration with Memorial Sloan Kettering Cancer Center (MSK) to evaluate ONA-XR in combination with Ibrance (palbociclib) and Femara (letrozole) in first line (1L) metastatic breast cancer patients with biochemically recurrent disease, defined as circulating tumor DNA (ctDNA) positive. This is potentially a new clinical opportunity for the estimated 20% of 1L patients who are at high risk of early disease progression on Ibrance plus Femara combination therapy and Phase 1b data is expected in mid-2022. In 2021, the first stage of a Phase 2 investigator-sponsored trial initiated by MSK to evaluate ONA-XR in recurrent granulosa cell tumors (GCT) of the ovary was completed. In July 2021, MSK initiated the second stage of this trial evaluating ONA-XR in combination with Arimidex, and preliminary data is expected in the second half of 2022. Also in 2021, a Phase 2 investigator-sponsored trial was initiated in collaboration with Wisconsin Oncology Network (WON) to evaluate ONA-XR in combination with Faslodex (fulvestrant) in second line (2L) or third line (3L) metastatic breast cancer. This trial is intended to evaluate potential ONA-XR plus Faslodex drug synergy after treatment failure of CDK4/6 and/or PIK3 $\alpha$  inhibitors, and preliminary data is expected in the second half of 2022. In 2022, WON intends to initiate a sub-study of its Phase 2 trial in 2L/3L metastatic breast cancer that will evaluate the uptake of radiolabeled progesterone (F-FFNP) via PET imaging in breast tumors.

#### *Progesterone receptor background*

Progesterone receptor (PR) is a member of the nuclear hormone receptor family of ligand-dependent transcription factors that is expressed primarily in female reproductive tissues. In response to the endogenous steroid hormone, progesterone, PR regulates the expression of gene networks to control development, differentiation, and proliferation of target tissues and the pathological processes in endocrine-based cancers. Anti-progestins are a class of nuclear receptor ligands that act to antagonize PR by binding to the progesterone binding site within the PR-ligand binding domain.

Recently, the role of progesterone in carcinogenesis has gained further clarity. Mechanistically, published data suggest that 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. As shown in the figure below, these studies determined that supplemental estrogen was associated with a 23% decrease in cancer risk, whereas supplemental progesterone was associated with a 25% increase in cancer risk. The results demonstrated that women who were consistently exposed to progesterone had a higher risk of developing breast cancer than those who did not. This finding was confirmed by published data wherein mice treated with progesterone exhibited enhanced breast tumor growth whereas progesterone receptor inhibition via genetic knockdown conversely inhibited tumor growth.

## Association of progesterone and breast cancer risk

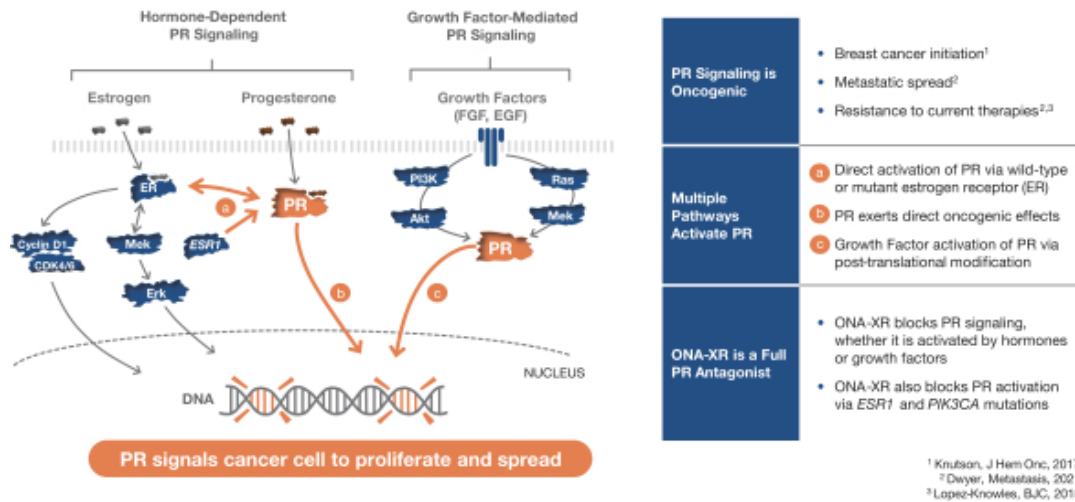


Source: Reprinted from the Journal of the American Medical Association Oncology, Chlebowski et al, Breast Cancer After Use of Estrogen Plus Progestin and Estrogen Alone: Analyses of Data From 2 Women's Health Initiative Randomized Clinical Trials, Copyright 2015. Reprinted with permission from American Medical Association.

Note: CEE: synthetic estrogen; E: estrogen; HRT: hormone replacement therapy; MPA: synthetic progesterone; P: progesterone.

As shown in the figure above, PR can be activated by ligand (progesterone) or ligand-independent (growth factor-mediated) mechanisms. Consistent with other steroid hormone receptor family members, PR is heavily post-translationally modified and thus acts as a molecular sensor for abnormally elevated or active signaling pathways. Little overlap exists between PR transcriptomes assayed in normal relative to neoplastic cells. In cancer cells, post-translational modifications (namely, phosphorylation and SUMOylation) via members of the growth factor signaling cascade create unique PR species whose altered behavior as ligand-dependent transcription factors is predicted to impact tumor initiation and progression. Due to the breadth of post-translational modifications of PR, there is limited selective mutational pressure to modify PR itself - thus, PR mutations are rare. However, when present, the PR mutations have a profound impact on PR activity and tumorigenesis.

## Illustrative mechanism of action



Note: ER: estrogen receptor; *ESR1*Y537S: estrogen receptor mutation.

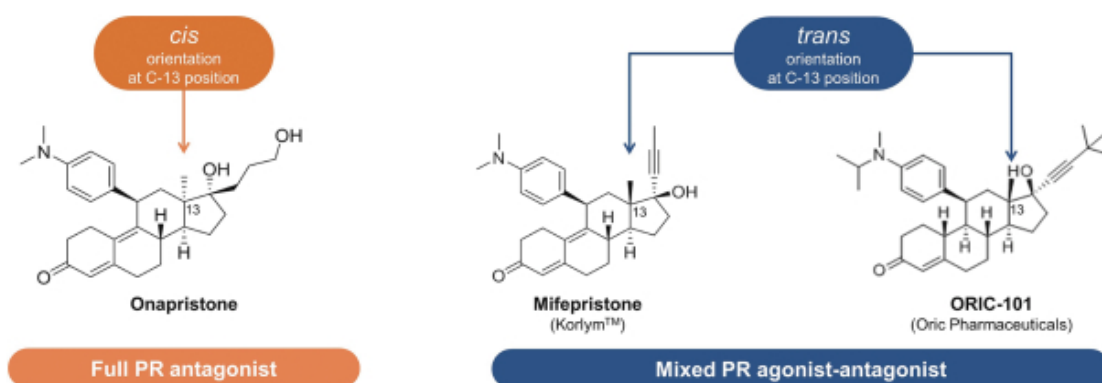
### The progesterone receptor as a mechanism of resistance

Recently, progesterone receptor has emerged as anti-estrogen resistance mechanism. Long term exposure of cancer cells to anti-estrogens results in a complex resistance profile that limits the utility of standard of care anti-estrogen and cyclin-dependent kinase 4/6 (CDK4/6) inhibitors. Mechanisms of resistance include mutations in the estrogen receptor (*ESR1*) estrogen binding domain and ER pathway signaling (e.g., MAPK, PI3K $\alpha$ /mTOR proteins and associated signaling pathways). The prevalence of resistance mutations is associated with PR enrichment and activity. Based on our preclinical data and recent published data, we believe therapeutic inhibition of PR with either ONA-XR alone or in combination with anti-estrogens and/or CDK4/6 inhibitors may result in the impaired growth or death of resistant cells.

### Limitations of other PR antagonists

Anti-progestins, the therapeutic inhibitors of PR, were first developed as oral contraceptives to block the maturation of the endometrium and subsequent ovulation. The first commercially available anti-progestin, Korlym (mifepristone), is a steroid derivative that acts both as a competitive progesterone receptor (PR) antagonist and as a partial PR agonist, depending on the physiological milieu. Mifepristone is approved for controlling hyperglycemia secondary to hypercortisolism in adult Cushing's syndrome associated with Type 2 diabetes. Mifepristone was also clinically evaluated in breast and ovarian carcinomas, and while showing evidence of efficacy in clinical studies, mifepristone was also associated with off-target glucocorticoid receptor (GR) modulation leading to cortisolemia and rare cases of cholestasis. In order to optimize PR antagonism while minimizing off-target activities, additional anti-progestins—including ulipristal, telapristone, lonaprisan and onapristone—were developed and evaluated in gynecological cancer.

## Unique Properties of Onapristone – Stereochemical Basis

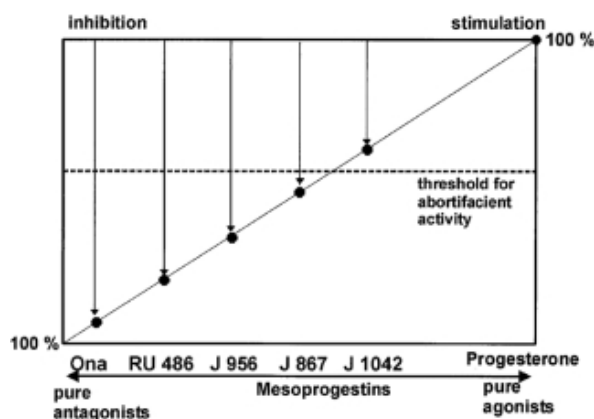


Note: AR: androgen receptor; C-13: carbon 13; n.a.: not applicable; 1L MBCa: first-line metastatic breast cancer.

### ONA-XR differentiation

Onapristone is a competitive PR antagonist that has no intrinsic activity for activating the receptor. As such, onapristone is also termed a “full” PR antagonist (inhibitor). Based on published data, all other anti-progestins that have reached the clinic demonstrate partial PR agonism. This differentiation may have a structural basis. It is well established that high energy, conformationally complex chemicals have improved selectivity and target affinity relative to low energy, flat counterparts. As shown above, all other anti-progestins have a roughly planar ring, low energy, A thru D conformation. In contrast, onapristone shows an inversion of stereochemistry at the C-13 methyl group that results in a high energy, chair conformation. This structural property is unique among clinically evaluated anti-progestins and may be important for onapristone’s full PR antagonist properties, as shown below.

### Onapristone PR binding properties vs. other anti-progestins and progesterone



Source: Reprinted from Steroids, Elger et al, Endocrine pharmacological characterization of progesterone antagonists and progesterone receptor modulators with respect to PR-agonistic and antagonistic activity, Copyright 2000. Reprinted with permission from Elsevier.

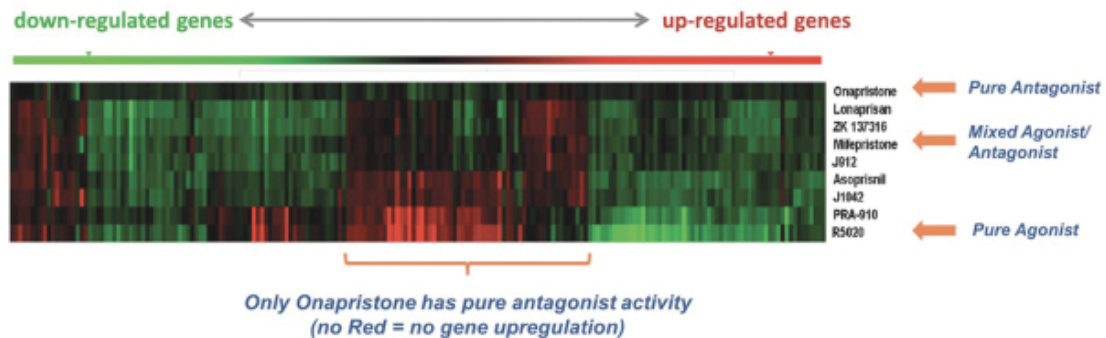
Note: RU 486: mifepristone; J 867: asoprisnil; Ona: onapristone.

Classic *in vitro* models have provided limited benefit in determining PR agonist versus antagonist properties. As the cost of gene expression profiling has decreased considerably over the last decade, it is now feasible to run comparative studies to determine how compounds are affecting the expression, positively or negatively, of target genes. Afhuppe *et al* (2009) conducted the first such study comparing anti-progestins in a gene array panel. T47D breast cancer cells (ER+, PR+) were grown in 2D, stimulated with estrogen (estradiol), and treated with anti-



progestins. An Affymetrix® gene chip analysis of the cells was then conducted to determine transcriptional activity on the level of target genes. Onapristone demonstrated the purest PR antagonist activity as indicated downregulation (green blocks) of almost all PR target genes analyzed, whereas mifepristone had a transcriptional profile closer to R5020, which is pure progesterone.

### Modulation of PR signaling genes by different anti-progestins



Source: Reprinted from The Journal of Steroid Biochemistry and Molecular Biology, Afhüppe et al, Global gene expression profiling of progesterone receptor modulators in T47D cells provides a new classification system, Copyright 2009. Reprinted with permission from Elsevier.

### Anti-progestin clinical trial data

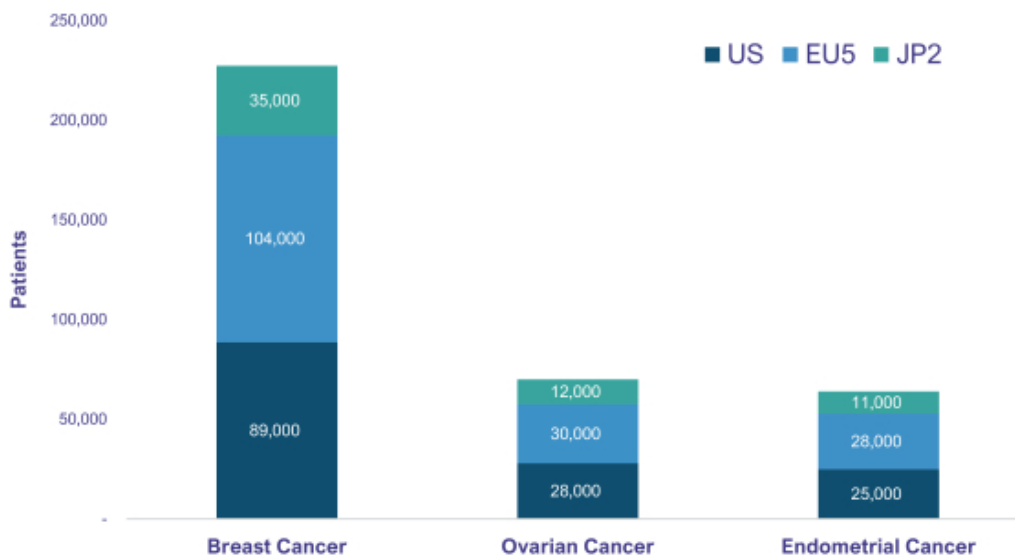
In subjects with breast cancer, clinical trials with mifepristone, lonapristone and onapristone demonstrated partial responses. Onapristone clinical efficacy in breast cancer was studied in two Phase 1-2 clinical studies treating hormone therapy-naïve and tamoxifen-resistant metastatic breast cancer, while the safety component of a third Phase 1-2 study has been reported by Cottu *et al.* (2018). The earlier onapristone trials in breast cancer dosed orally with a simple solid dosage form (an “immediate release” or “IR” form; onapristone IR; ONA-IR, ONA-IR 100mg once per day (QD), for periods exceeding 12 months. The third breast cancer study used the extended release form, ONA-XR, dosed at 50mg twice per day (BID). Robertson *et al* (1999) reported a 67% clinical benefit rate (CBR), defined as tumor shrinkage or tumor growth stabilization lasting for more than 6 months, while Jonat *et al* (2002) reported a 49% CBR. Both studies, therefore, indicated that onapristone could have a clinically meaningful impact on treatment of hormone-dependent breast cancer. Clinical development of ONA-IR for use in reproductive medicine and benign gynecological conditions was discontinued by the original sponsor (Schering AG), possibly due to concerns around drug-induced liver injury.

The extensive use of anti-estrogens, together with efficacy limits with earlier anti-progestins, has led to renewed interest in anti-progestins as therapies for breast and gynecologic cancer, as well as for uterine fibroids and endometriosis. Compared to earlier anti-progestin clinical trials, we believe we have a better tolerated formulation of onapristone (ONA-XR) and we will be able to better identify those patients who are most likely to benefit from anti-progestin therapy through the incorporation of biomarkers in our trials.

### Our current opportunities for ONA-XR

Within the G7 (EU5, Japan, US) countries, it is estimated that there are over 362,000 patients living with metastatic breast, ovarian, or endometrial cancer. Up to 70% of these patients are expected to be progesterone receptor positive and would potentially be eligible for treatment with ONA-XR.

**Prevalence in G7 countries for metastatic breast, ovarian, and endometrial cancers**



Source: secondary epidemiologic estimates, 2020 estimates.

Note: EU5: France, Germany, Italy, Spain, United Kingdom.

**Resistance to anti-estrogen therapy in breast cancer**

We have chosen PR antagonism in breast cancer as our initial therapeutic focus due to the well-documented biology of PR signaling as a mechanism of resistance to anti-estrogen therapy in patients with hormone-dependent breast cancer. Hormone-dependent breast cancer cells express estrogen (ER) and/or progesterone receptors (PR) that allow the cells to grow in the presence of the hormones estrogen and/or progesterone. Published data suggests that PR signaling is predominantly required for breast cancer cell renewal (i.e., stemness) and metastatic spread, whereas ER is predominantly required for breast cancer cell proliferation. By combining anti-progestin and anti-estrogen therapy, we have shown preclinically that breast cancer cell growth, renewal, and spread can be mitigated. Based on these data, we believe that ONA-XR, in combination with current standard-of-care anti-estrogens, has the potential to significantly improve clinical outcomes.

**Breast cancer overview**

Breast cancer is the most frequent cancer among women, impacting 2.1 million women globally each year, and causing the greatest number of cancer-related deaths among women. In 2018, it is estimated that 627,000 women died from breast cancer worldwide — that is approximately 15% of all cancer deaths among women according to the World Health Organization. According to the American Cancer Society, the prevalence of women in the United States living with adjuvant, first line metastatic, or second/third line metastatic breast cancer are an estimated 250,000, 75,000, and 35,000 respectively.

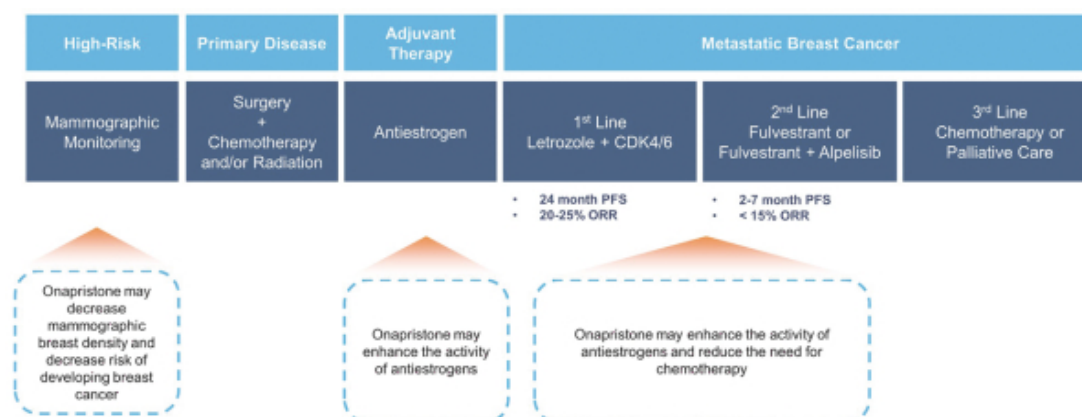
Breast cancer treatment is primarily determined by the presence or absence of three proteins: estrogen receptor (ER), progesterone receptor (PR), and HER2. The presentation of these proteins determines the subtype of breast cancer, which helps determine the optimal form of treatment for the patient. Patients who are ER+,PR+,HER2- are considered to be hormone receptor positive (i.e., hormone-dependent) and represent about 70% of breast cancers. HER2+ patients and triple negative patients (ER-,PR-,HER2-) represent the remaining 30% of breast cancers.

Estrogen-deprivation (anti-estrogen) therapy is the core treatment modality in patients with hormone receptor positive metastatic breast cancer according to NCCN Guidelines®. Anti-estrogen therapy options for postmenopausal women with ER+ advanced breast cancer include:

- Selective ER modulators (SERM): tamoxifen
- ER antagonists: fulvestrant
- Selective nonsteroidal aromatase inhibitors: anastrozole and letrozole
- Steroidal aromatase inhibitors: exemestane

In addition, cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors are rapidly transforming the care of patients with ER+, HER2- advanced breast cancer. There are currently three CDK4/6 inhibitors that have been approved by the U.S. Food and Drug Administration: Ibrance, Kisqali, and Verzenio. It is generally recommended to use the combination of a CDK4/6 inhibitor along with an aromatase inhibitor (i.e., letrozole) for first line locally advanced or metastatic breast cancer treatment.

### Illustrative breast cancer treatment landscape



Note: ORR: overall response rate; PFS: progression free survival.

Upon first line disease progression, second line therapy is most often fulvestrant (anti-estrogen) or fulvestrant plus alpelisib (Piqray), a PI3K $\alpha$  inhibitor, if the patients have PIK3CA-mutated hormone receptor-positive breast cancer. Fulvestrant plus Piqray was FDA approved in 2019 based on a Phase III trial of 572 patients that demonstrated a progression free survival (PFS) of 11.0 months vs. 5.7 months in the Piqray plus fulvestrant arm compared with fulvestrant alone (HR, 0.65, 95% CI 0.50–0.85). However, a total of 25% of patients discontinued Piqray plus fulvestrant therapy due to toxicities, thus, emphasizing the need for novel agents. Upon progression on second line therapy, mammalian target of rapamycin (mTOR) inhibitors, including everolimus (Afinitor), plus anti-estrogen based regimen or chemotherapy is administered. One key limitation of both the Afinitor and Piqray studies is the lack of data for the role of these agents after prior CDK4/6 inhibitor therapy. Most patients progress on these treatments and ultimately develop resistance. At that time, patients typically live for less than two years.

### Preclinical data

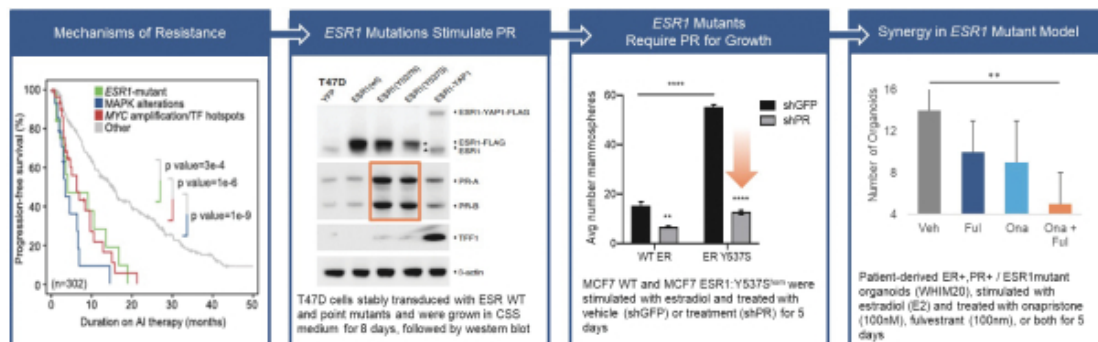
The female ovarian hormones estrogen and progesterone are master regulators of normal breast development and play a key role in breast cancer. Acting through ER and PR, estrogen and progesterone play complex, essential, and coordinated roles in the development of the lobular alveolar epithelial structures of the normal breast during puberty, the normal menstrual cycle, and pregnancy. It is likely that these actions become subverted in the development of breast cancer, implicating both estrogen and progesterone in the development and progression of this disease. Breast cancer is acknowledged to be a hormone-dependent disease and most breasts express ER and/or

PR. PR is expressed in humans as two major forms, progesterone receptor A (PR-A) and progesterone receptor B (PR-B), in normal cells and in certain malignant tissues. PR-A and PR-B mediate the effects of progesterone by association with a range of co-regulatory proteins and progesterone-regulated gene promoters. Over the past few decades, the estrogen receptor signaling pathway remains the most effective treatment for the management of ER+ breast cancer. Treatments include the selective estrogen receptor modulator (SERM) tamoxifen that binds to ER and prevents its activation, and aromatase inhibitors that block endogenous hormone synthesis.

Recent published data suggests that progesterone receptor may function as an anti-estrogen resistance mechanism. Long term exposure of cancer cells to anti-estrogens results in a complex resistance profile that limits the utility of standard of care anti-estrogen and CDK4/6 inhibitors. Mechanisms of resistance include mutations in estrogen receptor gene (*ESR1*) and ER pathway signaling (MAPK, PI3K $\alpha$ , mTOR), as 20-35% of ER+,PR+,HER2-metastatic breast tumors are *ESR1* mutated. The prevalence of resistance mutations is correlated with PR enrichment and activity. We have presented data showing that therapeutic inhibition of PR with either onapristone alone or in combination with anti-estrogens and/or CDK4/6 inhibitors results in the impaired growth or death of resistant cells.

As shown below, estrogen receptor (*ESR1*) mutational profiles of tumor biopsies were taken before and after prolonged treatment with anti-estrogen (fulvestrant) and CDK4/6 inhibitor (palbociclib) therapy. *ESR1*<sup>Y537S</sup> mutations are enriched by the end of therapy and are associated with worse outcomes in patients. To determine the effect of *ESR1* mutations, wild type (*ESR1*) and mutant (*ESR1*<sup>Y537S</sup> and *ESR1*<sup>Y537N</sup>) estrogen receptors were overexpressed in the T47D breast cancer cell line. The orange box denotes that both the PR-A and PR-B isoforms of progesterone receptor demonstrated increased expression upon exposure to the mutant form of *ESR1*. The increased expression of PR was found to be correlated with enhanced PR activity. To establish that *ESR1*<sup>Y537S</sup> cells require PR for growth and dual ER-PR inhibition (i.e., complete hormone blockade) results in growth inhibition, an *ex vivo* organoid model was conducted using the rapidly proliferating, CDK4/6 inhibitor resistant WHIM20 cell line. Organoid data demonstrates that dual blockade of ER and PR via treatment with fulvestrant and onapristone results in growth inhibition in a cell model that is intended to mimic human disease.

### Role of PR in *ESR1* mutations

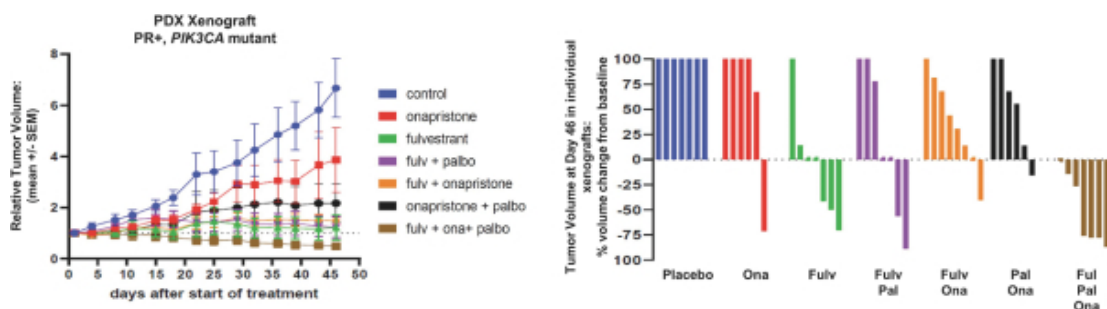


Source: Reprinted from Cancer Cell, Razavi et al, The Genomic Landscape of Endocrine-Resistant Advanced Breast Cancers, Copyright 2018. Reprinted with permission from British Journal of Cancer, Lopez-Knowles et al, Molecular characterisation of aromatase inhibitor-resistant advanced breast cancer: the phenotypic effect of *ESR1* mutations, Copyright 2018. Reprinted with permission from Nature Springer.

### Addition of Onapristone to Standard of Care Enhances Tumor Regression

Our hypothesis is that complete hormone blockade via downregulation of estrogen receptor (ER) and progesterone receptor (PR) signaling pathways, and their compensatory pathways, including CDK4/6, will lead to enhanced therapeutic outcomes in patients. To test this hypothesis, we utilized a patient-derived xenograft (PDX) model to evaluate the efficacy of the antiprogestin onapristone in combination with fulvestrant (antiestrogen) and palbociclib (CDK4/6 inhibitor) in PDX mouse models established from ER and PR positive bone metastasis of breast cancer. Two PDX models were tested, one with low level (data not shown) and one with high level of PR expression (data shown below). In the PDX model with high expression of PR, treatment by onapristone combined with palbociclib and fulvestrant resulted in enhanced tumor regressions.

All treatment arms were well tolerated. Blood and tumor samples were taken at the end of the study from both experiments. Different biological analyses will be performed to analyze ER/PR signaling by protein and RNAseq analyses.



Results from the experiment with the PR High Expression PDX are shown above. Treatment by onapristone alone resulted in a tumor growth inhibition (TGI) of 42%, while the combination onapristone (10 mg/kg) + palbociclib (75 mg/kg) resulted in a TGI of 67% and the triple combo onapristone + palbociclib + fulvestrant (5 mg/mouse) in a TGI of 92% with 6/7 xenografts showing tumor regression. The statistical analysis was performed with GraphPad software. Plasma and tumor samples were taken at the end of the study from 5 xenografts/group for further analysis.

### Resistance to hormone-dependent gynecologic cancer

#### Gynecologic cancer overview

Ovarian and endometrial cancer represent the majority of gynecologic cancers. It is estimated that there are more than 22,000 new cases of ovarian cancer and 61,000 new cases of endometrial cancer annually, resulting in 14,000 ovarian and 12,000 endometrial deaths in the United States (US) every year. As of 2019, it is estimated that there are 235,000 patients living with ovarian cancer and over 770,000 patients living with endometrial cancer in the US. By applying PR positivity (PR+) rates to the 2019 prevalence count, it is estimated that there are 300,000 patients with recurrent gynecologic cancer in the US, 130,000 of whom are PR+.

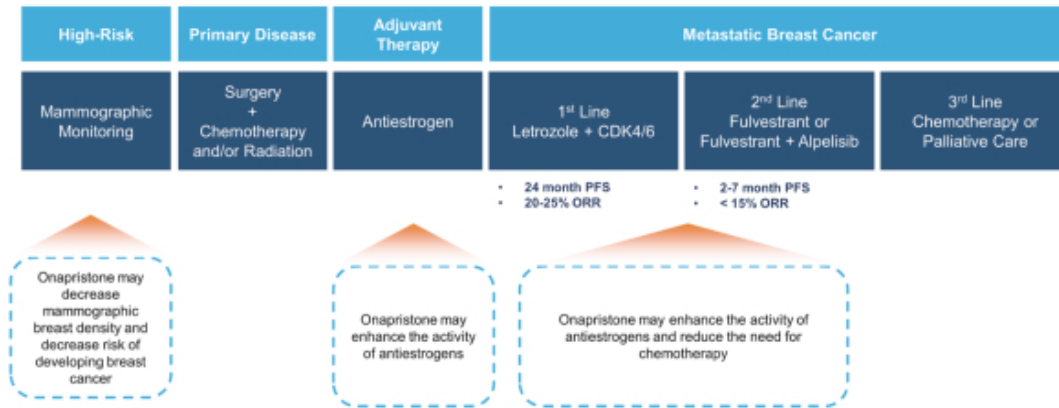
Maximal surgical debulking and platinum chemotherapy are the cornerstone treatments for primary gynecologic cancer. The aim of surgery is to confirm diagnosis, define extent of disease spread (staging), and resect all visible tumor tissue. The goal of cytoreductive surgery is removal of the entire tumor burden to achieve either complete removal of the tumor upon visual inspection (complete cytoreductive surgery) or a residual tumor of < 1 cm (optimal cytoreductive surgery). Even centers experienced in ovarian tumor cytoreductive surgery achieve optimal resection in only 50% of patients. Patients with incomplete/suboptimal cytoreductive surgery are at a significantly higher risk of recurrence and poor prognosis.

Following primary treatment for gynecologic cancer, the relapse rate is approximately 20-25% for early-stage disease and 70% for advanced (spread beyond primary site) disease. The survival curve after recurrence never plateaus, which means that the goal of treatment for recurrent gynecologic cancer is controlling the disease and disease-related symptoms, limiting treatment-related toxicity, and maintaining or improving quality of life. Primary or secondary resistance is the main cause for diminished effectiveness over time of platinum-based chemotherapy, contributing to the dismal outcome of advanced patients whose 5-year survival rate is less than 30%. Patients who are hormone receptor positive will often receive anti-estrogen therapy in the recurrent setting; however, anti-estrogen efficacy is modest in this setting. In general, treatment of recurrent disease is palliative and is initiated with the goals of controlling disease-related symptoms, limiting treatment-related toxicity, maintaining or improving quality of life, delaying time to progression, and prolonging survival.

## Illustrative hormone-dependent gynecologic treatment landscape

### ER+/PR+/HER2- Breast Cancer Treatment Landscape

- ~70% of patients have hormone-driven (ER+,PR+,HER2-) breast cancer
- 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



#### Reasons Why Such a Therapy is Needed

Cytoreductive surgery followed by combination platinum and taxane chemotherapy is the first-line treatment for most gynecologic cancer patients regardless of type. Outside of DNA repair deficient high grade serous ovarian cancer, there are limited treatment options for all other forms of ovarian and endometrial cancer. Given the above-mentioned 5-year survival rate of less than 30%, there is a critical need to identify a targeted treatment in the recurrent setting. Ovarian and endometrial cancer remains a serious, life threatening, unmet medical need, resulting in more than 26,000 estimated deaths in the US every year.

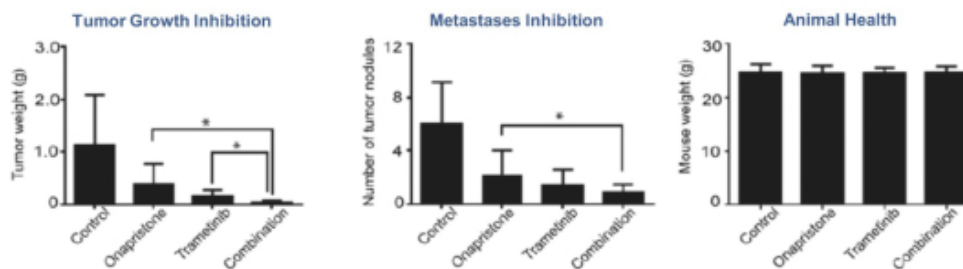
#### Preclinical data

#### PR in Endometrial Cancer

Progesterone receptor (PR)-targeted therapies are modestly active in patients with endometrial cancer, which may be attributed to an evolving understanding of the underlying molecular mechanisms of PR-targeted therapies for this disease. In the normal endometrium, estrogen drives proliferation of the endometrial glandular epithelium, whereas progesterone counteracts the effects of estrogen. Progesterone acts by binding to the PR and has a dual role through both genomic and nongenomic pathways. Anti-progestins such as onapristone have recently been shown to be efficacious in mouse models of uterine cancer, suggesting that PR blockade may be an effective approach for treating uterine cancer.

## Role of PR in endometrial cancer

### In Vivo Synergy: PR Antagonist and MEK Inhibitor



Source: Reprinted from Molecular Cancer Therapeutics, Huang et al, Inhibiting Nuclear Phospho-Progesterone Receptor Enhances Antitumor Activity of Onapristone in Uterine Cancer, Copyright 2017. Reprinted with permission from Elsevier.

Note: In vivo effect of onapristone, trametinib, and the combination of both drugs on tumor weight, number of tumor nodules, and body weight. Error bars indicate the SEM; \*,  $P < 0.05$ .

It has been reported that mitogen-activated protein kinases (MAPK) play a dual role in PR subcellular trafficking and aid in the rapid nuclear association of PR via Serine 294 (S294) phosphorylation in response to growth factors and in response to ligand (i.e., progesterone). In Huang *et al* 2017, PR+ endometrial cancer cells were implanted in mice and upon tumor engraftment were treated with onapristone and/or trametinib, a MEK inhibitor. If progesterone receptor does coordinate endometrial cancer response through MAPK via MEK signaling, then the MEK inhibitor, trametinib, should be anticipated to enhance onapristone sensitivity through blocking the nuclear translocation of phosphorylated PR. The study demonstrates that PR+ endometrial xenografts are sensitive to both onapristone and trametinib alone, and exhibit synergy when combined, indicating a rationale to develop onapristone alone or in combination with a MEK inhibitor for PR+ endometrial cancer.

### PR in Ovarian cancer

Progesterone and progesterone receptors (PR) are increasingly gaining attention for their emerging role as critical regulators of breast, ovarian, and endometrial cancer. Progesterone is a steroid hormone that is produced primarily by the corpus luteum in the ovaries during the second half of the menstrual cycle or luteal phase. Cyclical hormone exposure beginning at menarche and ending in menopause occurs monthly and regulates the growth and differentiation of specialized tissues within the reproductive tract and breast tissues. Until recently, little was known about the relative distribution of PR within the subtypes of ovarian tumors. In a cohort of 504 ovarian tumors, Diep *et al* (2013) reported that 35% of the tumors were progesterone receptor-positive (PR+) and that PR expression is associated with better outcomes, indicating a potential role for hormone therapy in PR+ ovarian cancer. Importantly, several subtypes were found to be highly enriched for PR. Retrospective studies evaluating the association of total PR expression and progression-free disease survival support the concept that subsets of PR+ ovarian tumors are highly sensitive to hormones and thus more likely to respond to endocrine therapy.

### Development of extended release formulation

#### Precedent Formulation – Onapristone IR (ONA-IR)

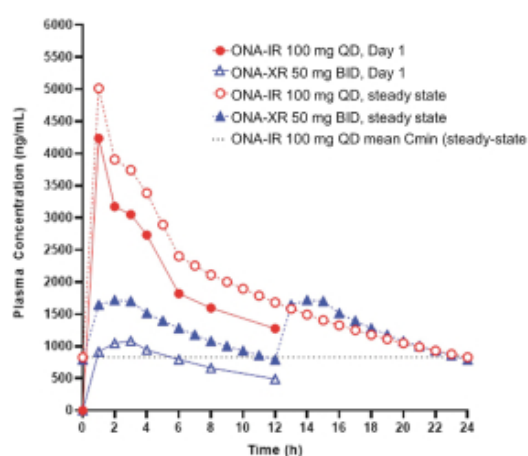
Onapristone was originally developed in an immediate release or “IR” form (onapristone IR; ONA-IR). ONA-IR was first evaluated as an oral contraceptive and was dosed up to 400 mg/day for periods of 7 days during single ovulatory cycles in healthy female subjects. Later, ONA-IR 100 mg/day was administered for periods exceeding 12 months in breast cancer studies. Discontinuation of ONA-IR development by the original sponsor, Schering AG, is thought to have been due to the observation of liver test abnormalities and the perceived risk of drug-induced liver injury (DILI) during a Phase 2 study of ONA-IR as first line therapy in breast cancer subjects. Liver test elevations were considered a concern for the planned contraception and benign gynecological indications (e.g., uterine fibroids,

endometriosis). However, renewed interest in anti-progestin therapy for PR-positive malignancies has led to the consideration of new strategies for reducing potential hepatotoxic effects of onapristone.

In developing new strategies for anti-progestin use, one consideration is that mifepristone, ulipristal, telapristone, and onapristone all contain a 17-carbon steroid ring structure that is typical of steroids. Anti-progestins with steroidal cores often display significant cross-reactivity with closely related steroid receptors, namely, androgen receptor (AR), glucocorticoid receptor (GR), and mineralocorticoid receptor (MR). This functional overlap is partly responsible for the side effects linked with the steroidal drugs, which themselves carry a potential DILI risk. Because onapristone binds to GRs less efficiently than to PRs, one strategy to minimize liver test elevations was to seek a new onapristone formulation that yielded steady state pharmacokinetic (PK) parameters where: (a)  $C_{max}$  is lower than the  $C_{max}$  associated with ONA-IR 100mg QD (to target a reduced risk for LFT elevations); and (b)  $C_{min}$  is at least approximately equal to the  $C_{min}$  associated ONA-IR 100mg QD (to target at least equivalent, sustained suppression of PR activity). Various formulation strategies were evaluated and a 50mg, BID (twice-daily), extended release tablet (onapristone XR; ONA-XR) was selected to be the second-generation dosage form for the clinical evaluation of onapristone in PR-positive cancers.

### Pharmacokinetic Comparison of ONA-XR versus ONA-IR

**ONA-XR versus ONA-IR: plasma onapristone concentrations at Day 1 and at steady-state**



- PK dataset enabled a direct comparison between  $C_{max}$  and steady-state trough concentrations ( $C_{min-ss}$ ) ONA-IR 100mg QD and ONA-XR 50mg BID
- Dosing with ONA-XR resulted in a steady-state  $C_{max}$  almost 3X lower than for ONA-IR
- Steady-state  $C_{min}$  was similar for both onapristone formulations

#### Compared to ONA-IR, ONA-XR has:

- Lower peak drug concentration ( $C_{max}$ ) to improve tolerability
- Similar trough drug concentration ( $C_{min}$ ) to maintain target coverage and efficacy

Source: Reprinted from Drug Safety, Lewis et al, Onapristone Extended Release: Safety Evaluation from Phase I–II Studies with an Emphasis on Hepatotoxicity, Copyright 2020. Reprinted with permission from Nature Springer.

#### Novel Formulation – Onapristone XR

Pharmacokinetic (PK) parameters for ONA-IR 100mg QD and ONA-XR 50mg BID were previously evaluated within a dose escalation component of a Phase 1-2 clinical study in female subjects with endometrial carcinoma, breast cancer or ovarian cancer. This study (Cottu *et al* 2018) reported that ONA-XR showed “Clinical benefit with excellent tolerance”, while defining a recommended phase 2 dose level of ONA-XR of 50mg, BID. The PK dataset from this clinical study enabled a direct comparison between  $C_{max}$  and  $C_{min}$  for ONA-IR 100mg QD and ONA-XR 50mg BID. Steady-state pharmacokinetics of ONA were estimated using standard noncompartmental methods and the nonparametric superposition tool in Phoenix WinNonlin version 8.3 (Certara Inc., Princeton, NJ). These methods assume linear pharmacokinetics from the first dose to steady state. Dosing with ONA-XR 50mg BID resulted in a steady-state  $C_{max}$  almost 3 times lower than the  $C_{max}$  for ONA-IR 100mg QD, while the steady-state  $C_{min}$  for both formulations were similar: 829 ng/mL versus 790 ng/mL for ONA-IR versus ONA-XR, respectively. The findings of the Phase 1-2 PK and safety evaluation support that the recently developed, extended release form of onapristone appears to have achieved the PK goals of the formulation exercise.



### Completed clinical trials

The initial IR formulation (ONA-IR), developed by Schering AG at various strengths, was dosed up to 400 mg/day in healthy volunteers and 100 mg/day for periods exceeding six months in oncology studies. Arno Therapeutics (Cranbury, NJ) subsequently developed onapristone extended release (“ONA-XR”) formulation and administered it in doses of 10, 20, 30, 40 and 50 mg ONA-XR BID for up to 52 weeks. We acquired ONA-XR from Arno Therapeutics. There are no associated future payments due to Arno.

### Summary of clinical trials evaluating on a pristone with IR or XR formulation

Antiprogesterin	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

Note: BID: twice per day; DoR: duration of response; ORR: overall response rate; PFS: progression free survival.

### Onapristone IR Clinical Data

Across first and second line metastatic breast cancer, onapristone IR (ONA-IR) demonstrated clinical activity comparable to anti-estrogen standard of care. We believe that by selecting for PR+ status and combining ONA-XR, an improved form of ONA-IR, with anti-estrogen therapy to promote complete hormone blockade, we will potentially generate superior efficacy data compared to the current standard of care treatment options.

### First Line Locally Advanced or Metastatic Breast Cancer

A Phase 2 study investigating onapristone (ONA-IR, 100 mg/day as a single daily dose) as first-line endocrine therapy in patients with breast cancer was conducted as an investigator-initiated study, as shown below. Nineteen patients, either with locally advanced breast cancer (n = 12) or who were elderly with primary breast cancer and considered unfit for standard of care (n = 7) received ONA-IR. In 17 of the 19 patients, tumors expressed ER while 12 of 18 tumors tested expressed PR.

Among 18 patients who were evaluable for response, 10 had a partial response and 2 had stable disease (“SD”) for six months or more. The median duration of objective response and SD was 70 weeks. Ten patients were ER-positive/PR-positive, of whom 7 achieved partial response (PR; tumor shrinkage of >30%) and 1 had SD. Overall, the clinical benefit rate was considered comparable to the current standard of care of letrozole (anti-estrogen) and palbociclib (CDK4/6 inhibitor).

### Comparison of ONA-IR to standard of care in 1L locally advanced or metastatic breast cancer

Treatment	Subtype	Patients (n)	CBR (%)	ORR (%)	Grade 3,4 AE (%)	Reference
ONA-IR	PR+	18	67	58	^GT (<5%)	Robertson (1999)
PAL + LET	HR+,HER2-	165	81	55	Neutropenia (55%), Leukopenia (25%)	PALOMA-1 (2014)

Note: CBR: clinical benefit rate; LET: letrozole; ONA: onapristone, ORR: overall response rate; PAL: palbociclib.

#### Second Line Metastatic Breast Cancer

A non-randomized, open label, multicenter Phase 2 study was conducted at 13 sites in Germany and the United Kingdom, as shown below. The study goal was to investigate the efficacy and safety of ONA-IR when given 100 mg/day to post-menopausal women with advanced breast cancer who had progressed on tamoxifen, a selective estrogen receptor modulator therapy. The study was also designed to assess the influence of onapristone on the levels of relevant endocrine parameters (cortisol, androstenedione, estrone and estradiol).

Of the 101 evaluable patients, 1 had a complete response (“CR”), 9 had a partial response, and 39 had SD for three months or more. The median duration of response was 11 months. Median time to progression was 4 months.

In second line metastatic breast cancer, ONA-IR exhibited monotherapy activity in patients who had progressed while on tamoxifen. In this trial, patients were not screened for progesterone receptor positive (PR+) status, meaning that only 60% of enrolled patients would have expected to be PR+ based upon historical prevalence in this setting and therefore derive clinical benefit from ONA-IR. Therefore, this trial potentially under-represents the likely true clinical benefit of ONA-IR had patients been stratified for the partial response biomarker. Despite administering a monotherapy without patient selection for PR+, ONA-IR demonstrated comparable clinical activity to standard of care anti-estrogens (FUL), CDK4/6 inhibitors (PAL), and the combination of the two (FUL + PAL).

### Comparison of ONA-IR to standard of care in 2L metastatic breast cancer

Treatment	Subtype	Patients (n)	CBR (%)	ORR (%)	Grade 3,4 AE (%)	Reference
ONA	All Comers	101	49	10	None reported	Jonat (1996)
PAL	HR+,HER2-	58	60	7	Neutropenia (55%), Leukopenia (25%)	TREnd (2017)
FUL	HR+,HER2-	174	40	10	Fatigue (<5%)	PALOMA-3 (2015)
PAL + FUL	HR+,HER2-	347	67	19	Neutropenia (65%), Leukopenia (25%)	PALOMA-3 (2015)

Note: CBR: clinical benefit rate; FUL: fulvestrant; LET: letrozole; ONA: onapristone, ORR: overall response rate; PAL: palbociclib.

#### Onapristone XR Clinical Data

Overall, over 140 subjects received at least a single dose of ONA-XR across both healthy volunteer and cancer trials through December 31, 2021. Multiple drug product formulations of onapristone have been developed for evaluation throughout the clinical development program. Clinical development was initiated with a 10 mg immediate release (IR) capsule. An IR tablet formulation (10mg, 25 mg) and extended release (XR) tablet formulation (2.5 mg, 5 mg, 10 mg, and 20 mg) were also developed. The tablets have been administered as a single tablet or in multiples in order to obtain the desired dosage. The XR tablet has been used in ongoing safety and efficacy studies. ONA-XR 50 mg BID (twice-per-day) is the recommended dose for our ongoing investigational trials.

## Completed clinical studies incorporating new formulation

Study Protocol (Status)	Study Design	N	Age	Dosage and Regimen	Endpoints
AR18-CT-001	Single dose PK study of oral immediate release (IR) formulation	12 Healthy female volunteers	18+	10 mg single dose, fasting and 2 weeks later with food or vice-versa	PK profile, food effect, safety
AR18-CT-101	Multi-center, open-label, randomized, two-stage study with a phase 2 expansion component in patients PR+ breast, ovarian, or endometrioid adenocarcinoma	58 post-menopausal females, recurrent or metastatic PR+ cancer	18+	10 mg XR BID 20 mg XR BID 30 mg XR BID 40 mg XR BID 50 mg XR BID 100 mg IR QD	Safety, RP2D, Efficacy, PK, Bioavailability
AR18-CT-102	Open-label, randomized, two-stage phase 1 study and a phase 2 expansion in combination with abiraterone in males with castration-resistant prostate cancer	36 males with adenocarcinoma of prostate	18+	10 mg XR BID 20 mg XR BID 30 mg XR BID 40 mg XR BID 50 mg XR BID	Safety, RP2D PK
ONAWA	Multi-center, open-label, randomized, two-stage window of opportunity trial	10 females, primary PR+ cancer	18+	50 mg XR BID	Safety, Efficacy
Single Patient INDs (Closed)	Single patient IND in patients with PR+ ovarian or endometrioid adenocarcinoma	2 females, recurrent or metastatic PR+ cancer	18+	50 mg XR BID	Safety, Efficacy

Note: BID: twice per day; IR: immediate release; PK: pharmacokinetic; PR: progesterone receptor; QD: once per day; XR: extended release.

As of December 31, 2021 thirty-two subjects (22%) of the total onapristone safety set (n = 144) experienced any treatment emergent adverse event (TEAE). Adverse events were generally consistent across all defined groups. Thirteen subjects experienced Grade 3 or Grade 4 TEAEs that were deemed related to ONA-XR with no correlation across dosing groups. The most common drug-related TEAEs included fatigue, abdominal pain, and an increase in gamma-glutamyltransferase. These events are generally consistent with disease progression and/or prior anti-progestin experience, including onapristone. In addition, there were no clinically significant post-dose changes in electrocardiograms (ECGs), vital signs, or safety laboratory results.

### Primary Breast Cancer

In a multicenter, open label, window of opportunity trial, Bellet *et al* (2021) enrolled 10 adult patients with ER+, PR+, HER2- breast cancer and Ki-67  $\geq 15\%$ . Patients received ONA-XR tablets of 50 mg BID for a short course of endocrine therapy before surgery. Assessment of the treatment effects was possible for the 10 patients who successfully completed the protocol and the 10 paired samples (100%) were analyzed. Main patient characteristics were mean age 68, mean tumor size 20.2 mm, stage I (40%) and grade 2 (100%). No patients achieved a CCCR (cell-cycle complete response). Tumor Ki-67 expression decreased, was stable and increased in 6, 1 and 3 patients, respectively. Mean percentage suppression of Ki-67 was 19.58%. Overall, no statistically significant change was observed in Ki-67 between paired samples ( $p=0.234$ ). Baseline IHC PgR (%) expression correlated with Ki-67 decrease ( $r = -0.60$ ). Mean percentage suppression of Ki-67 for tumors with IHC PgR expression  $\geq 90\%$  (N=4) and  $<90\%$  (N=6) was -62.0% and +8.7%, respectively. Six (60%) patients reported adverse events at any grade. Most

common grade 1 or 2 adverse events were post procedural pain, dry mouth and GGT (gamma-glutamyl transferase) increased. Grade 3 reversible GGT and AST (aspartate aminotransferase) increase occurred in one patient.

#### Advanced, Recurrent Metastatic Breast Cancer

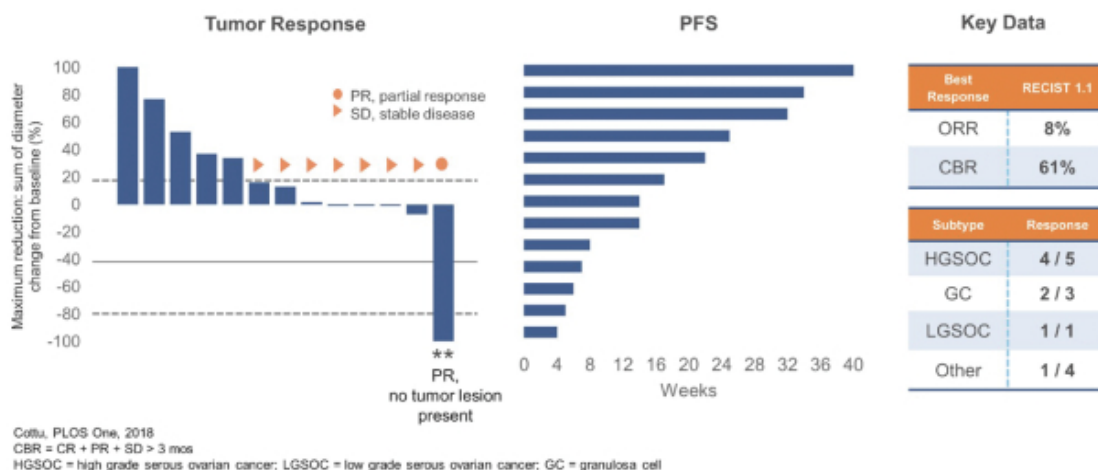
In a multicenter, open label, Phase 1 trial, Cottu *et al* (2018) enrolled 52 adult patients with PR+ tumors, including 20 patients with breast cancer. Patients were randomized to five cohorts of ONA-XR tablets of 10, 20, 30, 40 or 50 mg BID, or immediate release 100 mg QD until progressive disease or intolerability. All patients were heavily pre-treated; prior treatments included median (range): chemotherapy 4 (1–11), endocrine therapy 1 (1–7), biologic/small molecule therapy 1 (1–2), and radiotherapy 1 (1–3). Among the 20 heavily pre-treated breast cancer patients, no CR or partial response were observed, 7 patients had SD, including 3 patients with SD lasting for at least 24 weeks (15% clinical benefit rate). The number of prior therapies was 3, 7 and 7, respectively, for these 3 patients and 2 of these 3 patients had liver metastases at baseline. The study authors concluded that the new XR formulation of onapristone was well tolerated and resulted in meaningful clinical benefit in heavily pretreated patients with breast cancer. The only treatment-related serious adverse events were G3 LFT elevations (n = 4; 8%), all associated with disease progression in the liver as reviewed. These occurred across dose cohorts: 10 mg BID (AST increased, bilirubin increased), 20 mg BID (LFTs abnormal), and 40 mg BID (bilirubin increased). No relationship was found between adverse events and study drug exposure. No treatment-related deaths were reported. One patient died within 30 days of last dose (respiratory distress syndrome due to progressive lung metastases). No other significant adverse events attributable to the mechanism of action were recorded.

#### Advanced, Recurrent Metastatic Gynecologic Cancers

A Phase I dose escalation study of ONA-XR in breast, endometrial, and ovarian cancer patients found all doses tested to be safe and well tolerated, with 50mg BID administered orally recommended as the Phase 2 dose. The most common treatment-related adverse events reported by investigators (>10%) were nausea, fatigue and constipation. In that Phase I study, 33% of ovarian and 25% of endometrial cancer patients were seen to have sustained disease control.

Focusing on the ovarian cancer (n=13) subpopulation, all PR+ ovarian patients were heavily pre-treated; prior treatments included median (range): chemotherapy 4 (2–6), and treatment lines in metastatic setting 4 (2-10). All patients were platinum resistant. Clinical data is shown below.

#### Phase 1 ovarian cancer data



### Advanced, Recurrent Granulosa Cell Tumor of the Ovary

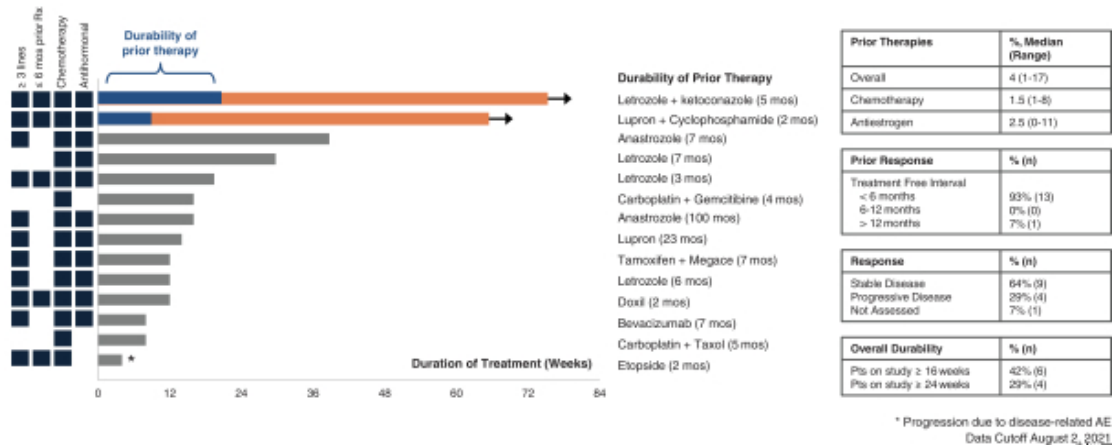
Granulosa cell tumors (GCT) of the ovary is a rare form of ovarian cancer. These tumors account for 2-5% of all ovarian malignancies and it is estimated that there are approximately 5,000 patients with recurrent disease in the US and EU.

Almost all GCT tumors are progesterone receptor (PR) positive, whereas about 50% are estrogen receptor (ER) positive. These tumors often produce estrogen and progesterone, which can cause symptoms such as abnormal vaginal bleeding or breast tenderness. Further, PR expression is correlated with worse outcomes in GCT patients. GCT tumors have a low mitotic ratio and few actionable mutations, which limits the applicability of chemotherapeutic and precision medicine approaches. Platinum-based chemotherapy is recommended as the first line of treatment for patients in the metastatic setting. Following progression to metastatic disease, patients typically cycle through chemotherapy, antihormonal treatments, and cytoreductive surgeries. There are currently no FDA treatments for GCT tumors of the ovary, and few, if any, open clinical trials.

Given that GCT tumors are hormone driven, it is plausible that complete hormone blockade via antiprogesterin and antiestrogen therapy may provide a therapeutic benefit to patients. In 2019, Memorial Sloan Kettering Cancer Center initiated an Investigator-sponsored Trial to evaluate onapristone extended release (ONA-XR) in women with GCT of the ovary who had progressed on multiple prior therapies.

### Phase 2 data evaluating ONA-XR in late line GCT of the ovary

Fourteen patients with progesterone receptor positive (PR+) GCT of the ovary were enrolled in the stage I trial, with thirteen of those patients completing at least one full cycle of treatment.



Four of the 14 patients (29%) had clinical benefit lasting at least 24 weeks, and 5 additional patients (64%) experienced stable disease as best response. Importantly, two patients (14%) remain on treatment after 12 months. To date, no significant treatment-related adverse events have been identified. The most common treatment-related adverse events reported were nausea, fatigue, and constipation.

Based on the Phase 2 monotherapy data presented above, a combination arm seeking to enroll 25 patients was activated to evaluate the combination of ONA-XR with Arimidex (anastrozole), a selective nonsteroidal aromatase inhibitor. Aromatase inhibitors are commonly used to treat recurrent granulosa cell tumors based on low response rates to chemotherapy and historically high rates of ER/PR expression within these tumors. However, objective response rate for anastrozole remains low and was found to be 2.5% in a recent clinical trial (Banerjee, JCO, 2018). We seek to test the combination of ONA-XR and anastrozole to enhance the response rate in patients with PR+ GCT tumors of the ovary.

### ***We have FDA Fast Track designation for PR+ ovarian cancer***

In August 2020, we received FDA Fast Track designation for ONA-XR in PR+ ovarian cancer. Fast Track designation is designed to facilitate the development and expedite the review of therapies for serious conditions and fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the product candidate and the specific indication for which it is being studied. If any of our product candidates receive Fast Track designation but do not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation does not change the standards for approval. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

### ***Clinical development plan for ONA-XR***

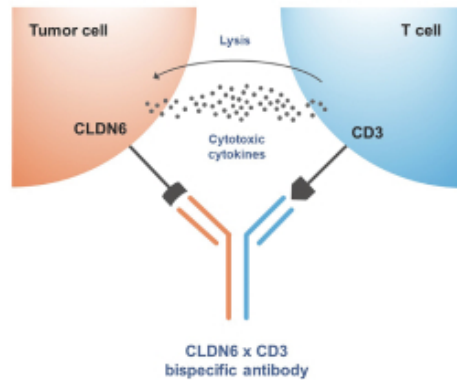
The PR signaling pathway has been implicated in female hormone-dependent cancers, including breast, ovarian, and endometrial cancer. Our clinical development effort for ONA-XR, a selective and potentially potent small molecule antagonist of PR, will initially focus on indications where there is evidence suggesting PR-mediated signaling contributes to resistance and disease progression. In 2020, we initiated a Phase 2 investigator-sponsored trial in collaboration with Jefferson Health to evaluate ONA-XR in combination with Arimidex (anastrozole) in PR+ endometrial cancer and preliminary data is expected in mid-2022. Also, in 2020 we initiated a Phase 0 trial of ONA-XR in a window of opportunity study in primary breast cancer, and we reported preliminary data at the San Antonio Breast Cancer Symposium in December 2021. In 2021, a Phase 1b/2 investigator-sponsored trial was initiated in collaboration with Memorial Sloan Kettering Cancer Center (MSK) to evaluate ONA-XR in combination with Ibrance (palbociclib) and Femara (letrozole) in first line (1L) metastatic breast cancer patients with biochemically recurrent disease, defined as circulating tumor DNA (ctDNA) positive. This is potentially a new clinical opportunity for the estimated 20% of 1L patients who are at high risk of early disease progression on Ibrance plus Femara combination therapy and Phase 1b data is expected in mid-2022. In 2021, the first stage of a Phase 2 investigator-sponsored trial initiated by MSK to evaluate ONA-XR in recurrent granulosa cell tumors (GCT) of the ovary was completed. In July 2021, MSK initiated the second stage of this trial evaluating ONA-XR in combination with Arimidex, and preliminary data is expected in the second half of 2022. Also in 2021, a Phase 2 investigator-sponsored trial was initiated in collaboration with Wisconsin Oncology Network (WON) to evaluate ONA-XR in combination with Faslodex (fulvestrant) in second line (2L) or third line (3L) metastatic breast cancer. This trial is intended to evaluate potential ONA-XR plus Faslodex drug synergy after treatment failure of CDK4/6 and/or PIK3 $\alpha$  inhibitors, and preliminary data is expected in the second half of 2022. In 2022, WON intends to initiate a sub-study of its Phase 2 trial in 2L/3L metastatic breast cancer that will evaluate the uptake of radiolabeled progesterone (F-FFNP) via PET imaging in breast tumors.

### **CLDN6xCD3 bispecific antibody program: CLDN6xCD3 bsAb**

#### ***Background CLDN6***

Claudin 6 (CLDN6) is an oncofetal tight junction protein involved in the cell-to-cell adhesion of epithelial and endothelial cell sheets. Although silenced in healthy adult human tissues, CLDN6 expression has been found in ovarian, gastric, pediatric, and other cancer tissues and can lead to a poor prognosis. Monoclonal antibody (MAb) discovery against CLDN6 has been encumbered by the high homology of endogenously expressed claudin 9 (CLDN9), which varies from CLDN6 by only 3 amino acids in the extracellular domain.

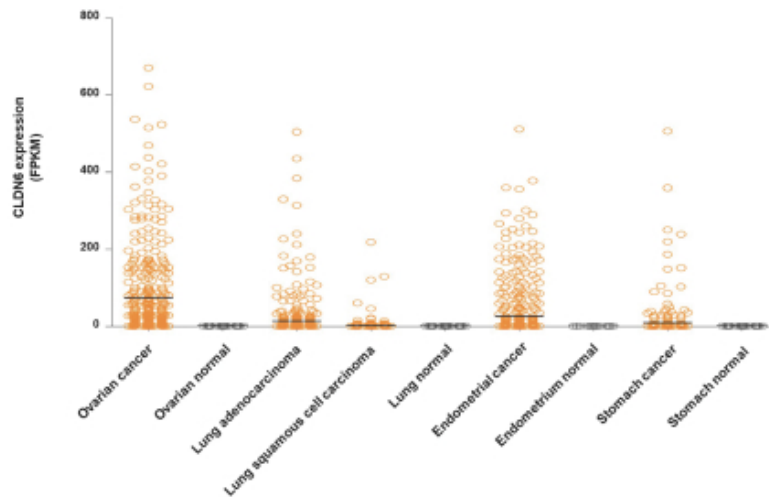
## Proposed mechanism of action



### Rationale for bispecific antibody

Cytotoxic T cells are considered to be the most potent effector cells of the immune system. As a consequence, broad T cell activation can lead to significant and sometimes lethal side effects. Therefore, to harness the potential of cytotoxic T cells, therapeutic strategies seek to pair T cell activation with drug targets that are restricted to cancer tissue so as to avoid unwanted toxicity. CLDN6 expression is restricted to various cancer types (i.e., a tumor specific antigen or TSA), making it an ideal target to help T cells recognize and eliminate cancer cells. Recently, a class of bispecific antibodies (TSAxCD3) with a native immunoglobulin format has emerged that can efficiently trigger T cell-mediated killing of tumor cells by linking a T cell to a tumor cell and activating the CD3/t cell receptor complex, as shown above.

### CLDN6 expression in cancer versus normal tissue



Source: Cancer RNAseq data from The Cancer Genome Atlas (TCGA); normal tissue RNAseq data from the Genotype-Tissue Expression (GTEx) project.

### Preclinical data

CLDN6xCD3 bsAb, is an anti-CD3 x anti-Claudin 6 (CLDN6xCD3) antigen bispecific monoclonal antibody (bsAbs) that is intended to redirect T-cell-mediated lysis toward malignant cells expressing CLDN6. As shown below, preclinical studies demonstrate that CLDN6xCD3 bsAb exhibits selectivity for CLDN6 over CLDN9 and

that CLDN6xCD3 bsAb mediates strong T-cell activation and specific lysis of cells expressing CLDN6. *In vivo* studies with a prototype bispecific of CLDN6xCD3 bsAb demonstrated dose-dependent tumor regressions in an established ovarian cancer xenograft model with an intact immune system. We expect to select a candidate to support IND-enabling studies for CLDN6xCD3 bsAb in the second half of 2022.

### CLDN6 x CD3 bispecific retains selectivity of parental mAb

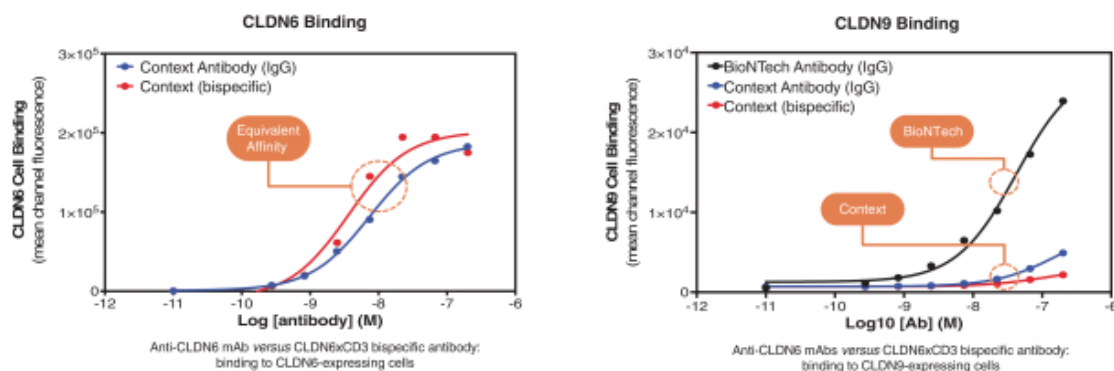


Figure above illustrates the results of a binding assay showing that Context's Claudin 6 monoclonal and bispecific antibodies bind to Claudin 6 preferentially over other Claudin proteins. Human embryonic kidney 293T (HEK-293T) cells were transiently transfected with DNA for the indicated Claudin protein along with GFP (pUC) for 22 hours.

### Context bispecifics activate T cells against CLDN6+ cells

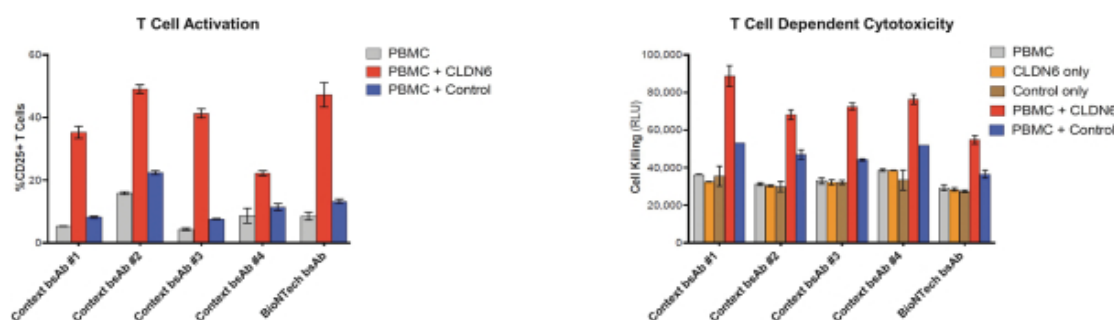


Figure above illustrates the results of immune assays showing that Context's CLDN6 x CD3 bispecific antibodies activate T cells and drive T-cell dependent cytotoxicity. All bispecific formats contain the same CD3 cassette. Activity was measured after 72 hours of treatment.

### Comparison of CLDN6 development programs

We have performed head-to-head *in vitro* studies comparing internally developed CLDN6 monoclonal antibodies and those from BioNTech and Xencor. Antibodies for BioNTech and comparative data for Xencor 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.

The results presented in the below table have been derived from publicly available reports of preclinical studies and clinical trials run independently of our trials or meta-analyses of such clinical results. We have not performed any head-to-head trials comparing any of these other therapies with CLDN6xCD3 bsAb. As such, the results of these other clinical trials may not be comparable to clinical results for CLDN6xCD3 bsAb. The design of these other



trials vary in material ways from the design of the clinical trials for CLDN6xCD3 bsAb. For further information and to understand these material differences, you should read the relevant reports or meta-analyses.

While the BioNTech and Xencor’s product candidates are not intended to compete with our CLDN6xCD3 bsAb, it is useful to compare the symptomatic results achieved by their devices and approaches a good proxy to understand the adoption of these therapies.

	Context	Xencor	BioNTech
<b>Program</b>	CLDN6xCD3 bsAb	CLDN6xCD3 bsAb	BNT211 BNT142
<b>Antibody Format</b>	Bispecific CLDN6xCD3	Bispecific CLDN6xCD3	CLDN6 CAR-T, and CLDN6xCD3 (bi(sFc))
<b>Stage</b>	Preclinical	Preclinical	Phase 1, Phase 1
<b>Status</b>	Active	Active	Active
<b>Selectivity CLDN6:9</b>	>100x	10x	7x

#### **Other preclinical programs**

In addition to our product candidates, we are leveraging our knowledge in hormone-dependent cancer to pursue discovery stage research programs.

In November 2015, the Company entered into a patent license agreement, as amended, (the “Drexel License Agreement”) with Drexel University (“Drexel”) for license rights to patents for certain intellectual property and know-how related to certain Sigma1 technology. As part of a strategic review of our pipeline, we have recently notified Drexel that we are terminating the Drexel License Agreement, effective as of April 27, 2022.

#### **Our collaboration and license agreements**

In March 2020, we entered into a manufacturing and development agreement with Tyligand Bioscience (Shanghai) Limited for ONA-XR (the “Tyligand Process Development Agreement”) that is intended to enhance our ability to meet manufacturing demands for commercial launch and expand our clinical trial footprint into Greater China. Under the terms of the agreement, Tyligand is responsible for ONA-XR manufacturing process optimization. As a part of the agreement, Tyligand is eligible to receive development milestone payments of \$0.8 million and a certain number of warrants exercisable for common stock upon successful completion of the manufacturing development plan, \$2.0 million upon the completion of scale-up of the first cumulative 100 kilograms of the GMP-grade compound and \$3.0 million upon our completion of scale-up of the first cumulative 300 kilograms of the GMP-grade compound. We will also pay Tyligand a 1% royalty of net sales of finished product commercialized in any country (other than the People’s Republic of China, including Hong Kong and Macau) utilizing the compound substantially manufactured in accordance with the process and specifications outlined in this agreement. This agreement terminated in August of 2021, subject to certain surviving and ongoing obligations. Please note that the foregoing is a summary of the agreement and is therefore qualified in its entirety by reference to the agreement attached hereto as Exhibit 10.2 and which is incorporated herein by reference.

In August of 2021, Tyligand achieved “successful completion” under the Tyligand Process Development Agreement as a result of Tyligand’s successful optimization of the ONA-XR manufacturing process. Because of this achievement, Tyligand has entered into a license agreement with us (the “Tyligand License Agreement”) whereby we have granted Tyligand an exclusive license to develop and commercialize ONA-XR in the People’s Republic of China, including Hong Kong and Macau (the “Tyligand Territory”), subject to Tyligand paying Context a mid-single digit royalty of net sales of ONA-XR in such countries. The royalty term of such exclusive license shall be the from period beginning on the date of the first commercial sale of ONA-XR in the Tyligand Territory and ending on the latest of (i) the sale of a generic product containing the same active pharmaceutical ingredients as ONA-XR in the Tyligand Territory, and (ii) fifteen (15) years after the date of the first commercial sale of ONA-XR in the Tyligand Territory. We have retained our global exclusive rights for ONA-XR for the remainder of the world. As a result of the completion of this milestone, Tyligand was granted a warrant to purchase 111,576 shares of our common stock at an exercise price of \$7.17 per share (which was automatically exercised and cancelled in

connection with our initial public offering), we paid Tyligand \$800,000, and Tyligand will be eligible to receive manufacturing and development milestone payments totaling up to \$5.0 million upon the achievement of certain future milestones. The Tyligand License Agreement provides for termination in the event of (a) insolvency, (b) a material breach of the agreement, and (c) in the event that Tyligand does not meet certain regulatory milestones. Please note that the foregoing is a summary of the agreement and is therefore qualified in its entirety by reference to the agreement attached hereto as Exhibit 10.5 and which is incorporated herein by reference.

In April 2021, we entered into a license agreement with Integral for the exclusive worldwide rights (the “Integral License Agreement”) to certain Claudin 6 antibody patents in the field of bispecific antibodies. Under the terms of the license and development agreement, we are responsible for all costs associated with CLDN6xCD3 bsAb development as well as certain success-based payments, including milestone and royalty payments, to Integral. We paid an upfront license fee of \$0.3 million and granted 418,559 shares of Series A Stock with a fair market value of approximately \$2.8 million. As a part of the agreement, Integral will be eligible to receive development and regulatory milestone payments totaling up to \$55.3 million, sales milestone payments totaling up to \$130 million, and tiered royalties of up to 12% of net sales of certain products developed under this agreement. We shall continue to pay royalties on a country-by-country and licensed-by-licensed product basis, until the later of: (i) the expiration of the patent covering such product in such territory, (ii) the expiration of any regulatory exclusivity granted with respect to a product in such territory and (iii) ten years from the first commercial sale of such product in such country. The agreement shall continue in full force and effect, until either (a) royalty payments for all products in all territories have expired or (b)(i) we provide written notice of termination, (ii) during three successive quarters we do not use commercially reasonable efforts to develop a product, (iii) if the agreement is breached or (iv) if a party goes bankrupt. Please note that the foregoing is a summary of the agreement and is therefore qualified in its entirety by reference to the agreement attached hereto as Exhibit 10.1 and which is incorporated herein by reference.

### **Commercialization**

We retain worldwide development and commercialization rights for ONA-XR outside of Greater China and retain full worldwide development and commercialization rights to certain CLDN6 antibody patents in the field of bispecific antibodies. We periodically evaluate out-license opportunities for our product candidates, including our lead product candidate ONA-XR, and seek to identify drug candidates for novel indications and/or patient subpopulations with an oncology focus that we might in-license. Our commercial plans and strategy for each particular program may change as programs advance, markets change, and we receive more clinical data, and will depend on availability of current and future capital.

### **Sales and marketing**

We currently have no sales, marketing, or commercial product distribution capabilities, and we may explore partnerships with larger pharmaceutical organizations to out-license our product candidates, including our lead product candidate ONA-XR. We intend to build the necessary infrastructure and capabilities over time for the United States, and potentially other regions, following further advancement of our product candidates.

### **Manufacturing**

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates obtain marketing approval. We also rely, and expect to continue to rely, on third parties to package, label, store and distribute our investigational product candidates, as well as for our commercial products if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our product candidates.

To date, we have obtained active pharmaceutical ingredients (API) and drug product for our product candidates from several third party contract manufacturers. We are in the process of developing our supply chain for each of our product candidates and intend to put in place additional framework agreements under which third-party contract

manufacturers will generally provide us with necessary quantities of API and drug product on a project-by-project basis based on our development needs.

As we advance our product candidates through development, we will consider our lack of redundant supply for the API and drug product for each of our product candidates to protect against any potential supply disruptions.

We generally expect to rely on third parties for the manufacture of any companion diagnostics we may develop.

## **Competition**

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. While we believe that our technology, the expertise of our executive and scientific team, research, clinical capabilities, development experience and scientific knowledge provide us with competitive advantages, we face increasing competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions may result in even more resources being concentrated in our competitors.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety and convenience.

For ONA-XR, our small molecule PR antagonist, we are aware of several companies developing PR antagonists, including Allergan, Evestra, and Gedeon Richter. To our knowledge, there are no PR antagonists approved for the treatment of cancer and the most advanced such PR antagonist is in a Phase 2 clinical trial.

For CLDN6xCD3 bsAb, our CLDN6xCD3 bispecific antibody, we are aware of several companies developing antibodies against this target, including Abbvie, Amgen, Astellas, AstraZeneca, BioNTech, Chugai, I-Mab, NovaRock, and Xencor. These companies are developing CDLN6 products in naked antibody, bispecific, CAR-T, and mRNA vaccine formats. To our knowledge, BioNTech has the only CLDN6 product in clinical trials.

## **Intellectual property**

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to our business, including seeking, maintaining and defending our patent rights. We own the issued patent and patent applications relating to our first program and lead product candidate ONA-XR, and retain full worldwide development and commercialization rights to certain CLDN6 antibody patents in the field of bispecific antibodies. Our policy is to seek to protect our proprietary position by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States directed to our proprietary technology, inventions, improvements and product candidates that are important to the development and implementation of our business. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates and continuing innovation to develop, strengthen and maintain our proprietary position in the field of oncology. We also plan to rely on data exclusivity, market exclusivity and patent term extensions when

available. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our product candidates, technology, inventions and improvements; to preserve the confidentiality of our trade secrets; to defend and enforce our proprietary rights, including any patents that we may own or license in the future; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.

As of March 14, 2022, our patent portfolio consisted of pending or issued patents that we own or license related to our ONA-XR product candidate and various other compounds and programs. Specifically, we owned four issued U.S. patents, three pending U.S. patent applications, one granted Canadian patent, two granted Chinese patents, one granted Japanese patent, three granted Australian patents, one granted Hong Kong patent, and 18 pending foreign patent applications, two of which are Australian applications, three of which are Canadian applications, two of which are Chinese applications, three of which are European regional patent applications, two of which are Hong Kong applications, one of which is a Mexican application, two of which are Japanese applications, two of which are Korean applications, and one international PCT application.

More specifically with respect to ONA-XR, our issued U.S. patents in our owned portfolio described above have claims directed to our ONA-XR as pharmaceutical compositions, formulations, and related methods of use, and methods of making. These U.S. patents are expected to expire between 2034 and 2036, subject to any extensions or disclaimers.

We also possess substantial know-how and trade secrets relating to the development and commercialization of our product candidates, including related manufacturing processes and technology.

With respect to our product candidates and processes we intend to develop and commercialize in the normal course of business, we intend to pursue patent protection covering, when possible, compositions, methods of use, dosing and formulations. We may also pursue patent protection with respect to manufacturing and drug development processes and technologies.

Issued patents can provide protection for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In general, patents issued for applications filed in the United States can provide exclusionary rights for 20 years from the earliest effective filing date. In addition, in certain instances, the term of an issued U.S. patent that covers or claims an FDA approved product can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, which is called patent term extension. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The term of patents outside of the United States varies in accordance with the laws of the foreign jurisdiction, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of oncology has emerged in the United States. The relevant patent laws and their interpretation outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our product candidates, technology, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Moreover, even our issued patents may not guarantee us the right to commercialize our product candidates, if approved. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from

commercializing our product candidates and practicing our proprietary product candidates, and our issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar products. Furthermore, our competitors may independently develop similar products that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

## **Government Regulation**

### ***Regulatory Pathway***

We expect that ONA-XR will be classified and regulated by the FDA as a drug. We expect that our CLDN6xCD3 bsAb will be classified and regulated by the FDA as a biologic. A new drug application (“NDA”) is required to introduce a drug into interstate commerce. A biologics license application (“BLA”) is required to introduce a biologic product into interstate commerce. The specific requirements of NDAs and BLAs include applicant information, product information, manufacturing information, pre-clinical data, clinical data, and labelling. The most important, time-consuming, and expensive aspect of preparing for a BLA or NDA is conducting clinical trials to demonstrate safety and effectiveness. The requirements of such clinical trials heavily influence the eventual allowable product label claims. The FDA has a performance goal as defined in the Prescription Drug User Fee Act of ten months for a standard submission and six months for priority review. It is not uncommon for NDAs and BLAs to require medical advisory board review prior to the FDA granting marketing approval. A facility inspection verifying the manufacturing systems is also usually performed prior to FDA approval.

We have in the past used and intend to continue to utilize the services of third-party experts to supplement internal regulatory planning and implementation.

### ***Ongoing FDA Regulation***

After the FDA permits a product to enter commercial distribution, numerous and pervasive regulatory requirements continue to apply to our business operations, products and technologies. These include:

- the FDA’s quality system regulation, or QSR, which requires manufacturers, including third party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling and marketing regulations which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated;
- advertising and promotion requirements, including FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses and FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;
- restrictions on sale, distribution or use;
- product establishment, registration and listing requirements and reporting requirements;
- recall requirements, including a mandatory recall if there is a reasonable probability that a product would cause serious adverse health consequences or death;
- an order of repair, replacement or refund; and

- post-market surveillance activities and regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data.

The FDA has broad post-market and regulatory enforcement powers. Manufacturers of biologic products and drug products like our product candidates are subject to unannounced inspections by the FDA and other state, local and foreign regulatory authorities to assess compliance with the QSR and other applicable regulations, and these inspections may include the manufacturing facilities of any suppliers.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, untitled letters, Form 483s, fines, injunctions, consent decrees and civil penalties;
- recall or seizure of products;
- operating restrictions, partial suspension or total shutdown of production;
- the FDA's refusal of requests for approval of new products or indications for existing products;
- the FDA's refusal to issue certificates to foreign governments needed to export products for sale in other countries;
- withdrawing approvals that have already been granted; and
- criminal prosecution.

### ***Privacy and Security Laws***

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information, including health information. Among others, the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, (collectively referred to as HIPAA), establish privacy and security standards that limit the use and disclosure of protected health information, or PHI, and require covered entities and business associates to implement administrative, physical, and technical safeguards to ensure the confidentiality, integrity and availability of individually identifiable health information in electronic form, among other requirements.

Violations of HIPAA may result in civil and criminal penalties. Companies subject to HIPAA must also comply with HIPAA's breach notification rule which requires notification of affected patients and the U.S. Department of Health and Human Services, or HHS, and in certain cases of media outlets, in the case of a breach of unsecured PHI. The regulations also require business associates of covered entities to notify the covered entity of breaches by the business associate. State attorneys general also have the right to prosecute HIPAA violations committed against residents of their states, and HIPAA standards have been used as the basis for the duty of care in state civil suits, such as those for negligence or recklessness in misusing personal information. In addition, HIPAA mandates that HHS conduct periodic compliance audits of HIPAA covered entities and their business associates for compliance.

Many states have laws that protect the privacy and security of sensitive and personal information, including health information, to which we are subject. These laws may be similar to or even more protective than HIPAA and other federal privacy laws. For example, California enacted the California Consumer Privacy Act, or CCPA, which creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA went into effect on January 1, 2020, and the California Attorney General may bring enforcement actions for violations as of July 1, 2020. The CCPA has been amended from time to time, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted.

We may be subject to other state and federal privacy laws, including laws that prohibit unfair privacy and security practices and deceptive statements about privacy and security, laws that place specific requirements on

certain types of activities, such as data security and texting, and laws requiring holders of personal information to maintain safeguards and to take certain actions in response to a data breach.

European Union member states, the United Kingdom, Switzerland and other jurisdictions have also adopted data protection laws and regulations, which impose significant compliance obligations. In the EEA and the United Kingdom, the collection and use of personal data, including clinical trial data, is governed by the provisions of the General Data Protection Regulation, or GDPR. The GDPR became effective on May 25, 2018, repealing its predecessor directive and increasing responsibility and liability of pharmaceutical and medical device companies in relation to the processing of personal data of EU data subjects. The GDPR, together with national legislation, regulations and guidelines of the EU member states and the United Kingdom governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA or the United Kingdom, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. European data protection authorities may interpret the GDPR and national laws differently and impose additional requirements, which add to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices are often updated or otherwise revised.

### ***U.S. Healthcare Reform***

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our products. By way of example, the Patient Protection and Affordable Care Act, or PPACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the pharmaceutical, medical device and biologics industries, among others.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the PPACA, and we expect there will be additional challenges and amendments to the PPACA in the future. For example, in 2017, Congress enacted the Tax Cuts and Jobs Act, which eliminated the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseparable feature of the PPACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the PPACA are invalid as well. While the Texas District Court Judge, as well as then-president Trump’s Administration and CMS, have stated that the ruling will have no immediate effect, and on December 30, 2018 the Texas District Court Judge issued an order staying the judgment pending appeal. In December 2019, a U.S. District Court upheld a ruling that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. In November 2020, the Supreme Court of the United States heard oral arguments in the appeal of this case. While the Supreme Court issued its ruling in July 2021, in part finding that the plaintiff’s lacked standing, it is unclear how this and other efforts to challenge, repeal, or replace the ACA, or how future changes in the Presidency, Congress or Senate, will impact the ACA or our business.

There will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge and/or patients’ willingness to pay for our products. While in general it is too early to predict what effect, if any, any future healthcare reform legislation or policies will have on our business, current and future healthcare reform legislation and policies could have a material adverse effect on our business and prospects.

### ***Pricing and Reimbursement***

In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third party payors. Third party payors include government health administrative authorities, managed care providers, private health insurers, and other organizations. These third-party payors are increasingly challenging the price and examining the cost-

effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and efforts are underway to reduce the cost of medical products and services overall. We may need to conduct expensive studies in order to demonstrate the cost-effectiveness of our products. Our product candidates may not be considered cost-effective. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third-party payor's decision to cover a particular product or procedure using the product does not ensure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate revenue levels. Future legislation could limit payments for our product candidates.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of less costly products. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for our products. The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the United States has increased and will continue to increase the pressure on medical product and service pricing.

#### ***Anti-Kickback and False Claims Laws***

In the United States, the research, manufacturing, distribution, sale and promotion of pharmaceutical products and devices are subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, state Attorneys General, and other federal, state and local government agencies. For example, sales, marketing and scientific/educational grant programs must comply with the FFDCA, Anti-Kickback Statute, as amended, the False Claims Act, as amended, the privacy regulations promulgated under the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

As noted above, in the United States, we are subject to complex laws and regulations pertaining to healthcare "fraud and abuse," including, but not limited to, the federal Anti-Kickback Statute, the federal False Claims Act, and other state and federal laws and regulations. The Anti-Kickback Statute makes it illegal for any person, including a biological product manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase or order of an item for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. Due to the breadth of these federal and state anti-kickback laws and the potential for additional legal or regulatory change in this area, it is possible that our sales and marketing practices and/or our relationships with physicians might be challenged under anti-kickback laws, which could harm us. Because we plan to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we plan to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we are subject.

The federal False Claims Act prohibits anyone from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including pharmaceutical products, that are false or fraudulent. Although we would not submit claims directly to payers, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our activities relating to the reporting of wholesaler or estimated retail prices for our



products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been prosecuted under the federal False Claims Act in connection with their off-label promotion of drugs. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between \$11,665 and \$23,331 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine and may suffer a decline in our stock price. In addition, private individuals have the ability to bring actions under the federal False Claims Act and certain states have enacted laws modeled after the federal False Claims Act.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, a provision of the Patient Protection and Affordable Care Act, referred to as the Sunshine Act, requires pharmaceutical product manufacturers to track and report to the federal government certain payments or other transfers of value made to physicians, registered nurses and teaching hospitals, among others, in the previous calendar year. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

#### ***Other Federal Healthcare Fraud and Abuse Laws***

We may also be subject to other federal healthcare fraud and abuse laws, including provisions of HIPAA, which prohibit knowingly and recklessly executing a scheme or artifice to defraud any healthcare benefit program, including private payors, as well as knowingly and willfully falsifying, concealing or covering up a material fact by any trick, scheme or device or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government-sponsored programs. Similar to the federal Anti-Kickback Statute, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation.

#### ***Foreign Corrupt Practices Act***

The Foreign Corrupt Practices Act, or FCPA, prohibits U.S. businesses and their representatives from offering to pay, paying, promising to pay or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records, which in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the corporation, including international subsidiaries, if any, and to devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements. The scope of the FCPA includes interactions with certain healthcare professionals in many countries.

#### **Human Capital**

As of March 1, 2022, we had seven full-time employees, no part-time employees and three consultants. None of these employees are represented by labor unions or covered by collective bargaining agreements. We believe that our employee relations are good.

Culture is a critical element in the management of our organization. Our talented employees are focused on driving our business with the foundation for all our efforts being the development of treatments to transform care for female cancers and improving the lives of women living with cancer. Our goal is that each colleague feels a deep connection to what they do, loves coming to work, and is aligned to our mission.

Culture begins with our hiring process and continues throughout an employee's time with Context. We support our colleagues with a comprehensive offering of competitive pay and benefits. During the ongoing COVID-19 pandemic began, we strive to ensure the safety of our colleagues and continue to adapt over time to the changing environment.

### **Facilities**

Our principal office is located in Philadelphia, Pennsylvania, where we lease approximately 3,500 square feet of office space pursuant to a lease that expires in July 2023. We believe our facility is adequate to meet our current needs, although we may seek to negotiate new leases or evaluate additional or alternate space for our operations. We believe appropriate alternative space will be readily available on commercially reasonable terms.

### **Legal Proceedings**

From time to time we may be involved in disputes or litigation relating to claims arising out of our operations. We are not currently a party to any legal proceedings that could reasonably be expected to have a material adverse effect on our business, financial condition and results of operations.

### **Corporate Information**

We were incorporated under the laws of the State of Delaware in April 2021. Our corporate office is located at 2001 Market Street, Suite 3915, Unit #15, Philadelphia, PA 19103. Our telephone number is (267) 225-7416. We maintain an Internet website at [www.contexttherapeutics.com](http://www.contexttherapeutics.com). The information contained on our website is not incorporated by reference into this Form 10-K.

We make available free of charge under the "Investors & News" — "Financials" — "SEC Filings" section of our website all of our filings with the SEC, including our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and amendments to such documents, each of which is provided on our website as soon as reasonably practicable after we electronically file or furnish, as applicable, the information with the SEC.

## Item 1A. Risk Factors

*Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with general economic and business risks and all of the other information contained in this Annual Report on Form 10-K, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes, before making a decision to invest in our common stock. Our business, results of operations, financial condition or prospects could also be harmed by risks and uncertainties that are not presently known to us or that we currently believe are not material. If any of the risks actually occur, our business, results of operations, financial condition and prospects could be materially and adversely affected. In that event, the market price of our common stock could decline, and you could lose all or part of your investment. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of specific factors, including the risks described below. See "Note Regarding Forward-Looking Statements."*

### **Risks Related to Our Business and Industry**

***We have never been profitable and may never achieve or maintain profitability.***

We have not commercialized any products and have yet to generate any revenue from product sales. The amount of our future net losses will depend, in part, on our expenses and our ability to generate revenues. Our current and future product candidates will require substantial additional development time and resources before we may realize revenue from product sales, if at all. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue our current research and development programs, including conducting laboratory, preclinical and clinical studies for product candidates;
- initiate clinical trials for product candidates;
- seek to identify, assess, acquire or develop additional research programs or product candidates;
- maintain, expand and protect our intellectual property portfolio;
- seek marketing approvals for any product candidates that may successfully complete development;
- establish a sales, marketing and distribution infrastructure to commercialize any products that may obtain marketing approval;
- further develop and refine the manufacturing process for our product candidates;
- change or add additional manufacturers or suppliers of pharmaceutical or biological materials or product candidates;
- further develop our anti-hormonal resistance therapies;
- acquire or in-license other technologies;
- seek to attract and retain new and existing personnel; and
- expand our facilities.

Our first program and lead product candidate, ONA-XR, is currently in Phase 2 clinical trials. No clinical studies have begun on our second program, CLDN6xCD3 bsAb. It will be several years, if ever, before we obtain regulatory approval for a therapeutic product candidate, at which time any revenues for such product candidate will depend upon many factors, including, market conditions, costs and effectiveness of manufacturing, sales, marketing and distribution operations related to such product candidate, and the terms of any collaboration or other strategic

arrangement we may have with respect to such product candidate and levels of reimbursement from third-party payors.

If we are unable to develop and commercialize one or more product candidates either alone or with collaborators, including through the potential out-licensing of our product candidates, or if revenues from any product candidate that receives marketing approval or is commercialized are insufficient, we may not achieve profitability or sustain profitability, which would have an adverse effect on the value of our common stock which would be materially adversely affected.

***If we are unable to raise substantial additional capital on acceptable terms, or at all, we may be forced to delay, reduce or eliminate some or all of our research programs, product development activities and commercialization efforts.***

The process of identifying product candidates and conducting preclinical and clinical trials is time consuming, expensive, uncertain and takes years to complete. Our operations have consumed substantial amounts of cash since inception. We expect our expenses to increase in connection with our ongoing activities, particularly as we identify, continue the research and development of, initiate clinical trials of, and seek marketing approval for, product candidates. In addition, if any therapeutic product candidate that we develop alone or with collaborators obtains marketing approval, we may incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution efforts. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise sufficient capital when needed, we may be forced to delay, reduce or eliminate current or future research programs, product development activities and/or commercialization efforts.

Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to obtain sufficient funding on a timely basis or on favorable terms, we may be required to significantly delay, reduce or eliminate one or more of our research or product development programs and/or commercialization efforts or we might have to obtain funds through arrangements, such as out-licensing our product candidates, with collaborative partners or others that may require us to relinquish rights to our technologies or product candidates that we otherwise would not relinquish. We may also be unable to expand our operations or otherwise capitalize on business opportunities as desired. Any of these events could materially adversely affect our financial condition and business prospects.

***We have a limited operating history, which makes it difficult to evaluate our current business and future prospects and may increase the risk of your investment.***

We are a clinical-stage biopharmaceutical company with a limited operating history. We were founded in 2015 and spent the first three years of our company's history developing and refining our therapeutic approach, and only since then have we focused our efforts on advancing the development of product candidates.

Investment in biopharmaceutical product development is a highly speculative endeavor and entails substantial upfront capital expenditures. There is significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, obtain any required regulatory approvals or become commercially viable. Our product candidates and the therapeutic approach we are using are new and unproven. We have commenced Phase 2 human clinical trials for one of our product candidates, but have not demonstrated an ability to initiate clinical trials for our other product candidates or successfully complete any clinical trials, obtain any required marketing approvals, manufacture products, conduct sales, marketing and distribution activities, or arrange for a third party to do any of the foregoing on our behalf.

Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing products. Our limited operating history, particularly in light of the rapidly evolving nature of the biopharmaceutical industries and the female cancer therapeutics field, may make it difficult to evaluate our technology and business prospects or to predict our future performance.

***We may expend our limited resources pursuing particular research programs or product candidates that may be less successful or profitable than other programs or product candidates.***

Research programs to identify new product candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. The successful completion of a clinical trial with regard to any of our product candidates is not assured despite the expenditure of significant resources in pursuit of their development, and our spending on current and future research and development programs and product candidates may not yield any commercially viable products.

Additionally, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

***Our business may be adversely affected by the ongoing coronavirus pandemic.***

The outbreak of the novel Coronavirus (“COVID-19”) has evolved into a global pandemic. The extent to which the COVID-19 pandemic impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 and the actions to contain the virus or treat its impact, among others.

Should COVID-19 continue to spread, our business operations could be delayed or interrupted. For instance, our research and development may be affected by the pandemic. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. If COVID-19 continues to spread, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our research activities, including clinical trials.

Infections and deaths related to the pandemic have disrupted and may continue to disrupt the United States’ healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay FDA review and/or approval. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

In the event of a shelter-in-place order or other mandated local travel restrictions, our employees and consultants conducting research and development or manufacturing activities may not be able to access their laboratory or manufacturing space, and our core activities may be significantly limited or curtailed, possibly for an extended period of time.

The spread of COVID-19, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material economic effect on our business. New or renewed restrictions may be implemented in response to evolving conditions, new variants of the virus (including the Omicron variant) and overall uncertainty about the timing of widespread availability of vaccines. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our

research programs, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the situation closely.

***Our governing documents designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of state law actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.***

Our amended & restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the United States District Court for the District of Delaware) will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our amended & restated certificate of incorporation or amended & restated bylaws; (4) any action to interpret, apply, enforce or determine the validity of our amended & restated certificate of incorporation or amended & restated bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine. In addition, our amended & restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Notwithstanding the foregoing, the exclusive forum provision shall not apply to claims seeking to enforce any liability or duty created by the Exchange Act.

This choice of forum provision may limit our stockholders' ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and our directors, officers, employees and agents even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find this provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on our business, financial condition or results of operations.

#### **Risks Related to our Product Candidates**

***Our business is dependent on the successful development, regulatory approval and commercialization of our therapeutic product candidates, ONA-XR and CLDN6xCD3 bsAb, which are in the early stages of development.***

We have no products approved for sale. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of ONA-XR and CLDN6xCD3 bsAb, as well as other product candidates derived from our anti-hormone resistant therapy approach, which may never occur.

In the future, we may also become dependent on other product candidates that we may develop or acquire; however, not all of our product candidates have been tested in humans and given our early stage of development, it may be many years, if at all, before we have demonstrated the safety and efficacy of a female cancer treatment sufficient to warrant approval for commercialization.

We have not previously submitted a new drug application ("NDA") or biologics license application ("BLA"), to the FDA or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that our product candidates will be successful in clinical trials or receive regulatory approval. Further, any future product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market a product candidate, our revenue will be

dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates both in the United States and in selected foreign countries. While the scope of regulatory approval generally is similar in other countries, in order to obtain separate regulatory approval in other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of our product candidates, and we may be required to expend significant resources to obtain regulatory approval and to comply with ongoing regulations in these jurisdictions.

The clinical and commercial success of our current and any future product candidates will depend on a number of factors, including the following:

- our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to complete IND-enabling studies and successfully submit an IND;
- timely completion of our preclinical studies and clinical trials, which may be slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials or other studies beyond those planned to support approval of our product candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- our ability to consistently provide for manufacturing of our product candidates on a timely basis;
- our ability, and the ability of any third parties with whom we contract, to remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices (“cGMPs”);
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy and acceptable risk-benefit profile of our product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our lead product candidates or any future product candidates or approved products, if any;
- the willingness of physicians, operators of hospitals and clinics and patients to utilize or adopt our anti-hormone resistant therapy approach;
- our ability to successfully develop a commercial strategy and thereafter commercialize our current product candidates or any future product candidates in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others, including through the potential out-licensing of our product candidates;
- the availability of coverage and adequate reimbursement from managed care plans, private insurers, government payors (such as Medicare and Medicaid) and other third-party payors for any of our product candidates that may be approved;

- the convenience of our treatment or dosing regimen;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- patient demand for our current or future product candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our product candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our current or future product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any product candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our product candidate or any future product candidates to continue our business or achieve profitability.

***Our innovative therapy approach is based on novel ideas and technologies that are unproven and may not result in marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval.***

Our foundational science and product development approach are based on the selective targeting of female cancers, including by inhibiting progesterone receptor binding to chromatin, and by inhibiting CLDN6, in each case to elicit meaningful anticancer activity. We believe that this approach may offer an improved therapeutic effect by downregulating PR effector functions associated with anti-estrogen resistant and inhibit tumor growth, as well as redirect T-cell-mediated lysis toward malignant cells expressing CLDN6. However, this approach to treating cancer is novel and the scientific research that forms the basis of our efforts to develop therapeutics that effectively target anti-hormone treatment resistance and inhibit membrane protein targets is both preliminary and limited.

As such, we cannot assure you that even if we are able to develop cancer therapeutic candidates capable of addressing anti-estrogen resistance or redirecting T-cell-mediated lysis toward malignant cells, that such therapy would safely and effectively treat cancers. We may spend substantial funds attempting to develop this approach and never succeed in developing a marketable therapeutic.

Furthermore, no regulatory authority has granted approval for a cancer therapy based on a selective targeting of PR+ or Claudin 6 positive cancers. As such, we believe the FDA has limited experience with evaluating our approach, which may increase the complexity, uncertainty and length of the regulatory approval process for our product candidates. We may never receive approval to market and commercialize any product candidate. Even if we obtain regulatory approval, the approval may be for targets, disease indications, lines of therapy or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings.

***Results of preclinical studies, early clinical trials or analyses may not be indicative of results obtained in later trials.***

The results of preclinical studies, early clinical trials or analyses of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. In addition, conclusions based on promising data from analyses of clinical results may be shown to be incorrect when implemented in prospective clinical trials. Even if our ongoing clinical trials for ONA-XR and future clinical trials for our other product candidates are completed as planned, we cannot be certain that their results will support the safety and efficacy sufficient to obtain regulatory approval.



***Interim “top-line” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publish interim “top-line” or preliminary data from our clinical studies. Interim or preliminary data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or “top-line” data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

***Our product candidates may cause serious adverse events or undesirable side effects, which may delay or prevent marketing approval, or, if approved, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.***

Serious adverse events or undesirable side effects caused by ONA-XR, CLDN6xCD3 bsAb or any other product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of any clinical trial we conduct could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Patients treated with ONA-XR to date, at high doses have experienced adverse events that include, but are not limited to, fatigue, liver enzyme elevations and nausea.

If unacceptable side effects arise in the development of our product candidates, we, the FDA or the institutional review boards at the institutions in which our studies are conducted, or the data safety monitoring board, if constituted for our clinical trials, could recommend a suspension or termination of our clinical trials, or the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. In addition, drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or contraindication;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, if approved, and could significantly harm our business, results of operations and prospects.

***The success of our business depends primarily upon our ability to identify, develop and commercialize products using our proprietary technologies.***

Besides our ONA-XR product candidate, all of our current product candidates and product development programs are still in the IND validation process. We may be unsuccessful in advancing those product candidates into clinical development or in identifying and developing additional product candidates.

Our ability to identify and develop product candidates is subject to the numerous risks associated with preclinical and early stage biopharmaceutical development activities, including that:

- we may not be able to assemble sufficient resources to acquire or discover additional product candidates, including through the potential out-licensing of our product candidates;
- we may not be able to enter into collaborative arrangements to facilitate development of product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- our product candidates may be covered by third parties' patents or other exclusive rights;
- the regulatory pathway for a product candidate may be too complex, expensive or otherwise difficult to navigate successfully; or
- our product candidates may be shown to not be effective, have harmful side effects or otherwise pose risks not outweighed by such product candidate's benefits or have other characteristics that may make the products impractical to manufacture, unlikely to receive any required marketing approval, unlikely to generate sufficient market demand or otherwise not achieve profitable commercialization.

Even if we do commence additional clinical trials of product candidates and continue to identify new product candidates, such product candidates may never be approved. Failure to successfully identify and develop new product candidates and obtain regulatory approvals for our products would have a material adverse effect on our business and financial condition and could cause us to cease operations.

***If our product candidates do not achieve projected development milestones or commercialization in the announced or expected timeframes, the further development or commercialization of such product candidates may be delayed, and our business will be harmed.***

We sometimes estimate, or may in the future estimate, the timing of the accomplishment of various scientific, clinical, manufacturing, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies or clinical trials, the submission of regulatory filings, the receipt of marketing approval or the realization of other commercialization objectives.

The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions, including assumptions regarding capital resources, constraints and priorities, progress of and results from development activities and the receipt of key regulatory approvals or actions, any of which may cause the timing of achievement of the milestones to vary considerably from our estimates.

If our collaborators or ourselves fail to achieve announced milestones in the expected timeframes, the commercialization of the product candidates may be delayed, our credibility may be undermined, our business and results of operations may be harmed, and the price of our common stock may decline.

***Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any products that we develop alone or with collaborators.***

We face an inherent risk of product liability and professional indemnity exposure related to the testing in clinical trials of our product candidates. We will face an even greater liability risk if we commercially sell any products that we or our collaborators may develop for human use.

Manufacturing defects, errors in product distribution or storage processes, improper administration or application and known or unknown side effects of product usage may result in liability claims against us or third parties with which we have relationships. These actions could include claims resulting from acts by our collaborators, licensees and subcontractors over which we have little or no control. For example, our liability could be sought by patients participating in clinical trials for potential therapeutic product candidates as a result of unexpected side effects, improper product administration or the deterioration of a patient's condition, patient injury or even death.

Criminal or civil proceedings might be filed against us by patients, regulatory authorities, biopharmaceutical companies and any other third party using or marketing any product candidates or products that we develop alone or with collaborators. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend ourselves against claims that product candidates or products we develop alone or with collaborators caused harm, we could incur substantial liabilities.

Clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug or biologic, even after regulatory approval, may exhibit unforeseen side effects. If our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities.

Product liability insurance coverage may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage when we expand our clinical trials and if our collaborators or ourselves successfully commercialize any products.

### **Risks Related to Our Organization, Structure and Operations**

***Our reliance on a central team consisting of a limited number of employees and consultants who provide various administrative, research and development, and other services across our organization presents operational challenges that may adversely affect our business.***

As of March 1, 2022, we had seven full-time employees. We also have three consultants who we rely on for research and development, business development and other services. While we believe this structure enables us to reduce certain infrastructure costs, the small size of our centralized team may limit our ability to devote adequate personnel, time and resources to support the operations of our business, including our research and development activities, and the management of financial, accounting and reporting matters. If our centralized team fails to provide adequate administrative, research and development, or other services across our entire organization, our business, financial condition and results of operations could be harmed.

***Our future success depends on our ability to retain our Chief Executive Officer, Chief Financial Officer, Chief Legal Officer, Chief Medical Officer, and other key executives and to attract, retain and motivate qualified personnel.***

We are highly dependent on the research and development experience, technical skills, leadership and continued service of certain members of our management and scientific teams, including Martin Lehr, our Chief Executive Officer, Jennifer Minai-Azary, our Chief Financial Officer, Alex Levit, our Chief Legal Officer, and Tarek Sahmoud, our Chief Medical Officer.

Although we have formal employment agreements and consulting agreements with substantially all of our executive officers, these agreements do not prevent them from terminating their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and, if we retain commercialization responsibility for any product candidate we develop alone or with collaborators, sales and marketing personnel, will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms or at all given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategies. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

The inability to recruit, integrate, motivate and retain additional skilled and qualified personnel, or the loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business.

***We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.***

We will need to significantly expand our organization, and our future financial performance, ability to develop and commercialize product candidates alone or with collaborators and ability to compete effectively will depend in part on our ability to effectively manage any future growth. We may have difficulty identifying, hiring and integrating new personnel.

Many of the biopharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history than we do. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can identify and develop product candidates, enter into collaborative arrangements and otherwise operate our business will be limited.

Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel.

Moreover, the expected physical expansion of our operations may lead to significant costs and may divert our management and business development resources from other projects, such as the development of product candidates. If we are not able to effectively manage the expansion of our operations, it may result in weaknesses in our infrastructure, increase our expenses more than expected, give rise to operational mistakes, loss of business opportunities, loss of employees, consultants and contractors and reduced productivity.

***Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.***

We do not carry insurance for all categories of risk that our business may encounter. If we obtain marketing approval for any product candidates that we or our collaborators may develop, we intend to acquire insurance coverage to include the sale of commercial products, but we may be unable to obtain such insurance on commercially reasonable terms or in adequate amounts. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and clinical trials or regulatory approvals for any of our product candidates could be suspended. As a public company it may be more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors, our board committees or as our executive officers.

Insurance coverage is becoming increasingly expensive, and in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. We do not know if we

will be able to maintain existing insurance with adequate levels of coverage, and any liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. A successful liability claim or series of claims brought against us could require us to pay substantial amounts and cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the development and commercialization of any product candidates that we or our collaborators may develop.

### **Risks Related to Our Reliance on Third Parties**

***We expect to depend on collaborations with third parties for certain research, development and commercialization activities, and if any such collaborations are not successful, it may harm our business and prospects.***

Working with collaborators poses several significant risks, including the following:

- limited availability of resource allocation and other developmental decisions made by our collaborators about the product candidates that we seek to develop with them may result in the delay or termination of research programs, studies or trials, repetition of or initiation of new studies or trials or provision of insufficient funding or resources for the completion of studies or trials or the successful marketing and distribution of any product candidates that may receive approval;
- collaborators could independently develop, or develop with third parties, product candidates that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way that could jeopardize or invalidate our proprietary information or expose us to potential litigation; and
- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization activities or that result in costly litigation or arbitration that diverts management attention and resources.

Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. If our collaborations, including those in which we may out-license our product candidates, do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive the expected deliverables or services from our collaborators, nor receive any future funding or milestone or royalty payments under the collaboration.

If we do not receive the funding or expected deliverables or services from our collaborators, we expect under these agreements, our development of product candidates could be delayed, and we may need additional resources to develop such product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators and may need to raise additional capital to pursue further development or commercialization of the applicable product candidates.

These events could delay development programs and negatively impact the perception of our company in business and financial communities. Failure to develop or maintain relationships with any current collaborators could result in the loss of opportunity to work with that collaborator or reputational damage that could impact our relationships with other collaborators in the relatively small industry communities in which we operate.

Moreover, all of the risks relating to product development, regulatory approval and commercialization described in this Form 10-K apply to the activities of our collaborators. If our existing collaboration agreements or any collaborative or strategic relationships we may establish in the future are not effective and successful, it may damage

our reputation and business prospects, delay or prevent the development and commercialization of product candidates and inhibit or preclude our ability to realize any revenues.

***We have relied on and we expect to continue to rely on third parties to conduct, supervise and monitor our clinical trials and some aspects of our research and preclinical testing, and if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements, or otherwise perform in a satisfactory manner, we may not be able to obtain regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed.***

We have relied on and we expect to continue to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as contract research organizations (“CROs”) to conduct preclinical studies and clinical trials for our product candidates. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on such third parties will not relieve us of our regulatory responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulations, commonly referred to as good clinical practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

Although we have designed and intend to design future trials for our product candidates either alone or with collaborators, third parties may conduct some parts of or all of the trials. As a result, many important aspects of our research and development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future studies and trials will also result in less direct control over the management of data developed through studies and trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes and difficulties in coordinating activities. Such third parties may have staffing difficulties, fail to comply with contractual obligations, experience regulatory compliance issues, undergo changes in priorities, become financially distressed or form relationships with other entities, some of which may be our competitors.

We also face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs or other third parties, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

If we, our collaborators, our CROs or other third parties fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We also are required to register certain ongoing clinical trials and post the results of such completed clinical trials on a government-sponsored database, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If our CROs or other third parties do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, trials for product candidates may be extended, delayed or terminated, and we or our collaborators may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develop. If we are required to repeat, extend the duration of or increase the size of any trials we conduct, it could significantly delay commercialization and require significantly greater expenditures.

As a result of any of these factors, our financial results and the commercial prospects for any product candidate that we or our collaborators may develop would be harmed, our costs could increase and our ability to generate revenues could be delayed.

***If we are unable to obtain sufficient quantities of raw materials and supplies, at acceptable prices and on a timely basis, it could harm our business.***

We are dependent on third parties for the supply of various pharmaceutical and biological materials and the manufacture of product supplies that are necessary to produce our product candidates. The supply of these materials could be reduced or interrupted at any time. In such case, identifying and engaging an alternative supplier or manufacturer could result in delay, and we may not be able to find other acceptable suppliers or manufacturers on acceptable terms, or at all.

Changing suppliers or manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. If we change suppliers or manufacturers for commercial production, applicable regulatory agencies may require us to conduct additional studies or trials. If key suppliers or manufacturers are lost, or if the supply of the materials is diminished or discontinued, we or our collaborators may not be able to develop, manufacture and market product candidates in a timely and competitive manner, or at all. If any of our product candidates receives approval, we will likely need to seek alternative sources of supply of raw materials or manufactured product supplies and there can be no assurance that we will be able to establish such relationships to provide such supplies on commercially reasonable terms or at acceptable quality levels, if at all. If we are unable to identify and procure additional sources of supply that fit our required needs, we could face substantial delays or incur additional costs in procuring such materials.

***We may rely on third parties for the manufacturing process of product candidates, and failure by those parties to adequately perform their obligations could harm our business.***

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and expect that we will rely on outside vendors, including vendors outside the United States, for at least a portion of the manufacturing process of product candidates that we or our collaborators may develop. The facilities used by our contract manufacturers to manufacture product candidates must be approved by the FDA or other foreign regulatory agencies pursuant to inspections that will be conducted after we submit an application to the FDA or other foreign regulatory agencies. To the extent that we or our collaborators engage third parties for manufacturing services, we will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing providers for compliance with cGMP requirements for manufacture of the product candidates.

We have not yet caused any product candidates to be manufactured or processed on a commercial scale and may not be able to do so. We will make changes as we work to optimize the manufacturing process, and we cannot be sure that even minor changes in the process will result in products that are safe and effective. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel.

If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market any of our or our collaborators' potential products.

***If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our research, development and commercialization plans.***

Our research and product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses, and we expect that we will continue to seek collaborative arrangements, including the potential out-licensing of our product candidates, for the development and potential commercialization of current and future product candidates or the development of ancillary technologies.

We face significant competition in establishing relationships with appropriate collaborators. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have

resulted in a reduced number of potential future collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include, among other things and as applicable for the type of potential product, an assessment of the opportunities and risks of our product candidate, the design or results of studies or trials, the likelihood of approval, if necessary, by the USDA, the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and industry and market conditions generally.

Collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we do enter into additional collaboration agreements, including out-licensing our lead product candidate, ONA-XR, the negotiated terms may force us to relinquish rights that diminish our potential profitability from development and commercialization of the subject product candidates or others. Such collaborations may also impact our ability to control the nature, timing and cadence of developing and commercializing the product candidates subject to such collaborations. If we are unable to enter into additional collaboration agreements, we may have to curtail the research and development of the product candidate for which we are seeking to collaborate, reduce or delay research and development programs, delay potential commercialization timelines, reduce the scope of any sales or marketing activities or undertake research, development or commercialization activities at our own expense.

### **Risks Related to Government Regulation**

***The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.***

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing, and distribution of drug products, including biologics and pharmaceuticals, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of anti-estrogen resistance inhibition therapies for cancer. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials, as the FDA often makes decisions consistent with the Advisory Committee's recommendations. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- obtaining regulatory authorization to begin a trial, if applicable;
- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an independent institutional review board, or IRB;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial, including having patients enrolled in clinical trials dropping out of the trial before the product candidate is manufactured and returned to the site, or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;



- addressing any patient safety concerns that arise during the course of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a patient by patient basis for use in clinical trials.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or based on a recommendation by the Data Safety Monitoring Committee. The FDA's review of our data of our ongoing clinical trials may, depending on the data, also result in the delay, suspension or termination of one or more clinical trials, which would also delay or prevent the initiation of our other planned clinical trials. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

***We expect that CLDN6xCD3 bsAb will be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated.***

The Biologics Price Competition and Innovation Act was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the Biologics Price Competition and Innovation Act, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the Biologics Price Competition and Innovation Act may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that CLDN6xCD3 bsAb, if approved in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

***The FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.***

If and when our ongoing Phase 2 clinical trials for ONA-XR and planned clinical trials for our other initial product candidates are completed and, assuming positive data, we expect to advance to potential registrational trials. The general approach for FDA approval of a new biologic or drug is for the sponsor to provide dispositive data from two well-controlled, Phase 3 clinical studies of the relevant biologic or drug in the relevant patient population. Phase

3 clinical studies typically involve hundreds of patients, have significant costs and take years to complete. If the results from our clinical trials are sufficiently compelling, we intend to discuss with the FDA submission of a BLA or NDA, as applicable for the relevant product candidate. However, we do not have any agreement or guidance from the FDA that our regulatory development plans will be sufficient for submission of a BLA or NDA, as applicable for the relevant product candidate. For example, the FDA may require that we conduct a comparative trial against an approved therapy, which would significantly delay our development timelines and require substantially more resources.

The FDA may grant accelerated approval for our product candidates and, as a condition for accelerated approval, the FDA may require a sponsor of a drug or biologic receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA that are more accelerated than those available for regular approvals. We believe an accelerated approval strategy is warranted given the limited alternatives for patients that our initial product candidates target, but the FDA may ultimately require a Phase 3 clinical trial prior to approval, particularly since our product candidates represent a novel treatment. In addition, the standard of care may change with the approval of new products in the same indications that we are studying. This may result in the FDA or other regulatory agencies requesting additional studies to show that our product candidate is superior to the new products.

Our clinical trial results may also not support approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval, including due to the heterogeneity of patient populations;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or NDA, as applicable, or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities will review our manufacturing process and inspect our commercial manufacturing facility and may not approve our manufacturing process or facility; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

***Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.***

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product

candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

***We will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.***

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a Risk Evaluation and Mitigation Strategy (“REMS”) in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspectional observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. In addition, the FDA could require us to conduct another study to obtain additional safety or biomarker information. Further, we will be required to comply with FDA promotion and advertising rules, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product’s approved uses (known as “off-label use”), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet and social media. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a risk evaluation and mitigation strategy program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

***Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.***

The use of progesterone receptor and protein inhibitors as potential cancer treatments are recent developments and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community and we may not be able to convince them to use our product candidates for many reasons. Additional factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

***Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates, if approved, profitably.***

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from third-party payors is critical to new product acceptance.

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, the Centers for Medicare & Medicaid Services, or the CMS, revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payors rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third-party payors, and reduce the willingness of physicians to use our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in Europe, the pricing of drugs and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. Some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more

products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

***The advancement of healthcare reform may negatively impact our ability to sell our product candidates, if approved, profitably.***

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private payors. Among the provisions of the ACA of importance to the pharmaceutical and biotechnology industries, which includes biologics, are the following:

- manufacturers and importers of certain biologics with annual sales of more than \$5 million made to or covered by specified federal healthcare programs are required to pay an annual, nondeductible fee according to their market share of all such sales;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% of the average manufacturer price for most branded drugs, biologics, and biosimilars and to 13.0% for generic drug, and cap of the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted, or injected;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health program, commonly referred to as the "340B Program;"
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, also known as the "Physician Payments Sunshine Act;"
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending; and
- a licensure framework for follow-on biologic products.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, legislation enacted in 2017 informally titled the Tax Cuts and Jobs Act of 2017, repealed the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage that is commonly referred to as the "individual mandate." In December 2019, a U.S. District Court upheld a ruling that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. In November 2020, the Supreme Court of the United States heard oral arguments in the appeal of this case. While the Supreme

Court issued its ruling in July 2021, in part finding that the plaintiff's lacked standing, it is unclear how this and other efforts to challenge, repeal, or replace the ACA, or how future changes in the Presidency, Congress or Senate, will impact the ACA or our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted which, among other things, have reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers.

These new laws or any other similar laws introduced in the future, as well as regulatory actions that may be taken by CMS, may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our customers and accordingly, our financial operations. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. Additionally, individual states in the United States have passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing and costs. Similar developments have occurred outside of the United States, including in the European Union where healthcare budgetary constraints have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers.

To obtain reimbursement or pricing approval in some European Union member states, we may be required to conduct studies that compare the cost-effectiveness of our product candidates to other therapies that are considered the local standard of care. It is also possible that additional governmental action is taken in response to address the COVID-19 pandemic. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States, particularly as a result of the recent presidential election, or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

### **Risks Related to Intellectual Property**

***Patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our business position.***

The patent positions of biopharmaceutical companies and other actors in our fields of business can be highly uncertain and typically involve complex scientific, legal and factual analyses. In particular, the interpretation and breadth of claims allowed in some patents covering biopharmaceutical compositions may be uncertain and difficult to determine, and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the United States Patent and Trademark Office (the USPTO) and its foreign counterparts are sometimes uncertain and could change in the future.

Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or designed around. U.S. patents and patent applications may also be subject to interference or derivation proceedings, and U.S. patents may be subject to reexamination, post-grant review and/or inter parties review proceedings in the USPTO.

International patents may also be subject to opposition or comparable proceedings in the corresponding international patent office, which could result in either loss of the patent or denial of the patent application, or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, derivation, reexamination, post-grant review, inter parties review and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

Furthermore, even if not challenged, our patents and patent applications may not adequately protect our technology and any product candidates or products that we develop alone or with collaborators or prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patents and patent applications that we hold with respect to our product candidates or potential products is

threatened, it could dissuade companies from collaborating with us to develop, and could threaten our or their ability to successfully commercialize, such product candidates or potential products.

In addition, changes in, or different interpretations of, patent laws in the United States and other countries may permit others to use our discoveries or to develop and commercialize our technology and product candidates or products without providing any compensation to us, or may limit the scope of patent protection that we are able to obtain. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We rely on our outside counsel and employ an outside firm to pay these fees due to USPTO and non-US patent agencies. The USPTO and various non-US governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Although an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market which would have a material adverse effect on our business.

If the patent applications we hold or have in-licensed with respect to our current and future research and development programs and product candidates fail to issue, if their validity, breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our technology or any products and product candidates that we or our collaborators may develop, it could dissuade companies from collaborating with us to develop product candidates, encourage competitors to develop competing products or technologies and threaten our or our collaborators' ability to commercialize future product candidates. Any such outcome could have a material adverse effect on our business.

***Our ability to compete effectively in our markets may decline if we do not adequately protect our proprietary rights, and our proprietary rights do not necessarily address all potential threats to our competitive advantages.***

We rely on patent protection as well as trademark, trade secret and other intellectual property rights protection and contractual restrictions to protect ONA-XR, CLDN6xCD3 bsAb and other product candidates. Our commercial success depends upon obtaining and maintaining proprietary rights to our intellectual property estate, including rights relating to ONA-XR, CLDN6xCD3 bsAb and other product candidates, as well as successfully defending these rights against third-party challenges and successfully enforcing these rights to prevent third-party infringement. We will only be able to protect ONA-XR, CLDN6xCD3 bsAb and other product candidates from unauthorized use by third parties to the extent that valid and enforceable patents or effectively protected trade secrets cover them.

Our ability to obtain and maintain patent protection for ONA-XR, CLDN6xCD3 bsAb and other product candidates is uncertain due to a number of factors, including the following factors:

- we may not have been the first to invent the technology covered by our pending patent applications or issued patents;
- we may not be the first to file patent applications covering product candidates, including their compositions or methods of use, as patent applications in the United States and most other countries are confidential for a period of time after filing;
- our compositions and methods may not be patentable;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our pending patent applications may not result in issued patents;



- others may independently develop identical, similar or alternative technologies, products or compositions, or methods of use thereof;
- others may design around our patent claims to produce competitive technologies or products that fall outside of the scope of our patents;
- we may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection;
- we may not seek or obtain patent protection in countries and jurisdictions that may eventually provide us a significant business opportunity;
- we may decide not to maintain or pursue patents and patent applications that, at some point in time, may cover our products, potential products, or product candidates;
- any patents issued to us may not provide a basis for commercially viable products, may not provide any competitive advantages or may be successfully challenged by third parties;
- others may identify prior art or other bases upon which to challenge and ultimately invalidate our patents or otherwise render them unenforceable;
- our representatives or their agents may fail to apply for patents in a timely fashion; and
- despite our efforts to enter into agreements with employees, consultants, collaborators, and advisors to confirm ownership and chain of title in patents and patent applications, an inventorship or ownership dispute could arise that may permit one or more third parties to practice our technologies or enforce our patent rights, including possible efforts to enforce patent rights against us.

Even if we have or obtain patents covering ONA-XR, CLDN6xCD3 bsAb or any other product candidates or compositions, others may have filed, and in the future may file, patent applications covering compositions, products or methods that are similar or identical to ours, which could materially affect our ability to successfully develop any product candidates or to successfully commercialize any approved products alone or with collaborators. In addition, because patent applications can take many years to issue, there may be currently pending applications unknown to us that may later result in issued patents that may cover ONA-XR, CLDN6xCD3 bsAb or any other product candidates or compositions. These patent applications may have priority over patent applications filed by us.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products.

In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited.

Without patent protection for current or future product candidates, we may be open to competition from generic or biosimilar versions of such potential products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to those we or our collaborators may develop.

In addition, we also try to protect our trade secrets, know-how and other proprietary information through non-disclosure and confidentiality provisions in our agreements with parties who have access to them, such as our employees, consultants and research partners. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets, know-how and/or other proprietary information in the event of

unauthorized uses or disclosure or other breaches of the provisions, and we may not be able to prevent such unauthorized uses or disclosure. Moreover, if a party having an agreement with us has an overlapping or conflicting obligation to a third party, our rights in and to certain intellectual property could be undermined. Monitoring unauthorized and inadvertent disclosure and uses is difficult, and we do not know whether the steps we have taken to prevent such disclosure and uses are, or will be, adequate. In addition, monitoring unauthorized disclosure and uses of our trade secrets is difficult, and we do not know whether the steps we have taken to prevent such disclosure and uses are, or will be, adequate. If we were to enforce a claim that a third-party had illegally obtained and was using our trade secrets, it would be expensive and time-consuming, and the outcome would be unpredictable, and any remedy may be inadequate. In addition, courts outside the United States may be less willing to protect trade secrets.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Because we may rely on third parties to manufacture our potential product candidates, and because we collaborate with various organizations and academic institutions on the advancement of our current and potential product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our manufacturers, collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, are used inappropriately to create new inventions or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

***If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.***

We are a party to intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. Additionally, we may need to outsource and rely on third parties for many aspects of the development, sales and marketing of any products covered under our current and future license agreements. Delay or failure by these third parties could adversely affect the continuation of our license agreements with our licensors. If we fail to comply with any of our obligations under these agreements, or we are subject to a bankruptcy, our licensors may have the right to terminate the license, in which event we would not be able to market any products covered by the license.

In some cases, patent prosecution of our licensed technology is controlled solely by the licensor. If such licensor fails to obtain and maintain patent or other protection for the proprietary intellectual property we license from such licensor, we could lose our rights to such intellectual property or the exclusivity of such rights, and our competitors could market competing products using such intellectual property. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

If we are unable to do so, we or our collaborators may be unable to develop or commercialize the affected product candidates, which could harm our business significantly. In other cases, we control the prosecution of

patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

***If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation with respect to our product candidates, thereby potentially extending the term of marketing exclusivity for such product candidates, our business may be harmed.***

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process.

In the European Union, our product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements.

Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is

not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

***Third parties may assert claims against us alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to defend or enforce our patents, either of which could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of product candidates, prohibit our use of proprietary technology or sale of potential products or put our patents and other proprietary rights at risk.***

Our commercial success depends in part upon our ability to develop, manufacture, market and sell product candidates without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the pharmaceutical, biotechnology is common, including patent infringement lawsuits, and such interference, derivation, reexamination, post-grant review, inter parties review and opposition proceedings before the USPTO and corresponding international patent offices.

The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors.

Numerous United States, EU and other internationally issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates, and as the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

As a result of any patent infringement claims, or in order to avoid any potential infringement claims, we may choose to seek, or be required to seek, a license from a third party, which may require payment of substantial royalties or fees, or require us to grant a cross-license under our intellectual property rights.

These licenses may not be available on reasonable terms or at all. Even if a license can be obtained on reasonable terms, the rights may be nonexclusive, which would give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we or our collaborators could be prevented from commercializing one or more product candidates, or forced to modify such product candidates, or to cease some aspect of our business operations, which could harm our business significantly.

We or our collaborators might also be forced to redesign or modify our technology or product candidates so that we no longer infringe the third-party intellectual property rights, which may result in significant cost or delay to us, or which redesign or modification could be impossible or technically infeasible. Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Further, if a patent infringement suit is brought against us, our collaborators or our third-party service providers, our development, manufacturing or sales activities relating to the product or product candidate that is the subject of

the suit may be delayed or terminated. In addition, defending such claims has in the past and may in the future cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages if we are found to be infringing a third party's patent rights.

These damages potentially include increased damages and attorneys' fees if we are found to have infringed such rights willfully. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

We may in the future be subject to third-party claims and similar adversarial proceedings or litigation in other jurisdictions regarding our infringement of the patent rights of third parties. Even if such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our or our collaborators' ability to further develop or commercialize the applicable product candidate unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable.

Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our technologies, compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to prohibit our use of those technologies, compositions, formulations, methods of treatment, prevention or use or other technologies, effectively blocking our or our collaborators' ability to develop and commercialize the applicable product candidate until such patent expires or is finally determined to be invalid or unenforceable or unless we or our collaborators obtain a license.

Competitors may infringe our patents. In the event of infringement or unauthorized use, we may file one or more infringement lawsuits, which can be expensive and time-consuming. An adverse result in any such litigation proceedings could put one or more of our patents at risk of being invalidated, being found to be unenforceable, and/or being interpreted narrowly and could put our patent applications at risk of not issuing and/or could impact the validity or enforceability positions of our other patents. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays or prohibit us from manufacturing, marketing or otherwise commercializing our products, services and technology.

Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operation, financial condition or cash flows.

***Changes in U.S. patent law, and the laws of other countries, could diminish the value of patents in general, thereby impairing our ability to protect our products.***

The United States has enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, the USPTO, and the courts and regulatory agencies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

## Risks Related to the Market for Our Common Stock

### *Our common stock may be volatile or may decline regardless of our operating performance.*

The market price for our common stock is likely to be volatile, in part because our shares have been traded publicly for a short time. In addition, the market price of our common stock may fluctuate significantly in response to several factors, most of which we cannot control, including:

- quarterly variations in our operating results compared to market expectations;
- adverse publicity about us, the industries we participate in or individual scandals;
- announcements of new offerings or significant price reductions by us or our competitors;
- stock price performance of our competitors;
- fluctuations in stock market prices and volumes;
- changes in senior management or key personnel;
- changes in financial estimates by securities analysts;
- the market's reaction to our reduced disclosure as a result of being an "emerging growth company" under the JOBS Act;
- negative earnings or other announcements by us or our competitors;
- defaults on indebtedness, incurrence of additional indebtedness, or issuances of additional capital stock;
- global economic, legal and regulatory factors unrelated to our performance; and
- the other factors listed in this "Risk Factors" section.

Volatility in the market price of our common stock may prevent investors from being able to sell their shares at or above their purchase price. As a result, you may suffer a loss on your investment.

### *If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the market price for the shares and trading volume could decline.*

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If research analysts do not establish and maintain adequate research coverage or if one or more of the analysts who covers us downgrades our common stock or publishes inaccurate or unfavorable research about our business, the market price for our common stock would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which, in turn, could cause the market price or trading volume for our common stock to decline.

### *We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to advance or complete the development and commercialization of our product candidates.*

Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- initiation, progress, timing, costs and results of preclinical studies and clinical trials, including patient enrollment in such trials, for ONA-XR, CLDN6xCD3 bsAb or any other future product candidates;
- clinical development plans we establish for ONA-XR, CLDN6xCD3 bsAb and any other future product candidates;

- obligation to make milestone, royalty and non-royalty sublicense receipt payments to third-party licensors, if any, under our licensing agreements;
- number and characteristics of product candidates that we discover or in-license and develop;
- outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;
- costs of filing, prosecuting, defending and enforcing any patent claims and maintaining and enforcing other intellectual property rights;
- effects of competing technological and market developments;
- costs and timing of the implementation of commercial-scale manufacturing activities; and
- costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

If we are unable to expand our operations or otherwise capitalize on our business opportunities due to a lack of capital, our ability to become profitable will be compromised.

***We do not expect to pay dividends in the foreseeable future, and you must rely on price appreciation of your shares for return on your investment.***

We have paid no cash dividends on any class of our stock to date and we do not anticipate paying cash dividends in the near term. For the foreseeable future, we intend to retain any earnings to finance the development and expansion of our business, and we do not anticipate paying any cash dividends on our stock. Accordingly, investors must be prepared to rely on sales of their shares after price appreciation to earn an investment return, which may never occur. Investors seeking cash dividends should not purchase our shares. Any determination to pay dividends in the future will be made at the discretion of our board of directors and will depend on our results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board deems relevant.

***We may issue additional debt and equity securities, which are senior to our common stock as to distributions and in liquidation, which could materially adversely affect the market price of our common stock.***

In the future, we may attempt to increase our capital resources by entering into additional debt or debt-like financing that is secured by all or up to all of our assets, or issuing debt or equity securities, which could include issuances of commercial paper, medium-term notes, senior notes, subordinated notes or shares. In the event of our liquidation, our lenders and holders of our debt securities would receive a distribution of our available assets before distributions to our stockholders. In addition, any additional preferred stock, if issued by our company, may have a preference with respect to distributions and upon liquidation, which could further limit our ability to make distributions to our stockholders. Because our decision to incur debt and issue securities in our future offerings will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings and debt financing.

Further, market conditions could require us to accept less favorable terms for the issuance of our securities in the future. Thus, you will bear the risk of our future offerings reducing the value of your common stock and diluting your interest in our company.

***We are subject to ongoing public reporting requirements that are less rigorous than Exchange Act rules for companies that are not emerging growth companies and our stockholders could receive less information than they might expect to receive from more mature public companies.***

We are required to publicly report on an ongoing basis as an “emerging growth company” (as defined in the JOBS Act) under the reporting rules set forth under the Exchange Act. For so long as we remain an emerging growth

company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other Exchange Act reporting companies that are not emerging growth companies, including but not limited to:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- being permitted to comply with reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- being exempt from the requirement to hold a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards.

We expect to take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until October 19, 2026, although if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of any June 30 before that time, we would cease to be an emerging growth company as of the following December 31.

Because we are subject to ongoing public reporting requirements that are less rigorous than Exchange Act rules for companies that are not emerging growth companies, our stockholders could receive less information than they might expect to receive from more mature public companies. We cannot predict if investors will find our common stock less attractive if we elect to rely on these exemptions, or if taking advantage of these exemptions would result in less active trading or more volatility in the price of our common stock.

***If we fail to maintain effective internal control over financial reporting and effective disclosure controls and procedures, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which may adversely affect investor confidence in our company.***

We are subject to the reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, as well as the Sarbanes-Oxley Act and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting. Commencing with our fiscal year ending December 31, 2022, we will be required, under Section 404 of the Sarbanes-Oxley Act, to include in our Form 10-K filing a report by management on, among other things, the effectiveness of our internal control over financial reporting as of December 31, 2022. As an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act until we are no longer an emerging growth company. At such time, our independent registered public accounting firm may issue a report that is adverse in the event material weaknesses have been identified in our internal control over financial reporting.

To comply with the requirements of being a public company, we have undertaken and will need to undertake additional actions, such as implementing new internal controls and procedures and hiring additional accounting or internal audit staff. Testing and maintaining internal control can divert our management's attention from other matters that are important to the operation of our business. In addition, when evaluating our internal control over financial reporting, we may identify material weaknesses that we may not be able to remediate in time to meet the applicable deadline imposed upon us for compliance with the requirements of Section 404. If we identify any material weaknesses in our internal controls over financial reporting or we are unable to comply with the requirements of Section 404 in a timely manner or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting once we are no longer an emerging growth company,



investors may lose confidence in the accuracy and completeness of our financial reports. As a result, the market price of our common stock could be materially adversely affected.

***Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.***

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity and/or debt financings and collaborations, licensing agreements or other strategic arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a common stockholder.

To the extent that we raise additional capital through debt financing, it would result in increased fixed payment obligations and a portion of our operating cash flows, if any, being dedicated to the payment of principal and interest on such indebtedness. In addition, debt financing may involve agreements that include restrictive covenants that impose operating restrictions, such as restrictions on the incurrence of additional debt, the making of certain capital expenditures or the declaration of dividends.

To the extent we raise additional capital through arrangements with collaborators or otherwise, we may be required to relinquish some of our technologies, research programs, product development activities, product candidates and/or future revenue streams, license our technologies and/or product candidates on unfavorable terms or otherwise agree to terms unfavorable to us. Furthermore, any capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to advance research programs, product development activities or product candidates.

***A significant portion of our total outstanding shares are restricted from resale but may be sold into the market in the near future. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that the holders of a large number of shares intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

As of March 18, 2022, there were 15,966,053 outstanding shares of our common stock. Various shareholders who held shares of our common stock before our October 2021 initial public offering are currently restricted from selling their shares for a 180-day period, which ends as of the end of the day April 17, 2022, pursuant to contractual lock-up agreements with the underwriters. Furthermore, the directors and certain officers of the Company are restricted from selling their shares for a 365-day period, which ends at the close of the market on October 19, 2022, pursuant to contractual lock-up agreements with the underwriters. The representatives of the underwriters may, in their sole discretion and at any time or from time to time before the termination of the 180-day period or 365-day period, respectively, release all or any portion of the securities subject to lock-up agreements. Additionally, these shares are also eligible for sale without registration under Rule 144, subject to volume limitations applicable to affiliates. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

## **General Risk Factors**

***We incur increased costs as a result of becoming a public company and in the administration of our organizational structure.***

As a public company, we have incurred significant legal, accounting, insurance, and other expenses, including costs associated with public company reporting requirements. We also have incurred and will incur costs associated with the Sarbanes-Oxley Act and related rules implemented by the SEC and ongoing periodic expenses in connection with the administration of our organizational structure. The expenses incurred by public companies generally for reporting and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming

and costly, although we are currently unable to estimate these costs with any significant degree of certainty. In estimating these costs however, we took into account expenses related to insurance, legal, accounting, and compliance activities, as well as other expenses not currently incurred. These laws and regulations could also make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

***We are subject to complex tax rules relating to our business, and any audits, investigations or tax proceedings could have a material adverse effect on our business, results of operations and financial condition.***

We are subject to income and non-income taxes in the United States and Ireland, as well as the tax laws and regulations related to such matters. Tax accounting and compliance often involves complex issues, and judgment and interpretation is required in determining our provision for income taxes and other tax liabilities as well as the application of tax laws and regulations. We could become subject to income and non-income taxes in non-US jurisdictions other than Ireland as well. In addition, many jurisdictions have detailed transfer pricing rules, which require that all transactions with related parties be priced using arm's length pricing principles within the meaning of such rules. The application of such transfer pricing rules, as well as of withholding taxes, goods and services taxes, sales taxes and other taxes is not always clear and we may be subject to tax audits relating to such rules or taxes. We believe that our tax positions are reasonable, and our tax provisions and reserves are adequate to cover any potential liability. We are also currently not subject to any tax audits.

However, various items cannot be accurately forecasted and future events may be treated as discrete to the period in which they occur. In addition, the Internal Revenue Service or other taxing authorities may disagree with our positions. In addition, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us (possibly with retroactive effect). If the Internal Revenue Service or any other tax authorities were successful in challenging our positions, or existing tax laws, statutes, rules, regulations or ordinances are so interpreted, changed or modified, we may be liable for additional tax and penalties and interest related thereto or other taxes, as applicable, in excess of any reserves established therefor, which may have a significant impact on our results and operations and future cash flow.

***Our business and operations would suffer in the event of system failures or security breaches.***

Despite the implementation of security measures, our computer systems, as well as those of third parties with which we have relationships, are vulnerable to damage from computer viruses, unauthorized access, natural and manmade disasters, terrorism, war and telecommunication and electrical failures. If we or a third party with which we have relationships were to experience a system failure, accident or security breach such an event could cause interruptions in our or their operations, or it could result in delays and/or material disruptions of our research and development programs. For example, the loss of trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the development of our product candidates could be delayed.

The U.S. federal and various state and foreign governments have enacted or proposed requirements regarding the collection, distribution, use, security and storage of personally identifiable information and other data relating to individuals, and U.S. federal and state consumer protection laws are being applied to enforce regulations related to the online collection, use and dissemination of data. In the ordinary course of our business, we and third parties with which we have relationships collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, consultants and contractors, in data centers and on networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our and our collaborators' security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad

actors, breaches due to employee error, technical vulnerabilities, malfeasance or other disruptions, and any such breach could compromise our or their networks and the information stored there could be accessed, publicly disclosed, lost or stolen.

Any such access, disclosure, notifications, follow-up actions related to such a security breach or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant costs, including regulatory penalties, fines and legal expenses, and such an event could disrupt our operations, cause us to incur remediation costs, damage our reputation and cause a loss of confidence in us and our or such third parties' ability to conduct clinical trials, which could adversely affect our reputation and delay our research and development programs.

***We or third parties with whom we have relationships may be adversely affected by natural or manmade disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Natural or manmade disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our facilities, that damaged our infrastructure or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time, and our research and development activities could be setback or delayed.

The disaster recovery and business continuity plan(s) we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business, and such an event could disrupt our operations, cause us to incur remediation costs, damage our reputation and cause a loss of confidence in us and our or third parties' ability to conduct clinical trials, which could adversely affect our reputation and delay our research and development programs.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

We may now and in the future employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees and consultants.

***FINRA sales practice requirements may limit a stockholder's ability to buy and sell our common stock.***

The Financial Industry Regulatory Authority ("FINRA") has adopted rules requiring that, in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative or low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA has indicated its belief that there is a high probability that speculative or low-priced securities will not be suitable for at least some customers. If these FINRA requirements are applicable to us or our securities, they may make it more difficult for broker-dealers to recommend that at least some of their customers buy our common stock, which may limit the ability of our stockholders to buy and sell our common stock and could have an adverse effect on the market for and price of our common stock.

***We could be subject to securities class action litigation.***

In the past, securities class action litigation has often been brought against companies following a decline in the market price of their securities. This risk is especially relevant for us because biotechnology companies have experienced significant share price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

Our corporate headquarters are located at 2001 Market Street, Suite 3915, Unit #15, Philadelphia, PA 19103, where we occupy approximately 3,500 square feet of office space pursuant to a sublease entered into in January 2022. Our lease for this space began on February 1, 2022 and is set to expire on July 30, 2023.

**Item 3. Legal Proceedings**

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any material legal proceedings.

**Item 4. Mine Safety Disclosures**

None.

## PART II.

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchase of Equity Securities

#### Market Information

Our common stock has been traded on the Nasdaq Stock Market under the symbol "CNTX" since October 20, 2021 following our initial public offering.

#### Stockholders

As of March 18, 2022, we had 15,966,053 shares of common stock outstanding held by 98 holders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

#### Dividends

We have not paid cash dividends on any class of our stock to date, and we do not anticipate paying any cash dividends in the near term. For the foreseeable future, we intend to retain any earnings to finance the development and expansion of our business, and we do not anticipate paying any cash dividends on our stock. Any determination to pay dividends in the future will be made at the discretion of our board of directors and will depend on our results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board deems relevant.

#### Securities Authorized for Issuance under Equity Compensation Plans

Information required by Item 5 of Form 10-K regarding our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

#### Recent Sales of Unregistered Securities

In December 2021, we sold an aggregate of 5,000,000 shares of common stock together with warrants to purchase 5,000,000 shares of common stock in a private placement to Altium Growth Fund, L.P., Hudson Bay Master Fund Ltd., Kepos Alpha Master Fund L.P., Sabby Volatility Warrant Master Fund L.P., Empery Asset Master, LTD and Empery Tax Efficient, LP for gross proceeds of \$31.3 million. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures.

These shares were issued in a private placement exempt from registration under Rule 506(b) of Regulation D.

#### Purchases of Equity Securities by the Issuer and Affiliated Parties

None.

#### Item 6. [Reserved]

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this Form 10-K. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business, and the potential impacts of the ongoing COVID-19 pandemic, contains forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" in this Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described below. Please also see the section entitled "Note Regarding Forward-Looking Statements." On April 23, 2021, we completed a reverse triangular merger, resulting in Context Therapeutics Inc. becoming the sole holder of 100% of the membership interests in Context Therapeutics LLC. In connection with the merger, all of the common units, preferred units and all options, warrants or other rights to purchase common or preferred units of Context Therapeutics LLC converted into common stock, preferred stock and all options, warrants or other rights to purchase common or preferred stock of Context Therapeutics Inc. Prior to the reorganization we operated as Context Therapeutics LLC. Based on this being a transaction between entities under common control, the carryover basis of accounting was used to record the assets, liabilities, and equity of Context Therapeutics LLC. Further, as a common control transaction, the consolidated financial statements of the Company reflect the merger transaction as if it had occurred as of the earliest period presented herein.*

### Overview

We are a clinical-stage biopharmaceutical company dedicated to improving the lives of women living with cancer. Our development team is advancing a pipeline of innovative therapies with a primary focus on treating female cancers, including breast, ovarian, and endometrial (uterine) cancer. Our first program and lead product candidate, ONA-XR, builds upon a foundation of successful drug development by our management team and advisors in the field of female hormone-dependent cancers. ONA-XR is a potent and selective antagonist of the progesterone receptor, which has been linked to resistance to multiple classes of cancer therapeutics, including anti-estrogen therapies, across female hormone-dependent cancers.

We were incorporated in April 2015 under the laws of the State of Delaware. Since inception, we have devoted substantially all of our resources to developing product and technology rights, conducting research and development, organizing and staffing our company, business planning and raising capital. We operate as one business segment and have incurred recurring losses, the majority of which are attributable to research and development activities, and negative cash flows from operations. We have funded our operations primarily through the sale of convertible debt, convertible preferred stock and common stock. Our net loss was \$10.5 million for the year ended December 31, 2021. As of December 31, 2021, we had an accumulated deficit of \$29.3 million.

In October 2021, we closed an initial public offering ("IPO") on the Nasdaq Stock Market, in which we issued and sold 5,750,000 shares at a public offering price of \$5.00 per share. We received gross proceeds of approximately \$28.8 million as a result of the offering. In December 2021, we sold 5,000,000 shares of common stock together with warrants to purchase 5,000,000 shares of common stock in a private placement for gross proceeds of approximately \$31.3 million. We expect our existing cash and cash equivalents will be sufficient to fund our operations into 2024. Currently, our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, in connection with the closing of our initial public offering, we have incurred and continue to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenses on other research and development activities.

We expect to continue to incur net operating losses for at least the next several years, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. We expect our expenses and capital requirements will increase significantly in connection with our ongoing activities as we:

- continue our ongoing and planned research and development of our first program and lead product candidate ONA-XR;
- continue nonclinical studies and initiate clinical trials for our anti-claudin 6 (“CLDN6”) bispecific monoclonal antibody (“BsMAb”) product and for any additional product candidates that we may pursue;
- continue to scale up external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates and related additional commercial manufacturing costs;
- develop, maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets and know how;
- acquire or in-license other product candidates and technologies;
- attract, hire and retain additional executive officers, clinical, scientific, quality control, and manufacturing management and administrative personnel;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- expand our operations in the United States and to other geographies; and
- incur additional legal, accounting, investor relations and other expenses associated with operating as a public company.

We will need to raise substantial additional capital to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we plan to finance our operations through the sale of equity, debt financings and/or other capital sources, which may include collaborations with other companies or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing as and when needed to finance our operations on terms acceptable to us, or at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to secure adequate additional funding, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more product candidates or delay our pursuit of potential in-licenses or acquisitions.

#### **The COVID-19 Pandemic and its Impacts on Our Business**

In March 2020, the World Health Organization declared the outbreak of COVID-19 a global pandemic. The spread of COVID-19 has caused worldwide economic instability and significant volatility in the financial markets. There is significant uncertainty as to the likely effects of this disease which may, among other things, materially impact the Company’s ongoing or planned clinical trials. This pandemic or outbreak could result in difficulty securing clinical trial site locations, contract research organizations (“CROs”), and/or trial monitors and other critical vendors and consultants supporting the trial. In addition, outbreaks or the perception of an outbreak near a clinical trial site location could impact the Company’s ability to enroll patients. These situations, or others associated with COVID-19, could cause delays in the Company’s clinical trial plans and could increase expected costs, all of which could have a material adverse effect on the Company’s business and its financial condition. At the current time, the Company is unable to quantify the potential effects of this pandemic on its future consolidated financial statements.



## Components of Our Results of Operations

### *Operating Expenses*

#### *Acquired In-process Research and Development Expense*

Acquired in-process research and development expense consists of initial up-front payments incurred in connection with the acquisition or licensing of products or technologies that do not meet the definition of a business under Accounting Standards Codification Topic 805, *Business Combinations*. Acquired in-process research and development expense reflects the cash paid and/or the estimated fair value of the equity consideration given.

#### *Research and Development Expenses*

Research and development expenses have consisted primarily of costs incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred, including:

- expenses incurred to conduct the necessary discovery-stage laboratory work, preclinical studies and clinical trials required to obtain regulatory approval;
- personnel expenses, including salaries, benefits and share-based compensation expense for our employees and consultants engaged in research and development functions;
- costs of funding research performed by third parties, including pursuant to agreements with clinical research organizations, or CROs, that conduct our clinical trials, as well as investigative sites, consultants and CROs that conduct our preclinical and clinical studies;
- expenses incurred under agreements with contract manufacturing organizations, or CMOs, including manufacturing scale-up expenses, milestone-based payments, and the cost of acquiring and manufacturing preclinical study and clinical trial materials;
- fees paid to consultants who assist with research and development activities;
- expenses related to regulatory activities, including filing fees paid to regulatory agencies; and
- allocated expenses for facility costs, including rent, utilities and maintenance.

We track outsourced development costs and other external research and development costs to specific product candidates on a program-by-program basis, fees paid to CROs, CMOs and research laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. However, we do not track our internal research and development expenses on a program-by-program basis as they primarily relate to compensation, early research and other costs which are deployed across multiple projects under development.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase significantly over the next several years as we increase personnel costs, including share-based compensation, conduct our clinical trials, including later-stage clinical trials, for current and future product candidates and prepare regulatory filings for our product candidates.

#### *General and Administrative Expenses*

General and administrative expenses have consisted primarily of personnel expenses, including salaries, benefits and share-based compensation expense, for employees and consultants in executive, finance and accounting, legal, operations support, information technology and business development functions. General and administrative expense also includes corporate facility costs not otherwise included in research and development expense, including rent, utilities and insurance, as well as legal fees related to intellectual property and corporate matters and fees for accounting and consulting services.

We expect that our general and administrative expenses will increase in the future to support our continued research and development activities, potential commercialization efforts and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, legal support and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with the requirements of Nasdaq and the Securities and Exchange Commission, or SEC, insurance and investor relations costs. If any of our current or future product candidates obtain U.S. regulatory approval, we expect that we would incur significantly increased expenses associated with building a sales and marketing team.

#### *Interest Expense*

Interest expense has consisted primarily of interest related to our convertible promissory notes that converted to Series A stock in 2020 and 2021. All of the outstanding Convertible Promissory Notes were converted as of February 2021.

#### *Other Income*

Other income is primarily due to the recognition of a gain on extinguishment of debt as a result of the forgiveness of our outstanding Paycheck Protection Program loan in July 2021.

### **Results of Operations**

#### ***Comparison of the Years Ended December 31, 2021 and 2020***

The following table sets forth our results of operations for the years ended December 31, 2021 and 2020:

	<b>Year ended December 31,</b>		<b>\$ Change</b>	<b>% Change</b>
	<b>2021</b>	<b>2020</b>		
Operating expenses:				
Acquired in-process research and development	\$ 3,087,832	\$ —	3,087,832	100 %
Research and development	3,805,067	1,641,501	2,163,566	132 %
General and administrative	3,632,920	930,667	2,702,253	290 %
Loss from operations	(10,525,819)	(2,572,168)	(7,953,651)	309 %
Interest expense	(64,240)	(661,224)	596,984	(90)%
Change in fair value of convertible promissory notes	9,317	9,877,857	(9,868,540)	(100)%
Other income	123,872	—	123,872	100 %
Net income (loss)	<u>\$ (10,456,870)</u>	<u>\$ 6,644,465</u>	<u>\$ (17,101,335)</u>	<u>(257)%</u>

#### *Acquired In-Process Research and Development Expenses*

Acquired in-process research and development expense of \$3.1 million for the year ended December 31, 2021 reflects the fair value of consideration paid/issued under the collaboration and licensing agreement with Integral Molecular, Inc. (“Integral”) for the development of an anti-claudin 6 (“CLDN6”) bispecific monoclonal antibody (“BsMAB”) for gynecologic cancer therapy. There was no such consideration paid/issued under collaboration arrangements in 2020.

#### *Research and Development Expenses*

Research and development expenses increased by \$2.2 million from \$1.6 million for the year ended December 31, 2020 to \$3.8 million for the year ended December 31, 2021. The increase was mainly due to an increase of \$0.6 million in clinical trial costs related to our Phase 2 trials evaluating ONA-XR, \$0.6 million in preclinical costs associated with conducting research for the development of a CLDN6 BsMAB for gynecologic cancer therapy, and an increase in contract manufacturing costs of \$0.5 million for ONA-XR. Additionally,

consulting services increased by approximately \$0.4 million as we increased the use of third-party contractors to focus on developing our product candidates.

#### *General and Administrative Expenses*

General and administrative expenses increased by \$2.7 million from \$0.9 million for the year ended December 31, 2020 to \$3.6 million for the year ended December 31, 2021. The increase was mainly due to an increase of \$1.1 million in compensation and share-based compensation as a result of an increase in our general and administrative headcount and changes to compensation arrangements. Additionally, expenses increased by \$1.6 million due to higher insurance costs of \$0.3 million, professional fees and consulting services of \$1.0 million, and other costs associated with operating as a public company.

#### *Interest Expense*

Interest expense decreased by \$0.6 million from \$0.7 million for the year ended December 31, 2020 to \$0.1 million for the year ended December 31, 2021 due to the conversion of all previously outstanding convertible promissory notes.

#### *Change in Fair Value of Convertible Promissory Notes*

The change in fair value of convertible promissory notes was \$9.9 million for the year ended December 31, 2020 and \$9,000 for the year ended December 31, 2021. This change was attributable to a decrease in the fair value of our common stock as well as the conversion of all previously outstanding convertible promissory notes.

#### *Other Income*

Other income of \$0.1 million for the year ended December 31, 2021 is primarily due to the recognition of a gain on extinguishment of debt as a result of the forgiveness of our outstanding Paycheck Protection Program loan in July 2021.

### **Liquidity and Capital Resources**

#### ***Overview***

Since our inception, we have not recognized any revenue and have incurred operating losses and negative cash flows from our operations. We have not yet commercialized any product and we do not expect to generate revenue from sales of any products for several years, if at all. Since our inception through December 31, 2021, we have funded our operations through the sale of convertible debt, convertible preferred stock and common stock. As of December 31, 2021, we had \$49.6 million in cash and cash equivalents and had an accumulated deficit of \$29.3 million. In October 2021, we closed an initial public offering (“IPO”) on the Nasdaq Stock Market and received gross proceeds of approximately \$28.8 million as a result of the offering. Additionally, in December 2021, we sold 5,000,000 shares of our common stock together with warrants to purchase 5,000,000 shares of our common stock in a private placement and received gross proceeds of approximately \$31.3 million. We expect our existing cash and cash equivalents will be sufficient to fund our operations into 2024. We have based these estimates on assumptions that may prove to be imprecise, and we could utilize our available capital resources sooner than we expect.

#### ***Funding Requirements***

Our primary use of cash is to fund operating expenses, which consist of research and development expenditures and various general and administrative expenses. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, timing, progress and results of discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs of manufacturing our product candidates for clinical trials and in preparation for regulatory approval and commercialization;
- the extent to which we enter into collaborations or other arrangements with additional third parties in order to further develop our product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the costs and fees associated with the discovery, acquisition or in-license of additional product candidates or technologies;
- expenses needed to attract and retain skilled personnel;
- costs associated with being a public company;
- the costs required to scale up our clinical, regulatory and manufacturing capabilities;
- the costs of future commercialization activities, if any, including establishing sales, marketing, manufacturing and distribution capabilities, for any of our product candidates for which we receive regulatory approval; and
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive regulatory approval.

We will need additional funds to meet our operational needs and capital requirements for clinical trials, other research and development expenditures, and general and administrative expenses. We currently have no credit facility or committed sources of capital.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and/or marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

## Cash Flows

The following table shows a summary of our cash flows for the periods indicated:

	2021	2020
Cash used in operating activities	\$ (8,799,487)	\$ (1,034,620)
Cash used in investing activities	(250,000)	—
Cash provided by financing activities	58,394,036	1,149,054
Net increase in cash and cash equivalents	\$ 49,344,549	\$ 114,434

## Comparison of the Years Ended December 31, 2021 and 2020

### Operating Activities

During the year ended December 31, 2021, we used \$8.8 million of cash in operating activities. Cash used in operating activities reflected our net loss of \$10.5 million, a gain of \$0.1 million from the extinguishment of debt and a net change in our operating assets and liabilities of \$2.2 million. This was primarily offset by non-cash in-process research and development charges of \$3.1 million, the non-cash fair value measurement of warrants for services of \$0.4 million and share-based compensation of \$0.5 million. The primary uses of cash were to fund our operations related to the development of our product candidates.

During the year ended December 31, 2020, we used \$1.0 million of cash in operating activities. Cash used in operating activities reflected the noncash change in fair value of convertible promissory notes of \$9.9 million, offset by our net income of \$6.6 million, noncash interest expense of \$0.7 million, share-based compensation of \$0.2 million and a \$1.3 million net change in our operating assets and liabilities. The primary use of cash was to fund our operations related to the development of our product candidates.

### Investing Activities

During the year ended December 31, 2021, cash used in investing activities was attributable to the initial upfront license fee of \$0.3 million related to the Company's acquired in-process research and development.

We did not have cash flows from investing activities during the year ended December 31, 2020.

### Financing Activities

During the year ended December 31, 2021, financing activities provided \$58.4 million, consisting of net proceeds of \$5.0 million from the sale of Series A Stock and warrants for common stock, net proceeds of \$24.4 million from the sale of common stock in connection with our IPO and net proceeds of \$29.0 million from the sale of common stock and warrants in connection with our private placement.

During the year ended December 31, 2020, financing activities provided \$1.1 million, consisting of \$1.0 million of proceeds from the sale of Series A Stock and warrants for common stock, \$25,000 from the issuance of convertible bridge notes, \$50,000 from the sale of Series Seed Stock and \$0.1 million of proceeds from the Paycheck Protection Program loan.

## Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities that were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. We do not engage in off-balance sheet financing arrangements. In addition, we do not engage in trading activities involving non-exchange traded contracts. We therefore believe that we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

## **Critical Accounting Policies**

This management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to prepaid/accrued research and development expenses, share-based compensation and fair value of convertible promissory notes. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 3 to our audited consolidated financial statements included elsewhere in this Form 10-K, we believe the following accounting policies are the most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

### ***Research and Development Expenses***

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidates. We expense research and development costs as incurred.

We accrue an expense for preclinical studies and clinical trial activities performed by our vendors based upon estimates of the proportion of work completed. We determine the estimates by reviewing contracts, vendor agreements and purchase orders, and through discussions with our internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. However, actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending upon a number of factors, including our clinical development plan.

We make estimates of our prepaid/accrued expenses as of each balance sheet date in our consolidated financial statements based upon facts and circumstances known at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the prepaid/accrual accordingly. Nonrefundable advance payments for goods and services, including fees for clinical trial expenses, process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed, or services are performed.

### ***Share-Based Compensation***

We measure compensation expense for all share-based awards based on the estimated fair value of the share-based awards on the grant date. We use the Black-Scholes option pricing model to value our share-based awards. We recognize compensation expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. We have not issued awards for which vesting is subject to market or performance conditions.

The Black-Scholes option-pricing model requires the use of subjective assumptions that include the expected stock price volatility and the fair value of the underlying common stock on the date of grant. See Note 8 to our audited consolidated financial statements included elsewhere in this Form 10-K for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our awards granted.

## **Recent Accounting Pronouncements**

See Note 3 to our audited consolidated financial statements found elsewhere in this Form 10-K for a description of recent accounting pronouncements applicable to our consolidated financial statements.

## **Qualitative and Quantitative Disclosures About Market Risk**

We are exposed to market risk related to changes in interest rates. As of December 31, 2021, we had cash and cash equivalents of \$49.6 million consisting of bank deposits and a commercial money market account. Due to the short-term duration of our cash equivalents, an immediate 10% change in interest rates would not have a material effect on the fair market value.

Inflation generally affects us by increasing our labor and clinical trial costs. We do not believe inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2021 and 2020.

## **Emerging Growth Company and Smaller Reporting Company Status**

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from complying with new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

Other exemptions and reduced reporting requirements under the JOBS Act include, without limitation, the requirements for providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements. We will remain an emerging growth company until the earlier to occur of (a) the last day of the fiscal year (i) following October 19, 2026, (ii) in which we have total annual gross revenues of at least \$1.07 billion or (iii) in which we are deemed to be a “large accelerated filer” under the rules of the SEC, which means that we have been required to file annual and quarterly reports under the Exchange Act for a period of at least 12 months and have filed at least one annual report pursuant to the Exchange Act and either (a) the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th, or (b) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates is less than \$700.0 million and our annual revenue is less than \$100.0 million during the most recently completed fiscal year. We will continue to be a smaller reporting company until either (i) the market value of our stock held by non-affiliates is less than \$250.0 million or (ii) our annual revenue is less than \$100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

## **Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

Not required for smaller reporting companies.

**Item 8. Financial Statements and Supplementary Data**

**Context Therapeutics Inc.  
Index To Consolidated Financial Statements**

	<b><u>Page</u></b>
<a href="#"><u>Report of Independent Registered Public Accounting Firm</u></a> (PCAOB ID 596)	<u>82</u>
<a href="#"><u>Consolidated Balance Sheets</u></a>	<u>83</u>
<a href="#"><u>Consolidated Statements of Operations</u></a>	<u>84</u>
<a href="#"><u>Consolidated Statements of Changes in Convertible Preferred Stock, Redeemable Common Stock and Stockholders' Equity (Deficit)</u></a>	<u>85</u>
<a href="#"><u>Consolidated Statements of Cash Flows</u></a>	<u>87</u>
<a href="#"><u>Notes to Consolidated Financial Statements</u></a>	<u>88</u>



## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders of  
Context Therapeutics Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Context Therapeutics Inc. and Subsidiaries (the “Company”) as of December 31, 2021 and 2020, and the related consolidated statements of operations, changes in convertible preferred stock, redeemable common stock and stockholders’ equity (deficit), and cash flows for the years then ended, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020 and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

### Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ CohnReznick LLP

We have served as the Company’s auditor since January 2021.

Holmdel, New Jersey  
March 23, 2022

**Context Therapeutics Inc.**  
**Consolidated Balance Sheets**

	December 31,	
	2021	2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 49,635,197	\$ 290,670
Prepaid expenses and other current assets	1,620,164	8,672
Total current assets	51,255,361	299,342
Restricted cash	50,389	50,367
Deferred offering costs	—	117,631
Total assets	<u>\$ 51,305,750</u>	<u>\$ 467,340</u>
<b>Liabilities, Convertible Preferred Stock, Redeemable Common Stock and Stockholders' Equity (Deficit)</b>		
Current liabilities:		
Convertible promissory notes	\$ —	\$ 5,829,292
Note payable—current	—	55,014
Accounts payable	1,826,294	2,707,861
Accrued expenses and other current liabilities	1,207,121	955,989
Total current liabilities	3,033,415	9,548,156
Note payable—noncurrent	—	69,040
Total liabilities	<u>3,033,415</u>	<u>9,617,196</u>
Commitments and Contingencies (Note 9)		
Convertible preferred stock, redeemable common stock and stockholders' equity (deficit):		
Convertible preferred stock and redeemable common stock (no shares authorized at December 31, 2021):		
Series A preferred stock—\$0.001 par value; no shares and 210,715 issued and outstanding at December 31, 2021 and 2020, respectively	—	1,400,935
Series Seed preferred stock—\$0.001 par value; no shares and 2,624,324 issued and outstanding at December 31, 2021 and 2020, respectively	—	6,341,288
Redeemable common stock—\$0.001 par value; no shares and 16,666 issued and outstanding at December 31, 2021 and 2020, respectively	—	29,000
Total convertible preferred stock and redeemable common stock	—	7,771,223
Stockholders' equity (deficit):		
Preferred stock—\$0.001 par value; 10,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock—\$0.001 par value; 100,000,000 shares authorized; 15,966,053 and 331,789 shares issued and outstanding at December 31, 2021 and 2020, respectively	15,966	332
Additional paid-in capital	77,510,809	1,876,159
Accumulated deficit	(29,254,440)	(18,797,570)
Total stockholders' equity (deficit)	48,272,335	(16,921,079)
Total liabilities, convertible preferred stock, redeemable common stock and stockholders' equity (deficit)	<u>\$ 51,305,750</u>	<u>\$ 467,340</u>

*The accompanying notes are an integral part of these consolidated financial statements.*

**Context Therapeutics Inc.**  
**Consolidated Statements of Operations**

	Year ended December 31,	
	2021	2020
Operating expenses:		
Acquired in-process research and development	\$ 3,087,832	\$ —
Research and development	3,805,067	1,641,501
General and administrative	3,632,920	930,667
Loss from operations	(10,525,819)	(2,572,168)
Interest expense	(64,240)	(661,224)
Change in fair value of convertible promissory notes	9,317	9,877,857
Other income	123,872	—
Net (loss) income	\$ (10,456,870)	\$ 6,644,465
Net (loss) income per common share, basic	\$ (3.69)	\$ 3.07
Net loss per common share, diluted	\$ (3.69)	\$ (3.96)
Weighted average shares outstanding, basic	2,833,674	348,368
Weighted average shares outstanding, diluted	2,833,674	2,054,875

*The accompanying notes are an integral part of these consolidated financial statements.*

**Context Therapeutics Inc.**

**Consolidated Statements of Changes in Convertible Preferred Stock, Redeemable Common Stock and Stockholders' Equity (Deficit)**

	Series A Preferred Stock		Series Seed Preferred Stock		Redeemable Common Stock		Common stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at January 1, 2020	—	—	—	—	16,666	\$ 126,000	324,145	\$ 324	\$ 1,480,955	\$ (25,442,035)	\$ (23,960,756)
Sale of Series A preferred stock	132,537	\$ 950,000	—	—	—	—	—	—	—	—	—
Conversion of bridge notes, including accrued interest, to Series A preferred stock	78,178	529,902	—	—	—	—	—	—	—	—	—
Fair value of warrants issued in conjunction with the Series A preferred stock	—	(78,967)	—	—	—	—	—	—	78,967	—	78,967
Sale of Series Seed preferred stock	—	—	8,771	\$ 50,000	—	—	—	—	—	—	—
Conversion of Junior Convertible Notes to Series Seed preferred stock	—	—	2,615,553	6,291,288	—	—	—	—	—	—	—
Share-based compensation expense, including vesting of restricted stock and issuance of common stock	—	—	—	—	—	—	7,644	8	219,237	—	219,245
Change in fair value of redeemable common stock to redemption value	—	—	—	—	—	(97,000)	—	—	97,000	—	97,000
Net income	—	—	—	—	—	—	—	—	—	6,644,465	6,644,465
Balance at December 31, 2020	210,715	1,400,935	2,624,324	6,341,288	16,666	29,000	331,789	332	1,876,159	(18,797,570)	(16,921,079)
Sale of Series A preferred shares, net of offering costs of \$310,021	738,445	4,982,835	—	—	—	—	—	—	—	—	—
Conversion of Senior Convertible Notes, including accrued interest, to Series A preferred stock	844,824	5,728,793	—	—	—	—	—	—	137,497	—	137,497
Fair value of Series A preferred stock issued in conjunction with collaboration and licensing agreement	418,559	2,837,832	—	—	—	—	—	—	—	—	—
Fair value of warrants issued in conjunction with the Series A preferred stock	—	(265,593)	—	—	—	—	—	—	265,593	—	265,593
Fair value of warrants issued as placement agent fees	—	(43,797)	—	—	—	—	—	—	43,797	—	43,797

Fair value of warrants issued for services	—	—	—	—	—	—	—	—	371,895	—	371,895
Change in fair value of redeemable common stock to redemption value	—	—	—	—	—	53,330	—	—	(53,330)	—	(53,330)
Conversion of convertible preferred shares and redeemable common shares upon initial public offering	(2,212,543)	(14,641,005)	(2,624,324)	(6,341,288)	(16,666)	(82,330)	4,853,533	4,853	21,059,770	—	21,064,623
Cashless exercise of warrants upon initial public offering	—	—	—	—	—	—	9,816	10	(10)	—	—
Sale of common stock in initial public offering, net of issuance costs of \$4,321,374	—	—	—	—	—	—	5,750,000	5,750	24,422,876	—	24,428,626
Sale of common stock in private placement, net of issuance costs of \$2,369,496	—	—	—	—	—	—	5,000,000	5,000	28,875,504	—	28,880,504
Share-based compensation expense, including vesting of restricted stock and issuance of common stock	—	—	—	—	—	—	20,915	21	511,058	—	511,079
Net loss	—	—	—	—	—	—	—	—	—	(10,456,870)	(10,456,870)
Balance at December 31, 2021	—	\$ —	—	\$ —	—	\$ —	15,966,053	\$ 15,966	\$ 77,510,809	\$ (29,254,440)	\$ 48,272,335

*The accompanying notes are an integral part of these consolidated financial statements.*

**Context Therapeutics Inc.**  
**Consolidated Statements of Cash Flows**

	Year ended December 31,	
	2021	2020
<b>Cash flows from operating activities:</b>		
Net (loss) income	\$ (10,456,870)	\$ 6,644,465
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Acquired in-process research and development charge	3,087,832	—
Fair value of warrants for services provided	371,895	—
Share-based compensation expense	511,079	219,245
Non-cash interest expense	46,315	661,224
Change in fair value of convertible promissory notes	(9,317)	(9,877,857)
Gain on extinguishment of debt	(125,577)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,611,492)	4,332
Accounts payable	(866,007)	556,270
Accrued expenses and other current liabilities	252,655	757,701
Cash used in operating activities	(8,799,487)	(1,034,620)
<b>Cash flows from investing activities:</b>		
Acquired in-process research and development	(250,000)	—
Cash used in investing activities	(250,000)	—
<b>Cash flows from financing activities:</b>		
Proceeds from the issuance of convertible bridge notes	—	25,000
Proceeds from the issuance of note payable	—	124,054
Proceeds from the sale of Series A preferred stock, net	4,982,835	950,000
Proceeds from the sale of Series Seed preferred stock	—	50,000
Proceeds from the sale of common stock in initial public offering, net	24,428,626	—
Proceeds from the sale of common stock in private placement, net	28,982,575	—
Cash provided by financing activities	58,394,036	1,149,054
Net increase in cash, cash equivalents and restricted cash	49,344,549	114,434
Cash, cash equivalents and restricted cash at beginning of year	341,037	226,603
Cash, cash equivalents and restricted cash at end of year	\$ 49,685,586	\$ 341,037
<b>Supplemental disclosure of non-cash financing activities:</b>		
Conversion of convertible promissory notes, including accrued interest, to Series A preferred stock and warrants	\$ 5,866,290	\$ —
Conversion of bridge notes, including accrued interest, to Series A preferred stock	\$ —	\$ 529,902
Conversion of convertible promissory notes, including accrued interest, to Series Seed preferred stock	\$ —	\$ 6,291,288
Issuance of warrants in conjunction with Series A preferred stock and placement agent fees	\$ 309,390	\$ 78,967
Series A preferred stock issued for acquired in-process research and development	\$ 2,837,832	\$ —
Unpaid offering costs in accounts payable	\$ 102,071	\$ 117,631
Change in fair value of redeemable common stock to redemption value	\$ 53,330	\$ 97,000
Conversion of preferred stock and redeemable common stock upon initial public offering	\$ 21,064,623	\$ —

*The accompanying notes are an integral part of these consolidated financial statements.*

**CONTEXT THERAPEUTICS INC.**  
**Notes to Consolidated Financial Statements**

**(1) Nature of Business**

Context Therapeutics Inc. (the “Company”) is a clinical-stage biopharmaceutical company dedicated to improving the lives of women living with cancer. The Company was organized in April 2015 under the laws of the State of Delaware. The Company’s operations are located in Philadelphia, Pennsylvania. In April 2021, the Company completed a reverse triangular merger, which resulted in Context Therapeutics Inc. becoming the sole holder of 100% of the membership interests in Context Therapeutics LLC. In connection with the merger, all common units, preferred units, options, warrants or other rights to purchase common or preferred units of Context Therapeutics LLC converted into common stock, preferred stock, options, warrants or other rights to purchase common or preferred stock of Context Therapeutics Inc. As this was a transaction between entities under common control, the carryover basis of accounting was used to record the assets, liabilities and equity of Context Therapeutics LLC. Further, as a common control transaction, the consolidated financial statements of the Company reflect the merger transaction as if it had occurred as of the earliest period presented herein.

**(2) Risks and Liquidity**

The Company has incurred losses and negative cash flows from operations since inception and had an accumulated deficit of \$29.3 million as of December 31, 2021. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant revenues from its product candidates currently in development. The Company’s primary source of liquidity to date has been the issuance of convertible promissory notes, convertible preferred stock and common stock.

In the first half of 2021, the Company raised \$5.0 million in net proceeds related to the sale of its Series A convertible preferred stock (“Series A Stock”) and warrants for common stock (see Note 7 for further discussion).

In October 2021, the Company closed an initial public offering (“IPO”) on the Nasdaq Stock Market, in which it issued and sold 5,750,000 shares at a public offering price of \$5.00 per share. In addition, at the closing of the IPO, the Company issued warrants to purchase up to 250,000 shares of common stock to designees of the placement agent. The placement agent’s warrants have an exercise price of \$6.25 per share and a term of five years from the date of issuance. Immediately prior to the completion of the IPO, all of the Company’s preferred stock and redeemable common stock converted into an aggregate of 4,853,533 shares of common stock and 480,415 warrants converted into 9,816 shares of common stock. The Company received net proceeds of \$24.4 million as a result of its initial public offering.

In December 2021, the Company sold 5,000,000 shares of its common stock together with warrants to purchase 5,000,000 shares of its common stock in a private placement and received net proceeds of \$28.9 million. Each share of common stock and accompanying warrant were sold together at a combined offering price of \$6.25. The warrants have a term of 5.5 years and an exercise price of \$6.25 per share. In addition, at the closing of the private placement, the Company issued warrants to purchase up to 250,000 shares of common stock to designees of the placement agent. The placement agent’s warrants have an exercise price of \$6.25 per share and a term of 5.5 years from the date of issuance.

The Company believes its cash and cash equivalents at December 31, 2021 are sufficient to fund its projected operations into fiscal year 2024. However, substantial additional capital will be needed by the Company to fund its operations and to commercially develop its current and future product candidates. There is no assurance that such financing will be available when needed or on acceptable terms.

The Company plans to secure additional capital in the future through equity and/or debt financings, partnerships, collaborations, or other sources to carry out the Company’s planned development activities. If additional capital is not available when required, the Company may need to delay or curtail its operations until such funding is received. Various internal and external factors will affect whether and when the Company’s product candidates become approved for marketing and successful commercialization. The regulatory approval and market acceptance of the Company’s product candidates, length of time and cost of developing and commercializing these

product candidates and/or failure of them at any stage of the approval process will materially affect the Company's financial condition and future operations.

The Company faces risks associated with companies whose products are in development. These risks include the need for additional financing to complete its research and development, achieving its research and development objectives, defending its intellectual property rights, recruiting and retaining skilled personnel, and dependence on key members of management, among others.

In March 2020, the World Health Organization declared the outbreak of COVID-19 a global pandemic. The spread of COVID-19 has caused worldwide economic downturn and significant volatility in the financial markets. There is significant uncertainty as to the likely effects of this disease which may, among other things, materially impact the Company's planned clinical trials. This pandemic or outbreak could result in difficulty securing clinical trial site locations, contract research organizations, and/or trial monitors and other critical vendors and consultants supporting the trial. In addition, outbreaks or the perception of an outbreak near a clinical trial site location could impact the Company's ability to enroll patients. These situations, or others associated with COVID-19, could cause delays in the Company's clinical trial plans and could increase expected costs, all of which could have a material adverse effect on the Company's business and its financial condition. At the current time, the Company is unable to quantify the potential effects of this pandemic on its future consolidated financial statements.

### **(3) Summary of Significant Accounting Policies**

#### ***Basis of Presentation and Principles of Consolidation***

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") promulgated by the Financial Accounting Standards Board ("FASB"). The consolidated financial statements include the accounts of the Company, Context Therapeutics LLC, Context Biopharma, Inc. and Context Ireland Ltd., the Company's wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

#### ***Reclassification of Prior Year Presentation***

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations.

#### ***Use of Estimates***

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and contingent liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Estimates and assumptions are periodically reviewed and the effects of the revisions are reflected in the accompanying consolidated financial statements in the period they are determined to be necessary. Significant estimates and assumptions made in the accompanying consolidated financial statements include, but are not limited to, the fair value of common stock, share-based compensation arrangements, the fair value of warrants, the fair value of convertible debt, and prepayments, accruals and associated expense related to research and development activities performed for the Company by third parties.

#### ***Concentrations of Credit Risk***

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.



### **Segment Information**

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment.

### **Fair Value of Financial Instruments**

At December 31, 2021 and 2020, the Company's level 1 financial instruments included cash equivalents and accounts payable. The carrying amounts of these assets and liabilities approximate fair value due to their short-term nature. Convertible promissory notes are recorded at approximate fair value on a recurring basis (see Note 4 for further discussion).

### **Cash, Cash Equivalents and Restricted Cash**

The Company considers all highly liquid investments that have original maturities of three months or less when acquired to be cash equivalents. Cash equivalents consist of amounts invested in money market accounts.

### **Restricted Cash**

The Company maintains approximately \$50,000 as collateral for the Company's credit card program. The Company has recorded this deposit and accumulated interest thereon as restricted cash on its consolidated balance sheets.

The following table presents the Company's cash, cash equivalents, and restricted cash as of December 31, 2021 and 2020:

	December 31,	
	2021	2020
Cash and cash equivalents	\$ 49,635,197	\$ 290,670
Restricted cash	50,389	50,367
Total cash, cash equivalents and restricted cash	\$ 49,685,586	\$ 341,037

### **Deferred Offering Costs**

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of an equity financing, the costs are recorded as a reduction of additional paid-in capital generated as a result of such offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations. As of December 31, 2020, the Company had deferred offering costs of \$0.1 million related to the Company's IPO and the Company's Series A Stock financing. All deferred offering costs related to the Company's Series A Stock financing were recorded against Series A Stock upon completion of the financing in April 2021 and all deferred offering costs related to the Company's IPO were recorded against additional paid-in capital upon completion of the IPO financing in October 2021. There were no deferred offering costs recorded as of December 31, 2021.

### **Convertible Preferred Stock and Redeemable Common Stock**

The Company accounts for its convertible preferred stock subject to possible conversion in accordance with ASC 480, *Distinguishing Liabilities from Equity*. Conditionally convertible preferred stock (including shares that feature conversion rights that are either within the control of the holder or subject to conversion upon the occurrence of uncertain events not solely within the Company's control) are classified as temporary equity. The Company's convertible preferred stock feature redemption rights that are considered by the Company to be outside of the Company's control and subject to the occurrence of uncertain future events. Accordingly, at December 31, 2020, the

convertible preferred stock subject to contingent redemption are presented as temporary equity, outside of the stockholders' deficit section of the Company's consolidated balance sheets.

#### ***Acquired In-Process Research and Development Costs***

Acquired in-process research and development ("IPR&D") expense consists of the initial up-front payments incurred in connection with the acquisition or licensing of products or technologies that do not meet the definition of a business under FASB ASC Topic 805, *Business Combinations*. The Company's acquired IPR&D expense of \$3.1 million for the year ended December 31, 2021 reflects the fair value of consideration ascribed to the collaboration and licensing agreement with Integral Molecular, Inc. ("Integral") for the development of an anti-claudin 6 ("CLDN6") bispecific monoclonal antibody ("BsMAb") for gynecologic cancer therapy. See Note 9 for further discussion.

#### ***Research and Development Costs***

Research and development costs are expensed as incurred. Research and development costs include external costs of outside vendors engaged to conduct clinical studies and other research and development activities, salaries, share-based compensation, and other operational costs related to the Company's research and development activities.

The Company makes estimates of prepaid/accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the prepaid/accrual accordingly.

Nonrefundable advance payments for goods and services, including fees for clinical trial expenses, process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

#### ***Patent Costs***

Costs related to filing and pursuing patent applications are recorded as general and administrative expense and expensed as incurred since recoverability of such expenditures is uncertain.

#### ***Share-Based Compensation***

The Company measures and recognizes share-based compensation expense for both employee and non-employee awards based on the grant date fair value of the awards. The Company recognizes share-based compensation expense on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. The Company recognizes forfeitures as they occur.

The Company classifies share-based compensation expense in its consolidated statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

The Company estimates the fair value of employee and non-employee stock awards as of the date of grant using the Black-Scholes option pricing model. Until its IPO that closed in October 2021, the Company had been a private company and lacked Company-specific historical and implied volatility information. Therefore, management estimates the expected share price volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own publicly traded share price. The expected term of the Company's stock awards has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" stock awards. The risk-free interest rate is determined by reference to the yield curve of a zero-coupon U.S. Treasury bond on the date of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

In addition, the Company measures and recognizes share-based compensation expense for advisors, officers and director restricted stock awards based on the grant date fair value of the awards.

### **Income Taxes**

Prior to April 2021, the Company was a limited liability company that was treated as a pass-through entity for income tax purposes. In April 2021, upon the completion of its reverse triangular merger, the Company converted to a corporation and is subject to federal, state and local corporate income taxes which have been provided for in the financial statements based upon ASC 740, *Income Taxes* (“ASC 740”). Context BioPharma, Inc. has always been subject to corporate income taxes.

Under ASC 740, deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax reporting. Deferred tax assets are reduced by a valuation allowance if a determination is made that it is more likely than not that some or all of the deferred tax assets will not be realized based on the weight of all available evidence.

As required by ASC 740, the Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an examination. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon settlement with the relevant authority.

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2021 and 2020, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company’s consolidated statements of operations.

### **Net (Loss) Income Per Share**

The Company computes net (loss) income per share using the weighted-average number of common shares outstanding during the year. For years with a net loss, basic and diluted net loss per share are the same because the conversion, exercise or issuance of all potential common stock equivalents, which includes convertible promissory notes, preferred stock, warrants and share-based awards outstanding, would be anti-dilutive.

The Company was in a net loss position for the year ended December 31, 2021 and therefore basic and diluted net loss per share was the same. The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of common stock outstanding for the years ended December 31, 2021 and 2020, as they would be anti-dilutive:

	<b>December 31,</b>	
	<b>2021</b>	<b>2020</b>
Stock options	506,691	24,830
Unvested restricted stock units	—	45
Warrants	5,500,000	160,108
	<u>6,006,691</u>	<u>184,983</u>

For the year ended December 31, 2020, the Company was in a net income position and therefore, used the two-class method to compute basic net income per common share. Under this method, undistributed earnings are allocated to common stock, the Series Seed Preferred Stock and the Series A Preferred Stock to the extent that the preferred stockholders may share in earnings. In periods of net loss, losses are not allocated to participating securities as the holders of such securities have no obligation to fund losses. The total earnings allocated to common stock is then divided by the weighted average common shares outstanding to determine the basic earnings per share.

For purposes of calculating diluted loss per common share, the denominator includes both the weighted average common shares outstanding and the number of common stock equivalents if the inclusion of such common stock equivalents would be dilutive. Dilutive common stock equivalents potentially include warrants and share-based awards using the treasury stock method. In addition, the Company considers the potential dilutive impact of its preferred stock and convertible debt using the treasury stock and if-converted methods, if either is more dilutive than the two-class method. The two-class method was more dilutive for the year ended December 31, 2020.

	Years Ended	
	December 31, 2021	December 31, 2020
<b>Basic net (loss) income per common share calculation:</b>		
Net (loss) income attributable to common shareholders	\$ (10,456,870)	\$ 6,644,465
Less: undistributed earnings to participating securities	—	(5,573,558)
Net (loss) income attributable to common shareholders - basic	\$ (10,456,870)	\$ 1,070,907
Weighted average common shares outstanding - basic	2,833,674	348,368
Net (loss) income per share - basic	\$ (3.69)	\$ 3.07
<b>Diluted net (loss) income per common share calculation:</b>		
Net (loss) income attributable to common shareholders	\$ (10,456,870)	\$ 6,644,465
Less: undistributed earnings to participating securities	—	(5,573,558)
Less: change in fair value of convertible promissory notes and interest expense	—	(9,216,633)
Net (loss) income attributable to common shareholders – diluted	\$ (10,456,870)	\$ (8,145,726)
Weighted average common shares outstanding - basic	2,833,674	348,368
Convertible securities	—	1,706,507
Weighted average common shares outstanding - diluted	2,833,674	2,054,875
Net (loss) income per share - diluted	\$ (3.69)	\$ (3.96)

#### **Emerging Growth Company Status**

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act, until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

#### **Recently Adopted Accounting Pronouncements**

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options* (ASC 470-20) and *Derivatives and Hedging—Contracts in Entity’s Own Equity* (ASC 815-40) (“ASU 2020-06”). ASU 2020-06 eliminated the beneficial conversion (and cash conversion) accounting models in ASC 470-20 that require separate accounting for embedded conversion features and simplified the settlement assessment to determine whether it qualifies for equity classification by removing certain conditions in ASC 815-40-25. In addition, the new guidance requires entities to use the if-converted method to calculate earnings per share for all convertible instruments and to include the effect of share settlement for instruments that may be settled in cash or shares. The Company adopted this standard on January 1, 2021, and the adoption did not have a material impact on its financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. This guidance applies to all entities and aims to reduce the complexity of tax accounting standards while enhancing reporting disclosures. This guidance is effective for fiscal years beginning after December 15, 2020

and interim periods therein. Early adoption is permitted for any annual periods for which financial statements have not been issued and interim periods therein. The Company adopted this standard on January 1, 2021, and the adoption did not have a material impact on its related disclosures.

#### Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, in order to increase transparency and comparability among organizations by, among other provisions, recognizing lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous GAAP. In transition, entities may also elect a package of practical expedients that must be applied in its entirety to all leases commencing before the adoption date, unless the lease is modified, and permits entities to not reassess (a) the existence of a lease, (b) the lease classification or (c) the determination of initial direct costs, as of the adoption date, which effectively allows entities to carryforward accounting conclusions under previous GAAP. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which provides entities an optional transition method to apply the guidance under Topic 842 as of the adoption date, rather than as of the earliest period presented. The Company adopted this standard on January 1, 2022 and the adoption did not have a material impact on its consolidated financial statements due to the fact that the Company did not have any material long-term leasing arrangements as of the date of adoption.

#### (4) Fair Value Measurements

The Company utilizes a valuation hierarchy that prioritizes fair value measurements based on the types of inputs used for the various valuation techniques related to its financial assets and financial liabilities. The three levels of inputs used to measure fair value are described as follows:

Level 1 – Observable inputs such as quoted prices in active markets.

Level 2 – Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly.

Level 3 – Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

In accordance with the fair value hierarchy described above, the following table sets forth the Company’s assets and liabilities measured at fair value on a recurring basis:

	December 31, 2021			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Financial assets</b>				
Cash equivalents and restricted cash (Money Market Accounts)	\$ 49,051,061	\$ 49,051,061	\$ —	\$ —
December 31, 2020				
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Financial assets</b>				
Restricted cash (Money Market Account)	\$ 50,367	\$ 50,367	\$ —	\$ —
<b>Liabilities</b>				
Convertible Promissory Notes	\$ 5,829,292	\$ —	\$ —	\$ 5,829,292

As further described in Note 6, the Company issued convertible promissory notes from inception through April 2019 (the “Junior Convertible Notes”) to various investors and from October 2019 through March 2020, the Company issued convertible bridge notes to the Co-Founder and Chief Executive Officer (the “Convertible Bridge

Notes”). During April 2020, certain of the Junior Convertible Notes were converted into Senior Convertible Notes (the “Senior Convertible Notes”) (collectively, the “Convertible Promissory Notes”).

Due to the number of embedded provisions contained in the Convertible Promissory Notes and Convertible Bridge Notes, the fair value option, as prescribed by ASC 815, *Derivatives and Hedging*, was elected and applied to all Convertible Promissory Note and Convertible Bridge Note issuances since the Company’s inception in 2015, in connection with the preparation of these financial statements. The fair value of the Convertible Promissory Notes and Convertible Bridge Notes was determined using a scenario-based analysis that estimates the fair value based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the noteholders, including various IPO, settlement, equity financing, corporate transaction and dissolution scenarios.

The Company adjusted the carrying value of its Convertible Promissory Notes and Convertible Bridge Notes to their estimated fair value at each reporting date, with any related increases or decreases in the fair value recorded as change in fair value of convertible promissory notes in the consolidated statement of operations. The change in fair value of convertible promissory notes within the years ended December 31, 2021 and 2020 consolidated statement of operations also includes reversals of gains and losses previously recognized by the Company upon conversion of the notes (Note 6).

The fair value of the Senior Convertible Notes at December 31, 2020 was calculated using an option pricing model (“OPM”) framework and utilized the back-solve method for inferring and allocating the equity value predicated on the concurrent sale of Series A Stock. This method was selected as it was concluded that the sale of the Series A Stock was an arm’s-length transaction. Application of the OPM back-solve method involves making assumptions for the expected time to liquidity and volatility, and then solving for the value of equity such that value for the most recent financing equals the amount paid.

The following table presents a roll-forward of the aggregate fair values of the Company’s Convertible Promissory Notes (Note 6) for which fair value is determined by Level 3 inputs:

	2021	2020
Balance at beginning of year	\$ 5,829,292	\$ 21,842,931
Issuance of Convertible Bridge Notes	—	25,000
Fair value adjustments	(9,317)	(9,877,857)
Accrued interest	46,315	660,408
Conversion of Junior Convertible Notes into Series Seed Stock	—	(6,291,288)
Conversion of Senior and Convertible Bridge Notes into Series A Stock	(5,866,290)	(529,902)
Balance at end of year	<u>\$ —</u>	<u>\$ 5,829,292</u>

## (5) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2021	2020
Compensation and benefits	\$ 436,990	\$ —
Clinical trial expenses	339,072	126,173
Manufacturing development expenses	—	560,000
Professional fees	345,530	—
Other accrued expenses and other current liabilities	85,529	269,816
Total accrued expenses and other current liabilities	<u>\$ 1,207,121</u>	<u>\$ 955,989</u>

## (6) Convertible Promissory Notes

### *Junior Convertible Notes*

From inception through December 2018, the Company issued Junior Convertible Notes and demand notes that converted into Junior Convertible Notes which, due to certain embedded features within the Junior Convertible Notes, the Company elected to account for these notes and all their embedded features under the fair value option. All of the outstanding principal and accrued but unpaid interest associated with the Junior Convertible Notes converted into 2,615,553 shares of Series Seed Stock in May 2020, of which 840,363 shares were issued to the Company's Chief Executive Officer and an immediate family member ("Related Party"). At the time of conversion, the estimated fair value of the Junior Convertible Notes was \$6.3 million and was reclassified to Series Seed convertible preferred equity. In connection with the conversion in 2020, the Company recorded a non-cash credit of \$7.7 million related to the final decrease in fair value of the Junior Convertible Notes.

### *Convertible Bridge Notes*

From October 2019 through March 2020, the Company issued convertible bridge notes to the Related Party in the amount of \$0.5 million. On December 22, 2020, the outstanding principal and accrued but unpaid interest associated with the Convertible Bridge Notes converted into 78,178 Series A Stock.

Due to certain embedded features within the Convertible Bridge Notes, the Company elected to account for these notes and all their embedded features under the fair value option. At the time of conversion, the estimated fair value of the Convertible Bridge Notes was \$0.5 million and was reclassified to Series A convertible preferred equity. In connection with the conversion in December 2020, the Company recorded a non-cash credit of \$0.1 million related to the final decrease in fair value of the Convertible Bridge Notes. For the year ended December 31, 2020, the Company recognized approximately \$30,000 of interest expense in connection with the Convertible Bridge Notes.

### *Senior Convertible Notes*

In April 2020, \$5.1 million of principal and \$0.6 million of accrued interest related to certain Junior Convertible Notes were converted into Senior Convertible Notes. Of the Senior Convertible Notes issued in 2020, \$2.5 million of principal and \$0.4 million of accrued interest were issued to the Related Party. During the year ended December 31, 2021, the outstanding principal and accrued but unpaid interest associated with the Senior Convertible Notes converted into 844,824 shares of Series A Stock.

For the year ended December 31, 2020, the Company recognized a credit of \$2.1 million in the consolidated statement of operations related to decreases in the fair value of the Senior Convertible Notes. For the year ended December 31, 2020, the Company recognized \$0.3 million of interest expense in connection with the Senior Convertible Notes, including \$0.1 million payable to the Related Party.

### ***Paycheck Protection Program***

In May 2020, the Company entered into an original loan agreement with Pacific Western Bank as the lender (“Lender”) for a loan in an aggregate principal amount of \$0.1 million (the “Loan”) pursuant to the Paycheck Protection Program (the “PPP”) under the Coronavirus Aid, Relief, and Economic Security (CARES) Act and implemented by the U.S. Small Business Administration. In June 2020, the Paycheck Protection Program Flexibility Act was enacted, which among other things, extended the deferral period for loan payments to either (1) the date that Small Business Administration remits the borrower’s loan forgiveness amount to the lender or (2) if the borrower does not apply for loan forgiveness, 10 months after the end of the borrower’s loan forgiveness covered period. The Loan was set to mature in two years and bore interest at a rate of 1.0% per year, with all payments deferred through September 5, 2021.

The outstanding principal balance of the Loan of \$0.1 million was forgiven in July 2021 and was recognized as a gain on extinguishment of debt within other income in the consolidated statement of operations.

### **(7) Convertible Preferred Stock, Redeemable Common Stock and Common Stock**

In May 2020, the Company converted \$11.7 million of principal and interest related to certain Junior Convertible Notes into 2,615,553 shares of Series Seed Stock at prices ranging from \$4.28 to \$4.56 per share. In May 2020, the Related Party purchased 8,771 shares of Series Seed Stock at a price of \$5.70 per share for \$50,000.

Throughout 2020, the Company sold 132,537 shares of Series A Stock to the Related Party for \$7.168 per share for proceeds of \$1.0 million. The Company also issued 33,129 warrants to purchase common stock at an exercise price of \$7.168 per share to the Series A Stock holder as part of the Series A Stock financing.

In December 2020, \$0.6 million in principal and accrued interest related to the Convertible Bridge Notes were converted into 78,178 shares of Series A Stock. The Company also issued 19,544 warrants to purchase common stock at an exercise price of \$7.168 per share to the Series A stockholders as part of the conversion from Convertible Bridge Notes to Series A Stock.

In February, March and April 2021, the Company sold 738,445 shares of Series A Stock for \$7.168 per share for net proceeds of \$5.0 million. The Company also issued 184,597 warrants to purchase common stock at an exercise price of \$7.168 to the Series A stockholders as part of the Series A Stock financing. Additionally, the Company issued 24,134 warrants to purchase common stock at an exercise price of \$7.168 to placement agents as a part of the Series A Stock financing.

In February 2021, the Company converted \$6.1 million of principal and interest related to Senior Convertible Notes into 844,824 shares of Series A Stock at a price of \$7.168 per share. In addition, warrants with a fair value of \$0.1 million associated with the Senior Convertible Notes were reclassified into additional paid-in capital.

In October 2021, the Company completed its IPO in which the Company sold 5,750,000 shares at a public offering price of \$5.00 per share. Immediately prior to the completion of the IPO, all of the Company’s preferred stock and redeemable common stock converted into an aggregate of 4,853,533 shares of common stock and all of the outstanding warrants converted into 9,816 shares of common stock. The Company received net proceeds of \$24.4 million as a result of the offering. The Company issued 250,000 warrants to a placement agent as part of the offering with an exercise price of \$6.25 per shares and a term of 5.0 years.

In December 2021, the Company sold 5,000,000 shares of common stock together with warrants to purchase 5,000,000 shares of common stock and received net proceeds of \$28.9 million in a private placement. Each share of common stock and accompanying warrant were sold together at a combined offering price of \$6.25. The warrants



have a term of 5.5 years and an exercise price of \$6.25 per share. The Company also issued 250,000 warrants to a placement agent as part of the offering with an exercise price of \$6.25 per share and a term of 5.5 years.

#### **Warrants for Common Stock**

At December 31, 2021, the Company had the following warrants outstanding to acquire common stock:

	Outstanding	Exercise price	Expiration dates
Issued in connection with IPO	250,000	\$ 6.25	October 2026
Issued as part of December 2021 private placement	5,250,000	\$ 6.25	June 2027
	<u>5,500,000</u>		

During its evaluation of equity classification for the Company's common stock warrants issued in 2021, the Company considered the conditions as prescribed within ASC 815-40, *Derivatives and Hedging, Contracts in an Entity's own Equity*. The conditions within ASC 815-40 are not subject to a probability assessment. The warrants do not fall under the liability criteria within ASC 480, *Distinguishing Liabilities from Equity*, as they are not puttable and do not represent an instrument that has a redeemable underlying security. The warrants do meet the definition of a derivative instrument under ASC 815, but are eligible for the scope exception as they are indexed to the Company's own stock.

#### **Reverse Stock Split**

In June 2021, the Company effected a one-for-6 reverse stock split of its common stock and convertible preferred stock. No fractional shares were issued in connection with the reverse stock split. Any fractional share resulting from the reverse stock split was rounded down to the nearest whole share, and in lieu of any fractional shares, the Company paid in cash to the holders of such fractional shares an amount equal to the fair value, as determined by the board of directors, of such fractional shares. All common stock, convertible preferred stock, per share and related information presented in the consolidated financial statements and accompanying notes have been retroactively adjusted to reflect the reverse stock split.

#### **(8) Share-based Compensation**

In April 2021, Context Therapeutics Inc. adopted the 2021 Long-Term Incentive Plan ("2021 Incentive Plan"). Under the 2021 Incentive Plan, the Company can grant stock options, stock appreciation rights, restricted stock, restricted stock units and stock grants. The 2021 Incentive Plan allows for the issuance of up to 1,266,092 shares of common stock (the "Share Limit"). The Share Limit will automatically increase on January 1st of each year, during the term of the 2021 Incentive Plan, commencing on January 1 of the year following the year in which the effective date occurs, in an amount equal to four percent (4%) of the total number of shares of the Company's common stock outstanding on December 31st of the preceding calendar year; provided that the Board may determine that there will be no such increase or a smaller increase for any particular year. As of December 31, 2021, 742,706 shares remained available for future grants.

#### **Stock Grants**

During the year ended December 31, 2020, the Company issued 7,512 shares of common stock to members of the board of managers as compensation for their services. The Company recorded share-based compensation expense of \$0.1 million in general and administrative expense during the year ended December 31, 2020.

#### **Stock Options**

Stock options generally vest over a period of one to four years, and stock options that lapse or are forfeited are available to be granted again. The contractual life of all stock options is 10 years. The expiration dates of the outstanding stock options range from January 2028 to November 2031.

The Company measures stock options at their grant-date fair value and records compensation expense on a straight-line basis over the service period of the awards. Stock option compensation expense is allocated to

employees and consultants based on their respective departments. All board of directors' compensation is charged to general and administrative expense.

The Company recorded stock option compensation expense of \$74,000 and \$404,000 in research and development and general and administrative expense, respectively, during the year ended December 31, 2021. The Company recorded stock option compensation expense of \$75,000 and \$29,000 in research and development and general and administrative expense, respectively, during the year ended December 31, 2020.

The weighted average assumptions used in the Black-Scholes option pricing model to determine the fair value of stock option awards granted to employees during 2021 and 2020 were as follows:

	2021	2020
Expected stock price volatility	97.06%	97.86%
Risk free interest rate	1.07%	0.51%
Expected term (in years)	5.78	5.44
Expected dividend yield	—	—

The following table summarizes the stock option activity for the periods presented:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)
Outstanding at January 1, 2020	10,414	\$ 20.67	8.2
Granted	14,416	\$ 15.79	
Outstanding at December 31, 2020	24,830	\$ 17.84	8.4
Granted	481,861	\$ 5.05	
Outstanding at December 31, 2021	506,691	\$ 5.68	9.3
Vested and exercisable at December 31, 2021	130,059	\$ 7.30	9.0
Vested and expected to vest at December 31, 2021	506,691	\$ 5.68	9.3

The weighted average fair value of share-based awards granted during the years ended December 31, 2021 and 2020 was \$3.84 and \$9.34, respectively. The aggregate intrinsic value of the options outstanding and exercisable as of December 31, 2021 was \$0. As of December 31, 2021, the unrecognized compensation cost related to outstanding stock options was \$1.5 million and is expected to be recognized as expense over a weighted-average period of approximately 1.73 years.

### **Restricted Stock Units**

The Company issues restricted stock units ("RSU") to employees and consultants that generally vest monthly over one to three-year periods. The fair value of an RSU is equal to the fair market value price of the Company's common stock on the date of grant. RSU expense is amortized straight-line over the service period.

The following table summarizes activity related to RSU share-based payment awards:

	Number of RSUs	Weighted Average Grant Date Fair value
Unvested balance at January 1, 2020	—	
Granted	177	\$ 13.55
Vested	(132)	\$ 13.55
Unvested balance at December 31, 2020	45	\$ 13.55
Granted	50,096	\$ 1.74
Vested	(20,915)	\$ 1.77
Cancelled	(29,226)	\$ 1.74
Unvested balance at December 31, 2021	—	

The Company recorded share-based compensation expense of \$33,000 in research and development expense for the year ended December 31, 2021 related to RSUs. The Company recorded share-based compensation expense of \$2,000 in general and administrative expense for the year ended December 31, 2020 related to RSUs. As of December 31, 2021, there was no remaining unrecognized expense related to RSUs.

## (9) Commitments and Contingencies

### *Patent License Agreement with Drexel University*

In November 2015, the Company entered into a patent license agreement, as amended, (the “Drexel License Agreement”) with Drexel for license rights to patents for certain intellectual property and know-how related to certain technology.

As part of the Drexel License Agreement, the Company issued Drexel 16,666 shares of common stock. In partial consideration of the Drexel License Agreement, the Company is required to pay to Drexel certain milestone payments, ranging from \$10,000 to \$0.2 million on the achievement of certain milestone events for each licensed product.

The Company has agreed to pay Drexel a royalty in the low single digits of net sales for each licensed product on a country-by-country, licensed product-by-licensed product basis on issued or pending valid claims. The Company may credit against amounts payable to Drexel, on a country-by-country, licensed product-by-licensed product basis up to 50% of any third-party payments which the Company must make on account of third-party license agreements.

In partial consideration of the Drexel License Agreement, the Company will pay to Drexel a de-escalating sublicense fee on a quarterly basis of a high single-digit percentage that decreases to a mid-single digit percentage as time passes. In addition, the Company will make payments of the fair market value of all other consideration received by the Company from sublicensees during the quarter, other than: (a) royalties paid to the Company by a sublicensee based upon sales or net sales by the sublicensee; (b) equity investments in the Company by a sublicensee up to the amount of fair market value of the equity purchased on the date of the investment; (c) loan proceeds paid to the Company by a sublicensee in an arm’s length, full recourse debt financing to the extent that such loan is not forgiven; and (d) sponsored research funding, paid to the Company by a sublicensee in a bona fide transaction for future research to be performed by the Company.

As part of a strategic review of its pipeline, the Company recently notified Drexel that it is terminating the Drexel License Agreement, effective as of April 27, 2022.

### *Collaboration Agreement with Tyligand Bioscience*

In March 2020, the Company entered into a license (the “Tyligand License Agreement”) and process development agreement (the “Tyligand Process Development Agreement”) (collectively, the “Tyligand

Agreements”) with Tyligand Bioscience (Shanghai) Limited (“Tyligand”) for the development, manufacturing, registration and future commercialization of onapristone extended release (“ONA-XR”).

Under the terms of the Tyligand Agreements, Tyligand will be solely responsible for the design and optimization of an improved manufacturing process for ONA-XR. Upon completion of specific performance-based milestones, Tyligand will be granted the exclusive right to ONA-XR and will be solely responsible for the development and commercialization of ONA-XR in China, Hong Kong and Macau (the “Territory”). The Company will retain rest of world rights to commercialize ONA-XR.

Under the Tyligand Process Development Agreement, the Company is obligated to pay Tyligand \$0.8 million and a certain number of warrants exercisable for common stock upon successful completion of the manufacturing development plan, \$2.0 million upon the completion of scale-up of the first cumulative 100 kilograms of the GMP-grade compound and \$3.0 million upon the Company’s completion of scale-up of the first cumulative 300 kilograms of the GMP-grade compound. In consideration of and upon Tyligand’s successful completion of the development plan, within 30 days at the end of each calendar quarter, the Company shall pay Tyligand 1% of net sales of finished product utilizing the compound substantially manufactured in accordance with the process and specifications outlined in the Tyligand Process Development Agreement.

Per the Tyligand License Agreement, Tyligand shall pay the Company a non-refundable, non-creditable royalty at a rate in the mid-single digits of the net sales of each product in the Territory in each calendar quarter commencing with the first commercial sale of such product in the field in the Territory and ending upon the latest of (i) the sale of a generic product in the territory and (ii) 15 years after the date of the first commercial sale of product in the territory.

In August 2021, upon successful completion of the process development plan with Tyligand, the Company issued Tyligand warrants to purchase 111,576 shares of common stock at an exercise price of \$7.17 per share all of which were cancelled in connection with the IPO. The Company recognized an expense and liability of \$0.4 million to account for the fair value of the warrants upon completion of the manufacturing development plan in June 2021. Upon issuance of the warrants in August 2021, the Company reclassified the \$0.4 million liability into equity. The Company has expensed \$0.8 million related to the process development plan as of December 31, 2021.

Additionally, while the Company’s license agreement with Tyligand was signed in March 2020, the parties acknowledged that such signature was premature since the ‘successful completion’ under the process development agreement had not yet occurred, and as such, the parties properly executed the license agreement upon such successful completion in August 2021.

#### ***Collaboration and Licensing Agreement with Integral Molecular***

In April 2021, the Company entered into a collaboration and licensing agreement with Integral Molecular, Inc. (“Integral”) for the development of an anti-claudin 6 (“CLDN6”) bispecific monoclonal antibody (“BsMAb”) for gynecologic cancer therapy. Under the terms of the agreement, Integral and the Company will develop CLDN6 bispecific antibodies that trigger the activation of T cells and eliminate cancer cells displaying CLND6. The Company will conduct preclinical and all clinical development, as well as regulatory and commercial activities through exclusive worldwide rights to develop and commercialize the novel CLDN6 candidates. The Company paid an upfront license fee of \$0.3 million and granted 418,559 shares of Series A Stock with a fair market value of approximately \$2.8 million, and these costs were expensed to acquired in-process research and development during the year ended December 31, 2021. As a part of the agreement, Integral will be eligible to receive development and regulatory milestone payments totaling up to \$55.3 million, sales milestone payments totaling up to \$130 million, and tiered royalties of up to 12% of net sales of certain products developed under this agreement.

#### ***Operating Leases***

During 2021, the Company leased its corporate offices in Philadelphia, Pennsylvania under a month-to-month lease arrangement. The Company recorded rent expense of approximately \$10,000 for the years ended December 31, 2021 and 2020.

In January 2022, the Company entered into a noncancellable operating sublease for corporate office space in Philadelphia, Pennsylvania. The sublease for this space commenced on February 1, 2022 and is set to expire on July 30, 2023. The minimum lease payments under the sublease is \$0.1 million.

### **Litigation**

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. The Company believes no matters existed at either December 31, 2021 or 2020 that will have a material impact to the Company's financial position, results of operations or cash flows.

### **(10) Income Taxes**

The Company had no income tax expense due to operating losses incurred for the years ended December 31, 2021 and 2020. The Company had also not recorded any income tax benefits for the net operating losses incurred in each period due to its uncertainty of realizing a benefit from those items. All of the Company's losses before income taxes were generated in the United States.

The tax effects of temporary differences that gave rise to significant portions of the deferred tax assets and liabilities were as follows:

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	\$ 4,983,415	\$ 3,199,412
Research and development credits	421,880	326,551
Share-based compensation	249,874	43,526
Other accruals	147,659	—
Gross deferred tax assets	5,802,828	3,569,489
Deferred tax liabilities:		
Prepaid expenses	(527,181)	—
Net deferred tax assets	5,275,647	3,569,489
Less: valuation allowance	(5,275,647)	(3,569,489)
	<u>\$ —</u>	<u>\$ —</u>

In assessing the need for a valuation allowance, management must determine that there will be sufficient taxable income to allow for the realization of deferred tax assets. Based upon the historical and anticipated future losses, management has determined that the deferred tax assets do not meet the more likely than not threshold for realizability. Accordingly, a full valuation allowance has been recorded against the Company's net deferred tax assets as of December 31, 2021 and 2020. The valuation allowance increased by \$1.7 million and \$0.2 million during the years ended December 31, 2021 and 2020, respectively.

A reconciliation of the federal income tax rate to the Company's effective tax rate is as follows:

	Year ended December 31,	
	2021	2020
Federal tax expense/(benefit) at statutory rate	21.0 %	21.0 %
State tax, net of federal benefit	2.5	11.8
Non-taxable partnership income	(7.5)	(25.5)
Permanent differences	(0.5)	(9.2)
Research and development	0.9	(1.2)
Other	(0.1)	—
Change in valuation allowance	(16.3)	3.1
	— %	— %

The following table summarizes carryforwards of federal, state and local net operating losses ("NOL") and research tax credits:

	December 31,	
	2021	2020
NOL carryforwards—Federal	\$ 14,887,383	\$ 8,030,123
NOL carryforwards—State	14,887,383	8,030,123
NOL carryforwards—Local	13,926,879	15,399,777
Research tax credits—Federal	421,880	326,551

The NOL carryforwards begin expiring in 2037 for federal and state income tax purposes; however, all federal NOL carryforwards generated subsequent to January 1, 2018, are able to be carried forward indefinitely. Local NOL carryforwards expire after three years with the 2019 NOL set to expire in 2022. As of December 31, 2021 and 2020, the Company had federal research and development tax credit carryforwards of \$0.4 million and \$0.3 million, respectively, that will begin to expire in 2037, unless previously utilized.

The NOL and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. To date, the Company has not performed an analysis to determine whether or not ownership changes have occurred since inception. State and local NOLs may also be limited.

As of December 31, 2021 and 2020, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's consolidated statement of operations. Due to NOLs and tax credit carry forwards that remain unutilized, income tax returns for tax years from all years remain subject to examination by the taxing jurisdictions. The NOL carryforwards remain subject to review until utilized.

#### **(11) Related Party Transactions**

Since inception through December 31, 2021, the Company entered into various convertible note agreements with the Related Party. The terms of the convertible notes and their subsequent conversions are further described in more detail in Note 6 and Note 7.

**(12) Subsequent Events**

In March 2022, the Company issued 360,000 warrants to purchase common stock with an exercise price of \$10.00 per share and a term of 5.76 years as compensation for professional consulting services performed in 2021. The estimated fair value of the warrants of \$0.3 million was recorded in general and administrative expense on the consolidated statement of operations for the year ended December 31, 2021.

## **Item 9. Changes in and Disagreements With Accountants**

None.

## **Item 9A. Controls and Procedures**

We have established disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the principal executive officer (our Chief Executive Officer) and principal financial officer (our Chief Financial Officer), to allow timely decisions regarding required disclosure. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

### ***Evaluation of Disclosure Controls and Procedures***

Our management has evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2021, our disclosure controls and procedures were effective.

### **Internal Control over Financial Reporting**

#### ***Management's Report on Internal Control over Financial Reporting***

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by the rules of the SEC for newly public companies.

#### ***Attestation Report of the Registered Public Accounting Firm***

This annual report does not include an attestation report of our registered public accounting firm due to an exemption provided by the JOBS Act for "emerging growth companies."

#### ***Changes in Internal Control Over Financial Reporting***

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended December 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, except as follows:

#### ***Material Weaknesses Remediation***

As previously reported, management recognized that the Company had material weaknesses in its internal control over financial reporting as of December 31, 2020. The material weaknesses that we and our independent registered public accounting firm identified related to the lack of an appropriate review of the internally prepared financial statements which resulted in the Company's failure to timely detect and correct certain misstatements within the consolidated financial statements. We also identified a material weakness as it relates to a lack of adequate segregation of accounting functions.



Management determined that the deficiencies, evaluated in the aggregate, could have potentially resulted in a material misstatement of the financial statements in a future annual or interim period that would not be prevented or detected. Therefore, the deficiencies constituted material weaknesses in internal control.

We initiated several steps to evaluate and implement measures designed to improve our internal control over financial reporting in order to remediate the control deficiencies noted above. These steps include hiring a Chief Financial Officer and a Controller who are responsible for the preparation and review of the Company's financial statements and related disclosures. In addition, we enhanced our reporting process thereby reducing the risk of undetected errors by (i) implementing a quarterly financial statement close process that includes formal reviews of financial statement account balances and journal entries, and (ii) creating a disclosure committee consisting of key executives and accounting personnel who review the Company's financial statements and related disclosures on a quarterly basis.

As a result of these efforts, the Company determined that the material weaknesses were remediated as of December 31, 2021.

**Item 9B. Other Information**

Not applicable.

**Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections**

Not applicable.

## **PART III.**

### **Item 10. Directors, Executive Officers and Corporate Governance**

The information required by this item is incorporated by reference to our Proxy Statement for our 2022 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2021.

As part of our system of corporate governance, our board of directors has adopted a code of business conduct and ethics. The code applies to all of our employees, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions), contractors, consultants and agents and representatives, including our independent directors and consultants, who are not employees of ours, with regard to their Company-related activities. Our code of business conduct and ethics is available on our website at [www.contexttherapeutics.com](http://www.contexttherapeutics.com) within the “Investors & News — Governance” section. We intend to post on this section of our website any amendment to our code of business conduct and ethics, as well as any waivers of our code of business conduct and ethics, that are required to be disclosed by the rules of the SEC or the Nasdaq Stock Market.

### **Item 11. Executive Compensation**

The information required by this item is incorporated by reference to our Proxy Statement for our 2022 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2021.

### **Item 12. Security Ownership of Certain Beneficial Owner and Management and Related Stockholder Matters**

The information required by this item is incorporated by reference to our Proxy Statement for our 2022 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2021.

### **Item 13. Certain Relationships and Related Transactions, and Director Independence**

The information required by this item is incorporated by reference to our Proxy Statement for our 2022 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2021.

### **Item 14. Principal Accounting Fees and Services**

The information required by this item is incorporated by reference to our Proxy Statement for our 2022 Annual Meeting of Shareholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2021.

## PART IV.

### Item 15. Exhibits and Financial Statement Schedules

We have filed the following documents as part of this Annual Report:

#### (a)(1) Financial Statements

The financial statements are included in Item 8. “Financial Statements and Supplementary Data.”

#### (a)(2) Financial Statement Schedules

All schedules are omitted as information required is inapplicable or the information is presented in the financial statements and the related notes.

(a)(3) The exhibits listed under Item 15(b), which are incorporated herein by reference, are filed or furnished as part of this report or are incorporated into this report by reference.

#### (b) Exhibits.

Exhibit No.	Description of Exhibit
3.1	<a href="#">Amended &amp; Restated Certificate of Incorporation of Context Therapeutics Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-40654), as filed with the SEC on October 22, 2021).</a>
3.2	<a href="#">Amended &amp; Restated Bylaws of Context Therapeutics Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-40654), as filed with the SEC on October 22, 2021).</a>
4.1	<a href="#">Form of Stock Certificate of Common Stock (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-256572), as filed with the SEC on May 27, 2021).</a>
4.2	<a href="#">Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-40654), as filed with the SEC on December 2, 2021).</a>
10.1#	<a href="#">Research Collaboration and License Agreement, dated April 6, 2021, between Context Therapeutics LLC and Integral Molecular, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-256572), as filed with the SEC on May 27, 2021).</a>
10.2#	<a href="#">Process Development Agreement, dated March 6, 2020, between Context Therapeutics LLC and Tyligand Bioscience (Shanghai) Limited (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1 (File No. 333-256572), as filed with the SEC on May 27, 2021).</a>
10.3#	<a href="#">Amendment No. 1 to Process Development Agreement, dated April 21, 2021, between Context Therapeutics LLC and Tyligand Bioscience (Shanghai) Limited (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-256572), as filed with the SEC on May 27, 2021).</a>
10.4	<a href="#">Amendment No. 2 to Process Development Agreement, dated June 3, 2021, between Context Therapeutics LLC and Tyligand Bioscience (Shanghai) Limited (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1/A (File No. 333-256572), as filed with the SEC on June 16, 2021).</a>
10.5#	<a href="#">License Agreement, dated August 23, 2021, between Context Therapeutics LLC and Tyligand Bioscience (Shanghai) Limited (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1/A (File No. 333-256572), as filed with the SEC on September 13, 2021).</a>
10.6†	<a href="#">Context Therapeutics LLC 2015 Option Plan (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-256572), as filed with the SEC on May 27, 2021).</a>

Exhibit No.	Description of Exhibit
10.7†	<a href="#">Context Therapeutics Inc. 2021 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-256572), as filed with the SEC on May 27, 2021).</a>
10.8†	<a href="#">Form of Stock Option Agreement under the Context Therapeutics Inc. 2021 Incentive Award Plan (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 (File No. 333-256572), as filed with the SEC on May 27, 2021).</a>
10.9†	<a href="#">Form of Stock Grant Agreement under the Context Therapeutics Inc. 2021 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 (File No. 333-256572), as filed with the SEC on May 27, 2021).</a>
10.10†	<a href="#">Form of Indemnification Agreement between Context Therapeutics Inc. and its officers and directors (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1/A (File No. 333-256572), as filed with the SEC on June 16, 2021).</a>
10.11#†	<a href="#">Consulting Agreement, dated May 7, 2021, between OncoStrategy, LLC and Context Therapeutics Inc. (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1 (File No. 333-256572), as filed with the SEC on May 27, 2021).</a>
10.12†	<a href="#">Form of Director Services Agreement (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 (File No. 333-256572), as filed with the SEC on May 27, 2021).</a>
10.13†	<a href="#">Amended and Restated Employment Agreement, dated October 22, 2021, between Context Therapeutics Inc. and Martin Lehr (incorporated by reference to the Company's Current Report on Form 8-K (File No. 001-40654), as filed with the SEC on October 22, 2021).</a>
10.14†	<a href="#">Employment Agreement, dated November 1, 2021, between Context Therapeutics Inc. and Jennifer Minai-Azary (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-40654), as filed with the SEC on November 1, 2021).</a>
10.15	<a href="#">Securities Purchase Agreement, dated December 1, 2021, by and between Context Therapeutics Inc. and the purchasers named therein (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q (File No. 001-40654), as filed with the SEC on December 2, 2021).</a>
10.16	<a href="#">Registration Rights Agreement, dated December 1, 2021, by and between Context Therapeutics Inc. and the purchasers named therein (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q (File No. 001-40654), as filed with the SEC on December 2, 2021).</a>
10.17*†	<a href="#">Employment Agreement, dated October 22, 2021, between Context Therapeutics Inc. and Alex Levit.</a>
10.18*†	<a href="#">Amendment No. 1 to Consulting Agreement, dated March 21, 2022, between OncoStrategy, LLC and Context Therapeutics Inc.</a>
21.1	<a href="#">Subsidiaries of the Company (incorporated by reference to Exhibit 21.1 to the Company's Registration Statement on Form S-1 (File No. 333-256572), as filed with the SEC on May 27, 2021).</a>
23.1*	<a href="#">Consent of CohnReznick LLP.</a>
31.1*	<a href="#">Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.</a>
31.2*	<a href="#">Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.</a>
32.1*+	<a href="#">Certification Pursuant to 18 U.S.C. Section 1350 of principal executive officer and principal financial officer.</a>
101	The following financial statements from Context Therapeutics Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2021, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets; (ii) Consolidated Statements of Operations; (iii) Consolidated Statements of Changes in Convertible Preferred Stock, Redeemable Common Stock and Stockholders' Deficit; (iv) Consolidated Statements of Cash Flows; and (v) Notes to the Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

---

\* Filed herewith

† Executive Compensation Plan or Agreement

# Certain information has been excluded from the exhibit because it both (i) is not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.

+ This certification is being furnished pursuant to 18 U.S.C. Section 1350 and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof.

**Item 16. Form 10-K Summary**

Not applicable.



## EMPLOYMENT AGREEMENT

This EMPLOYMENT AGREEMENT (“**Agreement**”) is made and entered into effective as of this 22<sup>nd</sup> day of October, 2021 (“**Effective Date**”) by and between Context Therapeutics Inc. (the “**Company**”) and Alex Levit (“**Executive**”). The Company and Executive are each referred to herein as a “**Party**” or together as the “**Parties.**” Capitalized words not immediately defined shall have the meaning in the “Definitions” Section below.

NOW, THEREFORE, in consideration of the mutual covenants contained and incorporated herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby expressly covenant and agree as follows:

**1. Employment Period.** The Company shall employ Executive pursuant to this Agreement beginning on the Effective Date and continuing until such employment is terminated pursuant to Section 4 below (the “**Employment Period**”). During the Employment Period, Executive shall remain in the employ of the Company and provide services to the Company in accordance with the terms of this Agreement.

**2. Position and Duties.**

**(a)** The Company shall employ Executive during the Employment Period as its Chief Legal Officer & Corporate Secretary (“**Executive Officer**”). During the Employment Period, Executive shall devote his full business time, energy, and talent to serving as Executive Officer of the Company, subject to the direction of the Company’s Chief Executive Officer (the “**CEO**”), board of directors (the “**Board**”) or the compensation committee of the Board (the “**Compensation Committee**”).

**(b)** Executive shall have the duties and responsibilities that are commensurate with his position as Executive Officer and any other or different duties that may be assigned to Executive by the CEO, Board or the Compensation Committee, and Executive shall perform all such duties faithfully and efficiently in compliance with applicable law and the policies of the Company, as such policies may be in effect from time to time. Executive shall have such authority and powers as are inherent to the undertakings applicable to Executive’s position and necessary to carry out the duties required of Executive hereunder.

**(c)** Executive’s principal place of business shall be at the Company’s corporate headquarters; however, it is understood that Executive may be required to travel both domestically and internationally in fulfillment of his duties as set forth herein.

**(d)** Notwithstanding the foregoing provisions of this **Section 2**, during the Employment Period, Executive may devote reasonable time to activities other than those required under this Agreement, including activities of a charitable, educational, religious, or similar nature to the extent such activities do not, in the judgment of the CEO or the Board, inhibit, prohibit, interfere with, or conflict with Executive’s duties under this Agreement or conflict in any material way with the business of the Company or any Affiliate; *provided, however*, that Executive shall not serve on the board of directors of any business (other than the Company or an Affiliate, or Strados Labs, Inc.) or hold any other position with any business without receiving the prior written consent of the CEO or the Board.



3. **Compensation and Benefits.** During the Employment Period, the Company shall compensate Executive for Executive's services as follows:

(a) Executive shall be paid a base salary at an annual rate of \$350,000 (the "**Annual Base Salary**"), which shall be payable in accordance with the normal payroll practices of the Company then in effect. The Executive's Annual Base Salary may be increased annually by the Compensation Committee beginning in the first calendar quarter of 2022; *provided* that the decision whether to increase the Executive's Annual Base Salary and by what amount, if any, shall be made in the good faith discretion of the Compensation Committee.

(b) Executive shall be eligible to receive performance-based annual incentive bonuses (each, an "**Incentive Bonus**") from the Company for each fiscal year ending during the Employment Period. Incentive Bonuses shall be as determined in the discretion of the Compensation Committee, or as may be pursuant to a new annual incentive plan as may be adopted and in effect from time to time, with any applicable performance metrics and goals to be established by the Compensation Committee, after consultation with Executive. Executive's initial target Incentive Bonus shall be 40% of Annual Base Salary ("**Target Bonus**"), which Target Bonus may be increased annually by the Compensation Committee beginning in the first calendar quarter of 2022; *provided* that the decision whether to increase the percentage of the Target Bonus and by what amount, if any, shall be made in the good faith discretion of the Compensation Committee. The actual amount of the Executive's Incentive Bonus, if any, shall be determined in the good faith discretion of the Compensation Committee, subject to the terms of any applicable incentive compensation plan that may be in effect from time to time. Notwithstanding the Effective Date of this Agreement being during the 2021 calendar year, the Executive's Incentive Bonus for 2021, if any, shall be based on the full 2021 calendar year. Except as otherwise provided herein, as may be provided by the Compensation Committee or as may otherwise be set forth in any applicable incentive compensation plan, the Executive must be employed by the Company on the day such Incentive Bonus is paid in order to earn or receive such Incentive Bonus. The Incentive Bonus, if any, will be paid to Executive during the period from January 1 through March 15 of the calendar year following the calendar year to which it relates.

(c) Executive and Company acknowledge that Executive received stock options (the "**Options**") intended to represent 0.75% (the "**Target Equity Percentage**") of the Company's common stock on a fully diluted basis as of the date the Options were granted. The Options will vest in substantially equal installments of 1/36 on the last day of each of the 36 months immediately following the respective grant date, subject to Executive's continuous service to the Company through each such date. Upon a Qualifying Financing, the Compensation Committee shall in good faith consider making an additional award of stock options in such amount necessary to maintain Executive's Target Equity Percentage. The Options will be subject to the terms and conditions of the Company's equity incentive plan under which such Options have been granted (attached hereto as Exhibit B), and the Option Agreement (as attached hereto as Exhibit C).

(d) Executive shall be eligible to participate, subject to the terms thereof, in all incentive plans of the Company as may be in effect from time to time with respect to senior executives employed by the Company in the United States, on as favorable a basis as other similarly situated and performing executives.

(e) Executive shall be eligible to participate, subject to the terms thereof, in all employee benefit plans (including pension, 401(k) and welfare benefit plans) available to the Company's executive employees, subject to the terms and conditions of such benefit plans as in effect from time to time. If the Company does not have in place a medical, vision and dental

insurance program, Company shall pay to Executive a monthly amount for Executive to purchase coverage in such amounts and on such terms as Executive and Company may agree.

(f) Executive shall be entitled to accrue paid time off and holidays in accordance with and subject to the Company's paid time off programs and policies relating to its employees in the United States as may be in effect from time to time, *provided* that Executive shall be entitled to a minimum of 20 days of paid time off per calendar year.

(g) Executive shall be reimbursed by the Company for all reasonable out-of-pocket expenses for entertainment, travel, meals, lodging, and similar items that are consistent with the Company's expense reimbursement policy and that are actually incurred by Executive in the promotion of the Company's business.

4. **Termination.** Executive's employment relationship with the Company shall be at-will. Either Party may terminate Executive's employment at any time, with or without Cause or Good Reason, for any or no reason (such date of termination, for any reason, the "**Termination Date**").

(a) **Minimum Benefits upon Termination.** Upon termination of Executive's employment by the Company for any reason, Executive shall be entitled, in addition to any other benefits to which Executive may be entitled under the following provisions of this **Section 4** or the express terms of any employee benefit plan or as required by law, to the following (together, the "**Accrued Benefits**"):

(i) Executive's earned but unpaid Annual Base Salary for the period ending on the Termination Date;

(ii) Executive's earned but unpaid Incentive Bonus, if any, for any completed fiscal year preceding the Termination Date; *provided, however*, that Executive shall not be entitled to any Incentive Bonus in the event of a Termination for Cause if the events giving rise to the Termination for Cause occurred in such prior fiscal year;

(iii) Executive's accrued but unpaid paid time off;

(iv) Executive's unreimbursed business expenses through and including the Termination Date, *provided* that all required submissions for expense reimbursement are made in accordance with the Company's expense reimbursement policy and within 45 days following the Termination Date; and

(v) The benefits, incentives, and awards described in **Section 4(h)(i)**.

Any benefits to be provided to Executive pursuant to this **Section 4(a)** shall be provided within 30 days after the Termination Date (except that payments under Section 4(a)(iv) shall be made within 30 days following submission for reimbursement); *provided, however*, that any benefits, incentives, or awards payable as described in **Section 4(h)(i)** shall be provided in accordance with the terms of the applicable plan, program, or arrangement. Except as may expressly be provided to the contrary in this Agreement, nothing in this Agreement shall be construed as requiring Executive to be treated as employed by the Company or any Affiliate following the Termination Date for purposes of any plan, program, or arrangement.

(b) **Termination for Death or Disability.** Executive's employment shall terminate automatically upon his death. The Company shall be entitled to terminate the employment of Executive upon Executive's Disability by giving written notice to Executive, in which event the date that the Company gives such notice shall be deemed the Termination Date.

Upon a Termination due to Executive's death or Disability, Executive (or Executive's estate, if applicable) shall be entitled to the following:

(i) The Accrued Benefits;

(ii) A payment, payable on the 45<sup>th</sup> day following the Termination Date, equal to the Target Bonus for the fiscal year in which the Termination Date occurs, prorated on a per diem basis for the number of days employed during such fiscal year prior to the Termination Date, divided by 365 (a "**Pro-Rated Bonus**");

(iii) All unvested Options and any other unvested incentive equity awards then held by Executive that are scheduled to vest within twelve (12) months after the Termination Date shall immediately vest; and

(iv) The continuation of benefits as provided in **Section 4(g)**, provided such benefit shall only be for a maximum period of twelve (12) months.

**(c) Termination by Executive for Good Reason or by Company Without Cause.** Executive shall be entitled to terminate his employment for Good Reason by giving at least 10 days', but not more than 30 days', prior written notice of termination to the Company, in which event the date specified in the notice of termination shall be deemed the Termination Date; *provided, however*, that (A) prior to giving such notice of Termination for Good Reason, Executive must give the Company written notice of the existence of any condition giving rise to Good Reason within 30 days of its initial existence and the Company shall have 30 days from the date of such notice in which to cure the condition giving rise to Good Reason, if curable, and if, during such 30-day period, the Company cures the condition giving rise to Good Reason, such condition shall not constitute Good Reason and (B) any Termination for Good Reason must occur within six months of the initial existence of the condition constituting Good Reason. The Company shall be entitled to terminate Executive's employment for any reason that does not constitute Cause, or no reason, by giving at least 10 days' prior written notice to Executive, in which event the date specified in the notice of termination shall be deemed the Termination Date. Upon a Termination by Executive for Good Reason or a Termination by the Company without Cause, Executive shall be entitled to the following:

(i) The Accrued Benefits;

(ii) Payment in an amount equal to 75% of Executive's Annual Base Salary in effect on the Termination Date, paid ratably over a period of nine (9) months in accordance with the Company's regular payroll cycle;

(iii) All unvested Options and any other unvested incentive equity awards then held by Executive that are scheduled to vest within twelve (12) months after the Termination Date shall immediately vest; and

(iv) The continuation of benefits as provided in **Section 4(g)**.

**(d) Termination Upon a Change in Control.** Notwithstanding Section 4(c) above, and in lieu of any payment owed under Section 4(c), if any, in the event that the Company (or its successor) terminates the Executive without Cause or the Executive resigns from employment with the Company for Good Reason, in each case upon a Change of Control (as such terms are defined below) or within the twelve (12) month period following the Change in Control, then Executive shall be entitled to the following:

(i) The Accrued Benefits;

(ii) Payment in an amount equal to the sum of (x) 100% of Executive's Annual Base Salary in effect on the Termination Date, and (y) 100% of the Target Bonus for the fiscal year in which the Termination Date occurs, paid ratably over a period of twelve (12) months in accordance with the Company's regular payroll cycle;

(iii) All unvested Options and any other unvested incentive equity awards then held by Executive that are scheduled to vest after the Termination Date shall immediately vest and become immediately exercisable on the Termination Date; and

(iv) The continuation of benefits as provided in **Section 4(g)**.

(e) **Termination for Cause.** The Company shall be entitled to terminate Executive's employment for Cause by giving written notice of termination to Executive, in which event the date that the Company gives such notice shall be deemed the Termination Date; *provided, however*, that with respect to clauses (iii) or (iv) of the definition of Cause set forth below, to the extent curable, Executive shall be entitled to at least 30 days' prior written notice of the Company's intention to terminate Executive's employment for Cause, which notice shall specify the grounds for Cause; and Executive shall be provided a reasonable opportunity to cure any conduct or act, if curable, alleged as grounds for Cause, and a reasonable opportunity to present to the Board Executive's position regarding any dispute relating to the existence of any grounds for Cause. Further, all rights Executive has or may have under this Agreement shall be suspended automatically during (i) the pendency of any investigation by the Board or the Compensation Committee, or (ii) any negotiations between the Board and Executive regarding any actual or alleged act or omission by Executive of the type that would warrant a Termination for Cause and any such suspension shall not give rise to a claim of Good Reason by Executive. Upon a Termination for Cause, Executive shall only be entitled to the Accrued Benefits, and all vested and unvested Options and any other incentive equity awards then held by Executive shall immediately be forfeited and expire on the Termination Date.

(f) **Termination due to Voluntary Resignation.** Executive shall be entitled to terminate his employment without Good Reason by giving at least 30 days' prior written notice to the Company, in which event the date that is 30 days after the date that Executive gives such notice shall be deemed to be the Termination Date. Upon a Termination by Executive without Good Reason, Executive shall only be entitled to the Accrued Benefits, and all unvested Options and other unvested incentive equity awards then held by Executive shall immediately expire on the Termination Date.

(g) **Medical, Vision and Dental Benefits.** If Executive's employment is terminated pursuant to **Section 4(b)**, **4(c)** or **4(d)** above, then, to the extent that Executive or any of Executive's dependents may be covered under the terms of any medical, vision or dental plans of the Company (or an Affiliate) for active employees immediately prior to the Termination Date and provided Executive is eligible for and elects to continue coverage (under the health care continuation rules of COBRA, *provided that* if, on the Termination Date, the Company is not subject to COBRA, the Company shall provide for continuation coverage as if it were subject to COBRA for the entire period to which COBRA would have applied if the Company had been subject to COBRA (collectively for purposes of this Agreement, "**COBRA**")), the Company shall provide Executive and those dependents with coverage equivalent to the coverage in effect immediately prior to the applicable Termination Date for a period of up to 12-months following the Termination Date, such that Executive shall be required to pay, on a monthly after-tax basis, the same amount as Executive would pay if Executive continued in employment with the Company during such period ("**Subsidized Coverage**") and the Company's portion of the cost of the Subsidized Coverage will be treated as taxable income to Executive, and thereafter Executive shall be responsible for the full cost of such continued coverage; *provided, however*, that Subsidized Coverage shall be provided as described above unless the Company determines,

based on a written legal opinion of counsel, that the Company's provision of Subsidized Coverage results in the violation of non-discrimination provisions of applicable law, as may be applicable to the Company, the imposition of a material additional tax or other material penalty being imposed on the Company (or an Affiliate) or any employee participating in such plans. If the Company makes such a determination, then the Company shall pay Executive an additional severance benefit equal to the cost to the Company of the Subsidized Coverage (had such Subsidized coverage been provided) to assist Executive with the cost of COBRA or, if not available, to assist Executive with the cost of comparable coverage for Executive and his eligible dependents. In the event Executive or any of Executive's dependents is or becomes eligible for coverage under the terms of any other medical and/or dental plan of a subsequent employer with plan benefits that are comparable to Company (or Affiliate) plan benefits, the Company's and its Affiliates' obligations under this **Section 4(g)** shall cease with respect to the eligible Executive and/or dependent. Executive and Executive's dependents must notify the Company of any subsequent employment and provide information regarding medical and/or dental coverage available.

**(h) Other Benefits.**

(i) Executive's rights following a Termination with respect to any benefits, incentives, or awards provided to Executive pursuant to the terms of any plan, program, or arrangement sponsored or maintained by the Company or its Affiliates, whether tax-qualified or not, which are not specifically addressed herein, shall be subject to the terms of such plan, program, or arrangement and this Agreement shall have no effect upon such terms except as specifically provided herein.

(ii) Except as specifically provided in this Agreement, the Company and its Affiliates shall have no further obligations to Executive under this Agreement following a Termination.

**(i) Removal from any Boards, Committees and Positions.** Unless otherwise agreed to in writing by the Parties at the time of Termination, upon a Termination, Executive shall be deemed to resign (i) if a member, from the Board and from the board of directors of any Affiliate and any other board or committee to which Executive has been appointed or nominated by or on behalf of the Company or an Affiliate, (ii) from each position with the Company and any Affiliate, including as an officer of the Company or an Affiliate and (iii) as a fiduciary of any employee benefit plan of the Company and any Affiliate.

5. **Release.** Notwithstanding any provision of this Agreement to the contrary, Executive shall not be entitled to any benefits under **Section 4(b), 4(c), 4(d) or 4(g)** (other than the Accrued Benefits), and shall repay to the Company any such benefits received, unless Executive (or Executive's estate, if applicable) executes (without subsequent revocation) and delivers to the Company a Release within 21 days (or such longer period to the extent required by applicable law) following the Termination Date.

6. **Restrictive Covenants.** Executive acknowledges that Executive has been and will continue to be provided intimate knowledge of the business practices, trade secrets, and other confidential and proprietary information of the Company (including the Confidential Information), which, if exploited by Executive, would seriously, adversely, and irreparably affect the interests of the Company and the ability of the Company to continue its business. Executive further acknowledges that, during the course of Executive's employment with the Company, Executive has produced and had access, and will continue to produce and have access, to Confidential Information.

(a) **Confidential Information.** During the course of Executive's employment and following a Termination:

(i) Executive shall not directly or through others use, disclose, copy, or make lists of Confidential Information for the benefit of anyone other than the Company, except to the extent that such information is, at the time of disclosure, lawfully available from public sources, or such disclosure is authorized in writing by the Company, required or permitted by law, or otherwise as reasonably necessary or appropriate in connection with the performance by Executive of Executive's duties to the Company.

(ii) Executive shall abide by the Company's policies, as in effect from time to time, respecting avoidance of interests conflicting with those of the Company and its Affiliates. In this regard, Executive shall not directly or indirectly render services to any person or Entity where Executive's service would involve the use or disclosure of Confidential Information other than as authorized on behalf of the Company.

(iii) Notwithstanding the foregoing, nothing in this Agreement prohibits Executive from initiating communications directly with, responding to any inquiries from, providing testimony before, providing confidential information to, reporting possible violations of law or regulation to, or from filing a claim or assisting with an investigation directly with a self-regulatory authority or a government agency or entity, including the U.S. Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Department of Justice, the Securities and Exchange Commission, Congress, and any agency Inspector General (collectively, the "**Regulators**"), or from making other disclosures that are protected under the whistleblower provisions of state or federal law or regulation. In connection with any such activity, Executive must identify any information that is confidential and ask the Regulator for confidential treatment of such information, except as permitted by law. Despite the foregoing, Executive is not permitted to reveal to any third party, including any governmental, law enforcement, or regulatory authority, information Executive came to learn during the course of Executive's employment with the Company that is protected from disclosure by any applicable privilege, including but not limited to the attorney-client privilege, attorney work product doctrine and/or other applicable legal privileges, except as otherwise required by law. The Company and its Affiliates do not waive any applicable privileges or the right to continue to protect its privileged attorney-client information, attorney work product, and other privileged information.

(b) **Documents and Property.**

(i) All records, files, documents, and other materials or copies thereof relating to the business of the Company or its Affiliates that Executive prepares, receives, or uses shall be and remain the sole property of the Company and, other than in connection with the performance by Executive of Executive's duties to the Company, shall not be removed from the premises of the Company or its Affiliates without the Company's prior written consent, and shall be immediately returned to the Company upon a Termination, together with all copies (including copies or recordings in electronic form), abstracts, notes, or reproductions of any kind made from or about the records, files, documents, or other materials.

(ii) Executive acknowledges that Executive's access to and permission to use the Company's and its Affiliates' computer systems, networks, and equipment, and all the Company and Affiliate information contained therein, is restricted to legitimate business purposes on behalf of the Company and reasonable personal use in accordance with the Company's applicable policies and procedures. Any other access to or use of such systems, networks, equipment, and information is without authorization and is prohibited. The restrictions contained in this **Section 6(b)** extend to any personal computers or other electronic devices of

Executive that are used for business purposes relating to the Company or its Affiliates. Executive shall not transfer any Company or Affiliate information to any personal computer or other electronic device that is not otherwise used for any business purpose relating to the Company or an Affiliate. Upon a Termination, Executive's authorization to access and permission to use the Company's and its Affiliates' computer systems, networks, and equipment, and any Company and Affiliate information contained therein, shall cease, and Executive shall delete any Company and Affiliate information from Executive's personal computer or other electronic device.

**(c) Non-Competition and Non-Solicitation.** In consideration of the enhanced compensation and benefits provided in this Agreement, and Executive's employment hereunder, Executive shall not, during Executive's employment with the Company or during the Restricted Period, directly or through others (all of which are collectively referred to in this Agreement as the "**Restrictive Covenant**"):

(i) Own, manage, operate, or control, participate in the management, operation, or control of, be employed by, serve as a director, officer, or consultant to, or render services to a Competitor conducting business in the Restricted Area. *However*, the ownership by Executive of shares of the capital stock of any Entity, which shares are listed on a securities exchange and that do not represent more than 5% of the Entity's outstanding capital stock, shall not violate any terms of this Agreement. Additionally, Executive's participation or inclusion on the board of any other entity, shall not violate any terms of this Agreement.

(ii) (A) Induce or attempt to induce any employee of the Company or an Affiliate to leave the employ of the Company or any Affiliate; (B) interfere with the relationship between the Company or an Affiliate, on the one hand, and any employee of the Company or an Affiliate, on the other hand; or (C) induce or attempt to induce any customer, supplier, licensee, advisor, consultant, or other business relation of the Company to cease doing business with the Company or interfere with the relationship between the Company and its respective customers, suppliers, licensees, advisors, consultants or other business relations.

**(d) Works Made for Hire; Ownership of Company Work Product.**

(i) The Parties understand and agree that all work prepared by Executive for the Company or for its Affiliates shall be a Work Made For Hire as such phrase is defined under the U.S. Copyright laws, 17 U.S.C. § 101 *et seq.*, and if such work does not qualify as a Work Made For Hire, Executive shall, and does, assign to the Company all of Executive's right, title, and interest in and to the work, including all patent, copyright, trademark, and other proprietary rights thereto. Executive waives and releases all moral rights in any of the works as Executive may possess by virtue of the Visual Artist's Moral Rights Act of 1990 and various country or state laws of attribution, authorship, and integrity commonly referred to as Moral Rights Law. Executive shall not assert any claim based upon such moral rights against the Company, the Affiliates, or any of their respective successors in interest or assigns. Executive shall have no right, title, or interest in any of the work and shall not be entitled to any royalties or other proceeds received by the Company or its Affiliates from the commercialization in any manner of the work.

(ii) Executive hereby assigns to the Company any right, title, and interest in and to all Company Work Product that Executive may have, by law or equity, without additional consideration of any kind whatsoever from the Company or its Affiliates.

(iii) Executive shall execute and deliver any instruments or documents and do all further acts (including the giving of testimony and executing any applications, oaths, and assignments) requested by the Company (both before and after a Termination) in order to

vest more fully in the Company or its Affiliates all ownership rights in the Company Work Product (including obtaining patent, copyright, trademark, or other intellectual property protection therefore in the United States and foreign countries).

(iv) The Company or its Affiliates shall at all times own and have exclusive right, title, and interest in and to all Confidential Information and Company Work Product, and the Company or its Affiliates shall retain the exclusive right to use, license, sell, transfer, and otherwise exploit and dispose of the same. Executive shall, and does, assign to the Company all of Executive's right, title, and interest in and to any and all Company Work Product work, including all patent, copyright, trademark, and other proprietary rights thereto. Executive acknowledges the Company's or its Affiliates' exclusive right, title, and interest in and to the Confidential Information and Company Work Product, and shall not contest, challenge or make any claim adverse to the Company's or its Affiliates' ownership of or the validity of the Confidential Information and Company Work Product, any future application for registration or registration thereof, or any rights of the Company or its Affiliates therein, or which, directly or indirectly, may impair any part of the Company's or its Affiliates' right, title, and interest therein.

(v) This **Section 6(d)** shall not apply to an invention by Executive for which no equipment, supplies, facility, or trade secret information of the Company or its Affiliates was used and that was developed entirely on Executive's own time, unless the invention (i) relates to the business of the Company or an Affiliate or to the Company's or an Affiliate's actual or demonstrably anticipated research or development or (ii) results from any work performed by Executive for the Company or an Affiliate.

(e) **Consent and Release.** From time to time, the Company's business locations may be the subject of a Promotional Work. Executive acknowledges that Executive is aware that Executive's name, image, and likeness may be captured in such Promotional Work, and hereby consents and agrees that the Company may use Executive's name, image, and likeness as captured in the Promotional Work in any manner, in connection with the Company's products and services or as part of any promotion of the Company, and, at all times, including after the term of this Agreement, the Company, its Affiliates, and, without limitation, their respective customers, successors, licensees, and assigns, may continue to use the Promotional Work that includes Executive's name, image, or likeness. Executive, Executive's heirs, predecessors, successors, assigns, and all affiliated entities hereby fully and finally release, remise, and forever discharge the Company, its Affiliates, their respective predecessors, successors, assigns, and all affiliated entities, and each of their respective directors, officers, members, shareholders, partners, employees, customers, agents, and attorneys, to the extent that such apply, of and from any and all manner of actions, causes of action, losses, claims, demands, liabilities, obligations, suits, debts, sums of money, accounts, reckonings, bonds, bills, specialties, covenants, controversies, agreements, promises, variances, trespasses, damages, judgments, and executions, in law or in equity, that arise out of or are related to the Company's or its Affiliates' use of a Promotional Work that includes Executive's name, image, or likeness.

(f) **Company Proprietary and Intellectual Property.**

(i) The Company or its Affiliates shall at all times own and have exclusive right, title, and interest in and to all Company Proprietary and Intellectual Property, and the Company or its Affiliates shall retain the exclusive right to use, license, sell, transfer, and otherwise exploit and dispose of the same. Executive acknowledges the Company's or its Affiliates' exclusive right, title, and interest in and to Company Proprietary and Intellectual Property, and shall not contest, challenge, or make any claim adverse to the Company's or its Affiliates' ownership of or the validity of Company Proprietary and Intellectual Property, any future application for registration or registration thereof, or any rights of the Company or its



Affiliates therein, or which, directly or indirectly, may impair any part of the Company's or its Affiliates' right, title, and interest therein. Executive shall not use or otherwise exploit any of Company Proprietary and Intellectual Property in any manner not authorized by the Company.

(ii) Notwithstanding any other provisions of this Agreement, pursuant to 18 USC Section 1833(b), Executive shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of the Company's or its Affiliate's trade secret that is made: (A) confidentially to a federal, state, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (B) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. If Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Executive may disclose a Company's or its Affiliate's trade secret to Executive's attorney and use the trade secret information in related court proceedings, provided that Executive files any document containing the trade secret information under seal and does not disclose the trade secret, except pursuant to court order.

**(g) Remedies for Breach of Restrictive Covenant.**

(i) Executive has reviewed the provisions of this Agreement with legal counsel, or has been given adequate opportunity to seek such counsel, and Executive acknowledges that the covenants contained in this **Section 6** are reasonable with respect to their duration, geographical area, and scope.

(ii) Executive acknowledges that (A) the restrictions contained in this **Section 6** are reasonable and necessary for the protection of the legitimate business interests of the Company, (B) such restrictions create no undue hardships, and (C) such restrictions were a material inducement to the Company to employ Executive and to enter into this Agreement and to provide the compensation, benefits and opportunities hereunder.

(iii) Executive agrees to communicate the existence and terms of this Agreement to any third party with whom Executive may seek or obtain future employment or other similar arrangement during the Restricted Period.

(iv) In the event of any violation or threatened violation of the restrictions contained in this **Section 6**, the Company, in addition to and not in limitation of, any other rights, remedies, or damages available to the Company under this Agreement or otherwise at law or in equity, may be entitled to preliminary and permanent injunctive relief to prevent or restrain any such violation by Executive and all persons directly or indirectly acting for or with Executive, as the case may be.

(v) If Executive violates the Restrictive Covenant and the Company brings legal action for injunctive or other relief, the Company shall not, as a result of the time involved in obtaining such relief, be deprived of the benefit of the full period of the Restrictive Covenant; accordingly, the Restrictive Covenant shall be deemed to have the duration specified herein computed from the date the relief is granted but reduced by the time between the period when the Restricted Period began to run and the date of the first violation of the Restrictive Covenant by Executive.

7. **Section 280G.** In the event it shall be determined that any payment, distribution or other action by the Company to or for the benefit of Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (each, a "**Payment**") would be subject to an excise tax imposed by Section 4999 of the Code (such excise tax referred to as the "**Excise Tax**"), the Company shall either make a payment to Executive of all amounts due without any adjustment, or reduce whatever payments are deemed to be

contingent on a transaction that constitutes either a “change in the ownership or effective control” of the Company, a “change in the ownership of a substantial portion of the assets” of the Company (as such phrases are used for purposes of Code Section 280G), to the extent necessary that no payments or benefits provided to Executive are subject to the Excise Tax, whichever approach results in a better economic result for Executive on a better economic result for Executive net of all taxes, including the Excise Tax. The determination of which approach shall be applied shall be made by a public accounting firm retained by the Company for purposes of making this determination (the “**Accounting Firm**”), which need not be the same firm otherwise retained by the Company for the provision of general accounting services. The reduction in payments or benefits provided to Executive under approach (b) shall be applied in a manner that the Accounting Firm determines to be the most appropriate, taking into account possible tax implications of Code Section 409A, and that avoids any unnecessary losses to Executive that may occur in the case of a reduction achieved by reducing the extent to which equity is vested on an accelerated basis.

**8. No Set-Off; No Mitigation.** Except as provided herein, the Company’s obligation to provide benefits under this Agreement and otherwise to perform its obligations hereunder shall not be affected by any circumstances, including any set-off, counterclaim, recoupment, defense, or other right the Company may have against Executive or others. In no event shall Executive be obligated to seek other employment or take any other action by way of mitigation of the amounts payable to Executive under any of the provisions of this Agreement, and such amounts shall not be reduced whether or not Executive obtains other employment.

**9. Notices.** Notices and all other communications under this Agreement shall be in writing and shall be deemed given when mailed by United States registered or certified mail, return receipt requested, postage prepaid, addressed as follows: if to the Company, to the principal headquarters of the Company, attention: Chairman of the Board; and if to Executive, to Executive’s most recent address in the Company’s records; or, in each respective case, to such other address as either Party may furnish to the other in writing, except that notices of changes of address shall be effective only upon receipt.

**10. Governing Law.** This Agreement shall be governed by and construed under the laws of the State of Delaware, without regard to principles of conflict of laws (whether in Delaware or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than Delaware.

**11. Choice of Venue and Consent to Jurisdiction.** Each Party hereby irrevocably submits to the exclusive jurisdiction of the federal and state courts located within Philadelphia County, Pennsylvania and New Castle County, Delaware for the purpose of any suit, action, or other proceeding arising out of or based on this Agreement or any other agreement contemplated hereby or any subject matter hereof, whether in tort, contract, or otherwise.

**12. Entire Agreement.** This Agreement constitutes the entire agreement between the Parties concerning the subject matter hereof, and supersedes all prior negotiations, undertakings, agreements, and arrangements with respect thereto, whether written or oral.

**13. Withholding of Taxes.** The Company may withhold from any benefits payable under this Agreement all federal, state, city and other taxes as may be required pursuant to any law, governmental regulation, or ruling.

**14. Assignment.** Executive’s right to receive benefits under this Agreement shall not be assignable or transferable whether by pledge, creation of a security interest, or otherwise, other than a transfer by will, by the laws of descent or distribution, or as otherwise provided in this Agreement. The Company may assign this Agreement, including to any Affiliate or in

connection with a merger or sale of equity or assets, and upon any such assignment all references to the Company herein shall be deemed to include the assignee. The Company need not obtain Executive's authorization or permission to assign this Agreement; however, if the Company assigns this Agreement, for any reason, the Company agrees to provide advance notice thereof to Executive and ensure the party to whom this Agreement is assigned has the resources to comply with the terms set forth herein. This Agreement shall inure to the benefit of and be enforceable by Executive's personal and legal representatives, executors, administrators, successors, heirs, distributees, devisees, and legatees. This Agreement shall be binding upon and inure to the benefit of the Company, its successors, and assigns.

15. **Amendment.** This Agreement may not be amended or modified except by written agreement signed by the Parties.

16. **Executive Acknowledgement.** Executive hereby represents that from and after the Effective Date the performance of Executive's duties hereunder will not breach any other agreement to which Executive is a party. Executive acknowledges that Executive has read and understands this Agreement, is fully aware of its legal effect, has not acted in reliance upon any representations or promises made by the Company other than those contained in writing herein, and has entered into this Agreement freely based on Executive's own judgment.

17. **Code Section 409A.** To the extent any provision of this Agreement or action by the Company would subject Executive to liability for interest or additional taxes under Code Section 409A, it shall be deemed null and void, to the extent permitted by law and deemed advisable by the Company. Payments under this agreement are intended to be exempt from Code Section 409A, and, if not exempt, to be compliant with the requirements of Code Section 409A. Notwithstanding any provision of this Agreement to the contrary, to the extent any payments are part of a plan or agreement that is subject to Code Section 409A and such payments are payable on termination of employment (or other similar concept), such payments shall only be made if the payment triggering event also constitutes a "separation from service" within the meaning of Code Section 409A. In addition, if (A) the Company has any class of equity securities traded on a stock exchange and (B) Executive is a "specified employee" (as that phrase is used for purposes of Code Section 409A) as of the date of Executive's "separation from service," any payment that is subject to Code Section 409A and is payable by reason of Executive's "separation from service," such payment shall not be made prior to the first day of the seventh (7<sup>th</sup>) calendar month following the date of Executive's "separation from service" or the date of Executive's death, if earlier. For purposes of Code Section 409A, all installment payments of deferred compensation made hereunder, or pursuant to another plan or arrangement, shall be deemed to be separate payments. To the extent any reimbursements or in-kind benefit payments under this Agreement are subject to Code Section 409A, such reimbursements and in-kind benefit payments shall be made in accordance with Treasury Regulation Section 1.409A-3(i)(1)(iv). This Agreement may be amended to the extent necessary (including retroactively) by the Company to avoid the application of taxes or interest under Code Section 409A, while maintaining to the maximum extent practicable the original intent of this Agreement. This Section 17 shall not be construed as a guarantee of any particular tax effect for Executive's benefits under this Agreement and the Company does not guarantee that any such benefits will satisfy the provisions of Code Section 409A or any other provision of the Code.

18. **Construction.**

(a) In this Agreement, unless otherwise stated, the following uses apply: (i) references to a statute refer to the statute and any amendments and any successor statutes, and to all regulations promulgated under or implementing the statute, as amended, or its successors, as in effect at the relevant time; (ii) in computing periods from a specified date to a later specified date, the words "from" and "commencing on" (and the like) mean "from and

including,” and the words “to,” “until,” and “ending on” (and the like) mean “to, and including”; (iii) references to a governmental or quasi-governmental agency, authority, or instrumentality also refer to a regulatory body that succeeds to the functions of the agency, authority, or instrumentality; (iv) the words “include,” “includes,” and “including” (and the like) mean “include, without limitation,” “includes, without limitation,” and “including, without limitation,” (and the like) respectively; (v) all references to sections and exhibits are to sections and exhibits in or to this Agreement; (vi) the words “hereof,” “herein,” “hereto,” “hereby,” “hereunder,” (and the like) refer to this Agreement as a whole (including exhibits); (vii) any reference to a document or set of documents, and the rights and obligations of the Parties under any such documents, means such document or documents as amended from time to time, and all modifications, extensions, renewals, substitutions, or replacements thereof; (viii) all words used shall be construed to be of such gender or number as the circumstances and context require; and (ix) the captions and headings of preambles, recitals, sections, and exhibits appearing in or attached to this Agreement have been inserted solely for convenience of reference and shall not be considered a part of this Agreement, nor shall any of them affect the meaning or interpretation of this Agreement or any of its provisions.

(b) If a court of competent jurisdiction determines that any provision of this Agreement is invalid or unenforceable, then the invalidity or unenforceability of that provision shall not affect the validity or enforceability of any other provision of this Agreement and all other provisions shall remain in full force and effect.

(c) The various covenants and provisions of this Agreement are intended to be severable and to constitute independent and distinct binding obligations.

(d) Without limiting the generality of the foregoing, if the scope of any covenant contained in this Agreement is too broad to permit enforcement to its full extent, such covenant shall be enforced to the maximum extent permitted by law, and such scope may be judicially modified accordingly.

(e) This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same Agreement.

**19. Definitions.** As used in this Agreement, the terms defined in this **Section 19** have the meanings set forth below.

(a) “**Affiliate**” means each Entity that, directly or indirectly, is controlled by, controls, or is under common control with, the Company, where “control” means (i) the ownership of more than 50% of the Voting Securities or other voting or equity interests of any Entity, or (ii) the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Entity.

(b) “**Cause**” means any of the following (in each case as determined by the Compensation Committee or the Board):

(i) Executive’s conviction of, or plea of *nolo contendere* or equivalent to, a crime of embezzlement or fraud or any felony under the laws of the United States or any state thereof;

(ii) An act of fraud, willful misconduct or dishonesty by Executive in the course of or related to his employment hereunder or that could reasonably be expected to be materially injurious to the Company or an Affiliate;

(iii) A material breach by Executive of any of the provisions of the Agreement; or

(iv) An act of moral turpitude by Executive in the course of, or related to, his employment hereunder or that could reasonably be expected to lead to a material harm (financial or reputational) to the Company or an Affiliate.

(c) **“Change in Control”** means the date on which:

(i) A change in the ownership of the Company which occurs on the date that any one person, or more than one person acting as a group (“Person”), acquires ownership of the stock of the Company that, together with the stock held by such Person, constitutes more than fifty percent (50%) of the total voting power of the stock of the Company; provided, however, that for purposes of this subsection (i), the acquisition of additional stock by any one Person, who is considered to own more than fifty percent (50%) of the total voting power of the stock of the Company will not be considered a Change in Control; or

(ii) A change in the effective control of the Company which occurs on the date that a majority of members of the Board is replaced during any twelve (12) month period by Directors whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election. For purposes of this clause (ii), if any Person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same Person will not be considered a Change in Control; or

(iii) A sale or other disposition of all or substantially all of the Company’s assets in one or more transactions, other than to any entity of which more than 50% of the total voting power is owned, directly or indirectly, by stockholders of the Company in substantially the same proportions as their ownership of the voting power of the stock of the Company immediately prior to the transaction which results in a sale or disposition as to all or substantially all of the Company’s assets; or

(iv) A merger, consolidation or similar transaction directly or indirectly involving the Company in which immediately after the consummation of such transaction, the stockholders of the Company immediately prior to such transaction do not directly or indirectly own more than 50% of the total voting power of the surviving entity in such transaction (or of any applicable Parent of such surviving entity), in substantially the same proportions as their ownership of the voting power of the stock of the Company immediately prior to the transaction.

For purposes of this definition of Change in Control, persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Company. Notwithstanding the foregoing, the occurrence of any event shall not be deemed a Change in Control: (i) with respect to any award or payment that is subject to Code Section 409A unless such event qualifies as a change in control event within the meaning of Code Section 409A, or (ii) if the sole purpose of the underlying transaction(s) is to change the jurisdiction of the Company’s incorporation or to create a holding company of which the total voting power is owned, directly or indirectly, by stockholders of the Company in substantially the same

proportions as their ownership of the voting power of the stock of the Company immediately prior to such transaction(s).

(d) **“Code”** means the Internal Revenue Code of 1986.

(e) **“Company Proprietary and Intellectual Property”** means all products, systems, methods, procedures, techniques, manuals, databases, plans, lists, inventions, discoveries, innovations, improvements, enhancements, concepts, ideas, and software conceived, created, compiled, or otherwise developed by the Company or its Affiliates and/or comprised, in whole or part, of Confidential Information, together with all patent rights, copyrights, trademarks, service marks, trade name rights and other source identifiers, trade secrets, and other intellectual property and property rights therein, if any.

(f) **“Company Work Product”** means all products, systems, methods, procedures, techniques, manuals, databases, plans, lists, inventions, discoveries, innovations, improvements, enhancements, concepts, ideas, and software conceived, created, compiled, or otherwise developed by Executive, alone or with others, in the course of Executive’s employment with the Company or its Affiliates and/or comprised, in whole or part, of Confidential Information, together with all patent rights, copyrights, trademarks, service marks, trade name rights, trade secrets, and other intellectual property and propriety rights therein, if any.

(g) **“Competitor”** means any entity offering, or having proposed to offer, the specific products offered by the Company during the two years prior to Executive’s separation. For purposes of clarity, “Competitor” does not include an entity simply because it offers oncology products or operates in the oncology field; rather, for an entity to be a Competitor, the entity must offer or have proposed to offer the specific products offered by the Company during the two years prior to Executive’s separation.

(h) **“Confidential Information”** means trade secret, confidential, proprietary or other non-public information concerning the Company or its Affiliates, including research, development, designs, formulae, processes, specifications, technologies, marketing materials, financial and other information concerning customers and prospective customers, customer lists, records, data, computer programs, source codes, object codes, database structures, trade secrets, proprietary business information, pricing and profitability information, policies, strategic planning, commitments, plans, procedures, litigation, pending litigation, and other information not generally available to the public.

(i) **“Disability”** means that (i) Executive is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than 12 months, or (ii) Executive is, by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than 12 months, receiving income replacement benefits for a period of not less than three months under long-term disability plan covering employees of the Company. In the event of a dispute regarding whether Executive has incurred a Disability, each of Executive and the Company shall choose a physician who together shall choose a third physician to make a final determination regarding whether Executive has incurred a Disability.

(j) **“Entity”** means any corporation, partnership, limited liability company, joint venture, association, partnership, business trust or other business entity.

(k) “**Financing**” means a transaction involving equity, debt, joint venture, licensing, merger or other similar arrangement resulting in cash proceeds to the Company, including the aggregate amount of capital raised without regard to any conditions placed on the Financing (such as milestone targets).

(l) “**Good Reason**” means the occurrence of any one of the following events, unless Executive agrees in writing that such event shall not constitute Good Reason:

(i) A material and adverse change in the nature, scope, or status of Executive’s position, authorities, responsibilities or duties from those in effect in accordance with **Section 2**, including, without limitation, Executive ceasing to be an “executive officer” (as defined under Rule 3b-7 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) of a company with a class of securities registered under Section 12(b) of the Exchange Act, or the assignment to Executive of any duties materially inconsistent with the duties and responsibilities of Executive Officer;

(ii) A material reduction in Executive’s then-current Annual Base Salary and/or Target Bonus, or a material reduction in Executive’s aggregate benefits or other compensation plans in effect immediately following the Effective Date;

(iii) A permanent relocation of Executive’s primary place of employment that increases Executive’s commuting distance from his primary residence by more than twenty-five (25) miles, as compared with Executive’s commute to Executive’s primary place of employment as initially agreed to by Executive and the Company; or

(iv) A material breach by the Company of this Agreement.

(m) “**Promotional Work**” means, without limitation, photographs, films, clips, sketches, segments, and other media and promotional works, including any derivative works thereof, used for reasonable purposes in connection with the business of the Company.

(n) “**Qualifying Financing**” means one or more Financings within the 12 months before or following the Effective Date resulting in gross proceeds of not less than \$15,000,000.

(o) “**Release**” means a general release and waiver as substantially in the form attached hereto as **Exhibit A** and otherwise as agreed upon by the Company and Executive.

(p) “**Restricted Area**” means each state in the United States in which the Company or its Affiliates are actively engaged in or pursuing business at the time of Executive’s termination of employment.

(q) “**Restricted Period**” means a period of 6 months immediately following the applicable Termination Date.

(r) “**Termination**” means termination of Executive’s employment with the Company and all Affiliates for any reason or no reason.

(s) “**Voting Securities**” means any securities that ordinarily possess the power to vote in the election of directors without the happening of any precondition or contingency.

**20. Survival.** The provisions of Section 6 shall survive the termination of this Agreement.

[Signature page to follow]



IN WITNESS WHEREOF, the Company has caused this Agreement to be executed in its name and on its behalf, and Executive acknowledges understanding and acceptance of, and agrees to, the terms of this Agreement, all as of the Effective Date.

<b>CONTEXT THERAPEUTICS INC.</b>  By: <u>/s/ Martin Lehr</u> Name: Martin Lehr Title: Chief Executive Officer	<b>Alex Levit</b>  <u>/s/ Alex Levit</u>
---	--

## EXHIBIT A

### Agreement and Release and Waiver

This **Agreement and Release** (“**Agreement**”) is made and entered into by and between **Context Therapeutics Inc.** (the “**Company**”) and [●] (“**Executive**”).

**Whereas**, Executive and the Company desire to settle fully and amicably all issues that Executive has with the Company, including any issues arising out of Executive’s employment with the Company and the termination of that employment; and

**Whereas**, Executive and the Company are parties to that certain Employment Agreement, made and entered into as of [●], as amended (the “**Employment Agreement**”).

**Now, therefore**, for and in consideration of the mutual promises contained herein, and for other good and sufficient consideration, receipt of which is hereby acknowledged, Executive and the Company (collectively, the “**Parties**” and, individually, each a “**Party**”), intending to be legally bound, hereby agree as follows:

**1. Termination of Employment.** Executive’s employment with the Company terminated effective as of the close of business on [●] (the “**Termination Date**”).

**2. Compensation and Benefits.** Subject to the terms of this Agreement, the Company shall compensate Executive under this Agreement as follows (collectively, the “**Severance Payments**”):

(a) Severance Payments. [●].

(b) Accrued Salary and Vacation. Executive shall be entitled to a lump sum payment in an amount equal to Executive’s earned but unpaid annual base salary and vacation pay for the period ending on the Termination Date, with such payment to be made on the first payroll date following the Termination Date.

(c) Executive Acknowledgement. Executive acknowledges that, subject to fulfillment of all obligations provided for herein, Executive has been fully compensated by the Company, including under all applicable laws, and that nothing further is owed to Executive with respect to wages, bonuses, severance, other compensation, or benefits. Executive further acknowledges that the Severance Payments (other than (b) above) are consideration for Executive’s promises contained in this Agreement, and that the Severance Payments are above and beyond any wages, bonuses, severance, other compensation, or benefits to which Executive is entitled from the Company under the terms of Executive’s employment or under any other contract or law, absent his execution of this Agreement.

(d) Withholding. The Severance Payments shall be treated as wages and subject to all taxes and other payroll deductions required by law.

**3. Termination of Benefits.** Except as provided in **Section 2** above or as may be required by law, Executive’s participation in all employee benefit (pension and welfare) and compensation plans of the Company shall cease as of the Termination Date. Nothing contained

herein shall limit or otherwise impair Executive's right to receive pension or similar benefit payments that are vested as of the Termination Date under any applicable tax-qualified pension or other plans, pursuant to the terms of the applicable plan.

**4. Release of Claims and Waiver of Rights.** Executive, on Executive's own behalf and that of Executive's heirs, executors, attorneys, administrators, successors, and assigns, fully releases and discharges the Company; each of its predecessors, successors, parents, subsidiaries, affiliates, and assigns; all of its and their current and former directors, officers, trustees, employees, and agents, both in their individual and official capacities; and the current and former trustees and administrators of each retirement and other benefit plan applicable to the employees and former employees of the Company, both in their official and individual capacities (the "**Releasees**") from all liability, claims, demands, and actions Executive now has, may have had, or may ever have, whether currently known or unknown, as of or prior to Executive's execution of this Agreement (the "**Release**"), including liability claims, demands, and actions:

- (a) Arising from or relating to Executive's employment or other association with the Company, or the termination of such employment,
- (b) Relating to wages, bonuses, incentive pay, equity, other compensation, or benefits,
- (c) Relating to any employment or change in control contract,
- (d) Relating to any employment law, including
  - (i) The laws of the United States and Commonwealth of Pennsylvania,
  - (ii) The Civil Rights Act of 1964,
  - (iii) The Civil Rights Act of 1991,
  - (iv) The Equal Pay Act,
  - (v) The Employee Retirement Income Security Act of 1974,
  - (vi) The Age Discrimination in Employment Act, as amended by the Older Workers Benefit Protection Act (the "**ADEA**"),
  - (vii) The Americans with Disabilities Act,
  - (viii) Executive Order 11246, and
  - (ix) Any other federal, state, or local statute, ordinance, or regulation relating to employment,
- (e) Relating to any right of payment for disability,
- (f) Relating to any statutory or contractual right of payment, and

(g) For relief on the basis of any alleged tort or breach of contract under the common law of the Commonwealth of Pennsylvania, or any other state, including defamation, intentional or negligent infliction of emotional distress, wrongful termination, breach of the covenant of good faith and fair dealing, promissory estoppel, and negligence.

Executive acknowledges that Executive is aware that statutes exist that render null and void releases and discharges of any claims, rights, demands, liabilities, actions, and causes of action that are unknown to the releasing or discharging party at the time of execution of the release and discharge. Executive waives, surrenders, and shall forego any protection to which Executive would otherwise be entitled by virtue of the existence of any such statutes in any jurisdiction, including the Commonwealth of Pennsylvania.

**5. Exclusions from General Release.** Excluded from the Release are any claims or rights that cannot be waived by law, claims for indemnification by the Company as an officer or former officer of the Company, whether by law, contract or articles or bylaws of the Company, as well as Executive's right to file a charge with an administrative agency or participate in any agency investigation. Executive is, however, waiving the right to recover any money from the Company and other Releasees in connection with a charge or investigation. Executive is also waiving the right to recover any money from the Company and other Releasees in connection with a charge filed by any other individual or by the Equal Employment Opportunity Commission or any other federal or state agency.

#### **6. Covenant Not to Sue.**

(a) A "covenant not to sue" is a legal term that means Executive promises not to file a lawsuit in court. It is different from the release of claims and waiver of rights contained in **Section 4** above. Besides waiving and releasing the claims covered by **Section 4** above, Executive shall never sue the Releasees in any forum for any reason covered by the Release. Notwithstanding this covenant not to sue, Executive may bring a claim against the Company to enforce this Agreement, to challenge the validity of this Agreement under the ADEA or for any claim that arises after execution of this Agreement. Executive may also file an administrative complaint or charge with a government agency, *provided, however*, that Executive shall not be entitled to recover any monies from the Releasees as a result of filing such administrative complaint or charge. If Executive sues any of the Releasees in violation of this Agreement, Executive shall be liable to them for their reasonable attorneys' fees and costs (including the costs of experts, evidence, and counsel) and other litigation costs incurred in defending against Executive's suit. In addition, if Executive sues any of the Releasees in violation of this Agreement, the Company can require Executive to return all but a sum of \$100 of the Severance Payments, which sum is, by itself, adequate consideration for the promises and covenants in this Agreement. In that event, the Company shall have no obligation to make any further Severance Payments.

(b) If Executive has previously filed any lawsuit against any of the Releasees, Executive shall immediately take all necessary steps and execute all necessary documents to withdraw or dismiss such lawsuit to the extent Executive's agreement to withdraw, dismiss, or not file a lawsuit would not be a violation of any applicable law or regulation.

**7. Representations by Executive.** Executive warrants that Executive is legally competent to execute this Agreement and that Executive has not relied on any statements or explanations made by the Company or its attorneys. **Executive acknowledges that Executive**

has been advised to consult legal counsel regarding the terms of this Agreement, including the Release. Executive acknowledges that Executive has been offered at least 21 days to consider this Agreement. After being so advised, and without coercion of any kind, Executive freely, knowingly, and voluntarily enters into this Agreement. Executive acknowledges that Executive may revoke this Agreement within seven days after Executive has signed this Agreement and acknowledges understanding that this Agreement shall not become effective or enforceable until seven days after Executive has signed this Agreement (the “Effective Date”), as evidenced by the date set forth below Executive’s signature on the signature page hereto. Any revocation must be in writing and directed to [●]. If sent by mail, any revocation must be postmarked within the seven-day period described above and sent by certified mail, return receipt requested.

**8. Restrictive Covenants.** Section 6 of the Employment Agreement (entitled “Restrictive Covenants”) shall continue in full force and effect as if fully restated herein.

**9. Non-Disparagement.** Executive shall not engage in any disparagement or vilification of the Releasees, and shall refrain from making any false, negative, critical, or disparaging statements, implied or expressed, concerning the Releasees, including regarding management style, methods of doing business, the quality of products and services, role in the community, or treatment of employees. The Company and its directors, officers and senior management employees, while associated with the Company, shall not engage in any disparagement or vilification of the Releasees, and shall refrain from making any false, negative, critical, or disparaging statements, implied or expressed, concerning Executive; *provided, however*, that each Party may make truthful statements as required by applicable law and the Company may make internal statements and statements to its attorneys and advisors for legitimate business reasons.

**10. Company Property.**

(a) Executive shall return to the Company all information, property, and supplies belonging to the Company or any of its affiliates, including any confidential or proprietary information, Company autos, keys (for equipment or facilities), laptop computers and related equipment, cellular phones, smart phones or PDAs (including SIM cards), security cards, corporate credit cards, and the originals and all copies of all files, materials, and documents (whether in tangible or electronic form) containing confidential or proprietary information or relating to the business of the Company or any of its affiliates.

(b) Executive shall not, at any time on or after the Termination Date, directly or indirectly use, access, or in any way alter or modify any of the databases, e-mail systems, software, computer systems, or hardware or other electronic, computerized, or technological systems of the Company or any of its affiliates. Executive acknowledges that any such conduct by Executive would be illegal and would subject Executive to legal action by the Company, including claims for damages and/or appropriate injunctive relief.

**11. No Admissions.** The Company denies that it or any of its affiliates, or any of their employees or agents, has taken any improper action against Executive, and this Agreement shall not be admissible in any proceeding as evidence of improper action by the Company or any of its affiliates or any of their employees or agents.

**12. Confidentiality of Agreement.** Executive shall keep the existence and the terms of this Agreement confidential, except for Executive's immediate family members and Executive's legal and tax advisors in connection with services related hereto and except as may be required by law or in connection with the preparation of tax returns.

**13. Non-Waiver.** The Company's waiver of a breach of this Agreement by Executive shall not be construed or operate as a waiver of any subsequent breach by Executive of the same or of any other provision of this Agreement.

**14. Governing Law.** This Agreement shall be governed by and construed under the laws of the State of Delaware, without regard to principles of conflict of laws (whether in Delaware or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than Delaware.

**15. Entire Agreement.** This Agreement sets forth the entire agreement of the Parties regarding the subject matter hereof, and shall be final and binding as to all claims that have been or could have been advanced on behalf of Executive pursuant to any claim arising out of or related in any way to Executive's employment with the Company and the termination of that employment; *provided, however* that nothing contained herein shall supersede or eliminate any post-separation obligations that Executive has pursuant to the Employment Agreement or otherwise.

**16. Counterparts.** This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same Agreement.

**17. Successors.** This Agreement shall be binding upon and inure to the benefit of the Company, its successors and assigns.

**18. Construction.** In this Agreement, unless otherwise stated, the following uses apply: (a) references to a statute refer to the statute and any amendments and any successor statutes, and to all regulations promulgated under or implementing the statute, as amended, or its successors, as in effect at the relevant time; (b) in computing periods from a specified date to a later specified date, the words "from" and "commencing on" (and the like) mean "from and including," and the words "to," "until," and "ending on" (and the like) mean "to, and including"; (c) references to a governmental or quasi-governmental agency, authority, or instrumentality also refer to a regulatory body that succeeds to the functions of the agency, authority, or instrumentality; (d) the words "include," "includes," and "including" (and the like) mean "include, without limitation," "includes, without limitation," and "including, without limitation," (and the like) respectively; (e) all references to sections are to sections to this Agreement; (f) the words "hereof," "herein," "hereto," "hereby," "hereunder," (and the like) refer to this Agreement as a whole (including exhibits); (g) any reference to a document or set of documents, and the rights and obligations of the parties under any such documents, means such document or documents as amended from time to time, and all modifications, extensions, renewals, substitutions, or replacements thereof; (h) all words used shall be construed to be of such gender or number as the circumstances and context require; (i) the captions and headings have been inserted solely for convenience of reference and shall not be considered a part of this Agreement, nor shall any of them affect the meaning or interpretation of this Agreement or any

of its provisions; and (j) all accounting terms not specifically defined herein shall be construed in accordance with GAAP.

**19. Future Cooperation.** In connection with any and all claims, disputes, negotiations, governmental, internal or other investigations, lawsuits, or administrative proceedings (the “**Legal Matters**”) involving the Company or any affiliate, or any of their current or former officers, employees or board members (collectively, the “**Disputing Parties**” and, individually, each a “**Disputing Party**”), Executive shall make himself reasonably available, upon reasonable notice from the Company and without the necessity of subpoena, to provide information and documents, provide declarations and statements regarding a Disputing Party, meet with attorneys and other representatives of a Disputing Party, prepare for and give depositions and testimony, and otherwise cooperate in the investigation, defense, and prosecution of any and all such Legal Matters, as may, in the good faith and judgment of the Company, be reasonably requested. The Company shall consult with Executive and make reasonable efforts to schedule such assistance so as not to materially disrupt Executive’s business and personal affairs. The Company shall reimburse all reasonable expenses incurred by Executive in connection with such assistance, including travel, meals, rental car, and hotel expenses, if any.

**In witness whereof**, the Parties have duly executed this Agreement as of the dates set forth below their respective signatures below.

**CONTEXT THERAPEUTICS INC.**

By: \_\_

Print Name: \_\_

Title: \_\_

Date: \_\_

**[INSERT NAME]**

—

Date: \_\_

## AMENDMENT NO. 1 TO CONSULTING AGREEMENT

This **AMENDMENT NO. 1 TO CONSULTING AGREEMENT** (this "**Amendment**") is entered into as of the 21<sup>st</sup> day of March 2022, but effective as of the 1<sup>st</sup> day of February, 2022 (the "**Amendment Effective Date**"), and is entered into by and between **OncoStrategy LLC**, ("**Provider**") and **Context Therapeutics Inc.**, a Delaware corporation, having its principal place of business at 2001 Market Street, Suite 3915, Unit#15, Philadelphia, PA 19103 ("**Company**"). Provider and Company are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

### RECITALS

**WHEREAS**, Provider and Company entered into that certain Consulting Agreement dated as of May 7, 2021 (the "**Agreement**"), which outlines the rights and obligations of Provider and Company with respect to the conduct of certain services to be performed by Provider;

**WHEREAS**, the Parties wish to enter into this Amendment in order to temporarily increase the hours and related compensation for services in accordance with the terms and conditions set forth herein;

**NOW THEREFORE**, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, hereby agree as follows:

1. **Defined Terms.** All capitalized terms used herein shall have the meaning ascribed to each of them as defined herein and, if not defined herein, shall have the meaning ascribed to each of them in the Agreement.
2. **Amendment to Agreement.** Effective as of the Amendment Effective Date, for the months of February, March, April and May 2022, Provider shall receive \$20,000 per calendar month in arrears, provided that Consultant provides on average approximately 40 hours of Consulting Services per month.
3. **Entire Agreement.** Each Party acknowledges that this Amendment, together with the Agreement, constitutes the entire agreement of the Parties with respect to the subject matter hereof.
4. **Full Force and Effect.** Except as expressly amended hereby, all of the other terms and conditions of the Agreement shall remain unchanged and in full force and effect in accordance with their original terms.
5. **Authority.** Each Party hereby represents and warrants that it has full power and authority to enter into this Amendment.

[Signature page follows.]



**IN WITNESS WHEREOF**, the Parties have each caused a duly authorized representative to execute this Amendment as of the Amendment Effective Date.

**COMPANY:**

**Context Therapeutics Inc.**

**PROVIDER:**

**OncoStrategy, LLC**

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

By: /s/ Tarek Sahmoud  
Name: Tarek Sahmoud  
Title: Principal & Founder

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statement of Context Therapeutics Inc. on Form S-8 (No. 333-260385) of our report dated March 23, 2022, on our audits of the consolidated financial statements of Context Therapeutics Inc. and Subsidiaries as of December 31, 2021 and 2020 and for the years then ended, included in this Annual Report on Form 10-K of Context Therapeutics Inc. for the year ended December 31, 2021.

/s/ CohnReznick LLP

Holmdel, New Jersey  
March 23, 2022

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF THE  
SARBANES-OXLEY ACT OF 2002**

I, Martin Lehr, certify that:

1. I have reviewed this Annual Report on Form 10-K of Context Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2022

By: /s/ Martin Lehr

Martin Lehr  
Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO SECTION 302 OF THE  
SARBANES-OXLEY ACT OF 2002**

I, Jennifer Minai-Azary, certify that:

1. I have reviewed this Annual Report on Form 10-K of Context Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2022

By: /s/ Jennifer Minai-Azary

Jennifer Minai-Azary  
Chief Financial Officer  
(Principal Financial Officer)

**CERTIFICATIONS PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350, as adopted), Martin Lehr, Chief Executive Officer (Principal Executive Officer) of Context Therapeutics Inc. (the “Company”), and Jennifer Minai-Azary, Chief Financial Officer (Principal Financial Officer) of the Company, each hereby certifies that, to the best of his or her knowledge:

(1) The Company’s Annual Report on Form 10-K for the year ended December 31, 2021 (the “Annual Report”), and to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended, and

(2) The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: March 23, 2022

/s/ Martin Lehr

Martin Lehr

Chief Executive Officer (Principal Executive Officer)

Date: March 23, 2022

/s/ Jennifer Minai-Azary

Jennifer Minai-Azary

Chief Financial Officer (Principal Financial Officer)

“This certification accompanies the Annual Report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Context Therapeutics Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.”