UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended June 30, 2022

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

For the transition period from _____ to _____.

Commission file number: 001-40654

CONTEXT THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware	**86-3738787**
(State of other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

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

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

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

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001 per share	CNTX	The Nasdaq Stock Market LLC

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 o

Indicate by check mark whether the registrant has submitted electronically 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 such files). Yes ☒ No o

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

The number of shares of common stock outstanding at August 9, 2022 was 15,966,053 shares.

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

Trademark Notice

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report (including, for purposes of this Note Regarding Forward-Looking Statements, any information or documents incorporated herein by reference) includes express and implied forward-looking statements. All statements other than statements of historical facts are forward-looking statements. 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 onapristone extended release ("ONA-XR"), anti-claudin 6 ("CLDN6") bispecific monoclonal antibody ("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 U.S. Food and Drug Administration 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 dependence on collaborations with third parties for certain research, development and commercialization activities;
- 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, 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”;

as well as other statements relating to our future operations, financial performance and financial condition, prospects, strategies, objectives or other future events. 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-Q. 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. As a result, you should not place undue reliance on forward-looking statements.

Additionally, the forward-looking statements contained in this Form 10-Q represent our views only as of the date of this Form 10-Q (or any earlier date indicated in such statement). While we may update certain forward-looking statements from time to time, we specifically disclaim any obligation to do so, even if new information becomes available in the future. However, you are advised to consult any further disclosures we make on related subjects in the reports that we file with the SEC.

The foregoing cautionary statements are intended to qualify all forward-looking statements wherever they may appear in this Form 10-Q. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Market, Industry and Other Data

This Form 10-Q contains estimates, projections, market research and other data generated by independent third parties, by third parties on our behalf and by us concerning markets for onapristone. Information that is based on estimates, projections, market research or similar methodologies is inherently subject to uncertainties and actual results, events or circumstances may differ materially from results, events and circumstances reflected in this information. As a result, you are cautioned not to give undue weight to such information.

This Form 10-Q 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 include 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.

Part I - Financial Information

Item 1. Financial Statements

Context Therapeutics Inc.
Condensed Consolidated Balance Sheets

	June 30, 2022 (Unaudited)	December 31, 2021 (Note 3)
Assets		
Current assets:		
Cash and cash equivalents	$ 42,921,214	$ 49,635,197
Prepaid expenses and other current assets	1,578,623	1,620,164
Total current assets	44,499,837	51,255,361
Operating lease right-of-use asset	95,251	—
Property and equipment, net	33,955	—
Other assets	67,750	—
Restricted cash	—	50,389
Total assets	$ 44,696,793	$ 51,305,750
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 945,462	$ 1,826,294
Accrued expenses and other current liabilities	2,001,003	1,207,121
Operating lease liability - current	93,062	—
Total current liabilities	3,039,527	3,033,415
Operating lease liability	7,967	—
Total liabilities	3,047,494	3,033,415
Commitments and contingencies (Note 9)		
Stockholders' equity:		
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 shares issued and outstanding at June 30, 2022 and December 31, 2021	15,966	15,966
Additional paid-in capital	78,312,621	77,510,809
Accumulated deficit	(36,679,288)	(29,254,440)
Total stockholders' equity	41,649,299	48,272,335
Total liabilities and stockholders' equity	$ 44,696,793	$ 51,305,750

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

Context Therapeutics Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Acquired in-process research and development	$ 500,000	$ 3,087,832	$ 500,000	$ 3,087,832
Research and development	1,517,243	1,333,101	2,868,738	1,771,840
General and administrative	1,990,568	604,602	4,082,035	1,006,181
Loss from operations	(4,007,811)	(5,025,535)	(7,450,773)	(5,865,853)
Interest income (expense), net	21,296	(309)	27,160	(63,294)
Change in fair value of convertible promissory notes	—	—	—	9,317
Other income (expense)	4	(4,320)	(1,235)	(2,383)
Net loss	$ (3,986,511)	$ (5,030,164)	$ (7,424,848)	$ (5,922,213)
Net loss per common share, basic and diluted	$ (0.25)	$ (14.18)	$ (0.47)	$ (16.82)
Weighted average shares outstanding, basic and diluted	15,966,053	354,829	15,966,053	352,048

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

Context Therapeutics Inc.
Condensed Consolidated Statement of Changes in Convertible Preferred Stock, Redeemable Common Stock and Stockholders' Deficit
(Unaudited)

	Series A Preferred Stock		Series Seed Preferred Stock		Redeemable Common Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at January 1, 2021	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 stock, net of offering costs of $213,073	453,094	3,034,526	—	—	—	—	—	—	—	—	—
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 warrants issued in conjunction with the Series A preferred stock	—	(158,658)	—	—	—	—	—	—	158,658	—	158,658
Fair value of warrants issued as placement agent fees	—	(13,388)	—	—	—	—	—	—	13,388	—	13,388
Share-based compensation expense, including vesting of restricted stock and issuance of common stock	—	—	—	—	—	—	4,218	4	25,509	—	25,513
Net loss	—	—	—	—	—	—	—	—	—	(892,049)	(892,049)
Balance at March 31, 2021	1,508,633	$ 9,992,208	2,624,324	$ 6,341,288	16,666	$ 29,000	336,007	$ 336	$ 2,211,211	$ (19,689,619)	$ (17,478,072)
Sale of Series A preferred stock, net of offering costs of $96,948	285,351	1,948,309	—	—	—	—	—	—	—	—	—
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	—	(106,935)	—	—	—	—	—	—	106,935	—	106,935
Fair value of warrants issued as placement agent fees	—	(30,409)	—	—	—	—	—	—	30,409	—	30,409
Share-based compensation expense, including vesting of restricted stock and issuance of common stock	—	—	—	—	—	—	6,262	6	119,357	—	119,363
Change in fair value of redeemable common stock to redemption value	—	—	—	—	—	53,330	—	—	(53,330)	—	(53,330)
Net loss	—	—	—	—	—	—	—	—	—	(5,030,164)	(5,030,164)
Balance at June 30, 2021	2,212,543	$ 14,641,005	2,624,324	$ 6,341,288	16,666	$ 82,330	342,269	$ 342	$ 2,414,582	$ (24,719,783)	$ (22,304,859)

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

Context Therapeutics Inc.
Condensed Consolidated Statement of Changes in Stockholders' Equity
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2022	15,966,053	$ 15,966	$ 77,510,809	$ (29,254,440)	$ 48,272,335
Fair value of warrants issued for services	—	—	345,530	—	345,530
Share-based compensation expense	—	—	214,958	—	214,958
Net loss	—	—	—	(3,438,337)	(3,438,337)
Balance at March 31, 2022	15,966,053	15,966	78,071,297	(32,692,777)	45,394,486
Share-based compensation expense	—	—	241,324	—	241,324
Net loss	—	—	—	(3,986,511)	(3,986,511)
Balance at June 30, 2022	15,966,053	$ 15,966	$ 78,312,621	$ (36,679,288)	$ 41,649,299

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

Context Therapeutics Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Six months ended June 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (7,424,848)	$ (5,922,213)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development charge	500,000	3,087,832
Fair value of warrants for services provided	—	371,895
Share-based compensation expense	456,282	144,876
Depreciation and amortization expense	2,881	—
Non-cash interest expense	—	63,294
Change in fair value of convertible promissory notes	—	(9,317)
Reduction in the carrying amount of operating lease right-of-use asset	35,237	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	41,541	(12,715)
Other assets	(67,750)	—
Accounts payable	(1,278,761)	(2,305,729)
Accrued expenses and other current liabilities	1,139,412	787,907
Operating lease liability	(29,459)	—
Cash used in operating activities	(6,625,465)	(3,794,170)
Cash flows from investing activities:		
Acquired in-process research and development	—	(250,000)
Purchase of property and equipment	(36,836)	—
Cash used in investing activities	(36,836)	(250,000)
Cash flows from financing activities:		
Payments for offering costs related to the private placement sale of common stock	(102,071)	—
Proceeds from the sale of Series A preferred stock, net	—	4,982,835
Cash (used in) provided by financing activities	(102,071)	4,982,835
Net (decrease) increase in cash, cash equivalents and restricted cash	(6,764,372)	938,665
Cash, cash equivalents and restricted cash at beginning of period	49,685,586	341,037
Cash, cash equivalents and restricted cash at end of period	$ 42,921,214	$ 1,279,702
Supplemental disclosure of non-cash activities:		
Conversion of convertible promissory notes, including accrued interest, to Series A preferred stock	$ —	$ 5,866,290
Issuance of warrants in conjunction with Series A preferred stock	$ —	$ 309,390
Series A preferred stock issued for acquired in-process research and development	$ —	$ 2,837,832
Deferred offering costs in accounts payable	$ —	$ 1,300,535
Acquired in-process research and development in accounts payable	$ 500,000	$ —
Issuance of warrants for services provided	$ 345,530	$ —
Right-of-use asset obtained in exchange for lease obligation	$ 130,488	$ —
Change in fair value of redeemable common stock to redemption value	$ —	$ 53,330

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

CONTEXT THERAPEUTICS INC.
Notes to Unaudited Condensed Consolidated Financial Statements

(1) Organization and Description 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 condensed 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 $36.7 million as of June 30, 2022. 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 believes its cash and cash equivalents of $42.9 million as of June 30, 2022 are sufficient to fund its projected operations for at least the next 12 months from the issuance date of these condensed consolidated financial statements. However, substantial additional financing 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.

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.

In October 2021, the Company closed an initial public offering ("IPO"), 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 approximately $24.4 million as a result of the 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 common stock in a private placement and received net proceeds of approximately $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 plans to seek 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 trials. 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) Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). Certain information and note disclosures normally included in annual financial statements prepared in accordance with U.S. generally accepted accounting principles ("GAAP") have been condensed or omitted pursuant to those rules and regulations, although the Company believes that the disclosures made are adequate to make the information not misleading. 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") of the Financial Accounting Standards Board ("FASB").

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals and estimates that impact the financial statements) considered necessary to present fairly the Company's financial position as of June 30, 2022, and its results of operations for the three and six months ended June 30, 2022 and 2021 and cash flows for the six months ended June 30, 2022 and 2021. Operating results for the three and six months ended June 30, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022. The unaudited condensed consolidated financial statements, presented herein, do not contain the required disclosures under GAAP for annual financial statements. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the annual audited consolidated financial statements and related notes as of and for the year ended December 31, 2021. The consolidated financial information as of December 31, 2021 included herein has been derived from the annual audited consolidated financial statements.

The unaudited condensed 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.

Use of Estimates

The preparation of condensed 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 unaudited condensed consolidated financial statements in the period they are determined to be necessary. Significant estimates and assumptions made in the accompanying unaudited condensed consolidated financial statements include, but are not limited to, the fair value of common stock, share-based compensation arrangements, the fair value of convertible debt and in recording the prepayments, accruals and associated expense for 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.

Fair Value of Financial Instruments

The carrying amount of the Company's financial instruments, which include cash and cash equivalents, restricted cash, and accounts payable, approximate their fair values given their short-term nature.

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.

The Company maintained approximately $50,000 as collateral for the Company's credit card program at December 31, 2021, which is reported as restricted cash on its condensed consolidated balance sheets. There were no amounts restricted as of June 30, 2022, as the collateral was released to the Company in the first quarter of 2022.

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 condensed consolidated statements of operations.

Property and Equipment

Property and equipment consists of office equipment, furniture, and leasehold improvements and is recorded at cost. Property and equipment is depreciated on a straight-line basis over their estimated useful lives. Leasehold improvements are amortized over the shorter of their economic lives or the remaining lease term.

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.

Costs for certain development activities, such as the provision of services for product candidate development, clinical and preclinical development and related supply and manufacturing costs, are estimated based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information provided to the Company by its vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be. The estimates are adjusted to reflect the best information available at the time of the financial statement issuance. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the Company's estimate of the status and timing of services performed relative to the actual status and timing of services performed may vary.

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 unaudited condensed consolidated statements of operations in the same manner in which the award recipients' 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. The Company lacks 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 share-based awards based on the grant date fair value of the awards.

Net Loss Per Share

Basic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during each period. Diluted net loss per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as convertible promissory notes, preferred stock, warrants and share-based awards, which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of common stock outstanding, as they would be anti-dilutive:

	June 30,	
	2022	2021
Series Seed convertible preferred stock	—	2,624,324
Series A convertible preferred stock	—	2,212,543
Stock options	1,366,749	436,437
Unvested restricted stock awards	—	39,659
Warrants	5,860,000	368,839
	7,226,749	5,681,802

Amounts in the above table reflect common stock equivalents.

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

condensed 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 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 condensed 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 for 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:

	June 30, 2022			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Financial assets				
Cash equivalents (Money Market Accounts)	$ 42,783,308	$ 42,783,308	$ —	$ —

	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)
Financial assets				
Cash equivalents (Money Market Accounts)	$ 49,051,061	$ 49,051,061	$ —	$ —

(5) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	June 30, 2022	December 31, 2021
Compensation and benefits	$ 398,218	$ 436,990
Research and development costs	1,525,735	339,072
Professional fees	26,981	345,530
Other	50,069	85,529
Total	$ 2,001,003	$ 1,207,121

(6) Convertible Promissory Notes and Other Debt

Senior Convertible Notes

The Company previously issued certain convertible promissory notes (the “Junior Convertible Notes”) to various investors which were converted into Senior Convertible Notes (the “Senior Convertible Notes”) collectively, (the “Convertible Promissory Notes”).

All of the outstanding principal and accrued but unpaid interest associated with the Senior Convertible Notes converted into 844,824 shares of Series A Stock in February 2021, of which 430,467 shares were issued to the Company's Chief Executive Officer and an immediate family member (the "Related Party"). Due to certain embedded features within the Senior Convertible 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 Senior Convertible Notes was $5.7 million and was reclassified to Series A convertible preferred stock. The Company recorded a non-cash credit of $9,000 in the condensed consolidated statement of operations for the six months ended June 30, 2021 related to the decrease in fair value of the Senior Convertible Notes. For the three and six months ended June 30, 2021, the Company recognized $46,000 of interest expense in connection with the Senior Convertible Notes, including $23,000 payable to the Related Party, respectively.

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 the 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. At June 30, 2021, the outstanding principal balance of the Loan was approximately $124,000. The entire PPP Loan was forgiven in July 2021.

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

Series A convertible preferred stock and Series Seed convertible preferred 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 share 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

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 during the year ended December 31, 2021 and was also reflected as a liability on the condensed consolidated balance sheet as of December 31, 2021. The liability was reclassified into additional paid-in capital in March 2022 upon the issuance of the warrants.

At June 30, 2022, the Company had the following warrants outstanding to acquire common stock:

	Outstanding		Exercise price	Expiration dates
Issued in connection with 2021 IPO	250,000	$	6.25	October 2026
Issued in connection with 2021 private placement	5,250,000	$	6.25	June 2027
Issued in 2022 for consulting services	360,000	$	10.00	December 2027
	5,860,000			

(8) Share-based Compensation

In April 2021, the Company 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 ("RSUs") 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 June 30, 2022, 521,290 shares remained available for future grants.

Share-based awards generally vest over a period of one to four years, and share-based awards that lapse or are forfeited are available to be granted again. The contractual life of all share-based awards is ten years. The expiration dates of the outstanding share-based awards range from January 2028 to June 2032.

The Company measures share-based awards at their grant-date fair value and records compensation expense on a straight-line basis over the service period of the awards. Share-based compensation is allocated to employees and consultants based on their respective departments. All board of directors' compensation is charged to general and administrative expense.

Share-based compensation expense related to the issuance of stock options was as follows for the three and six months ended June 30, 2022 and 2021:

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Research and development	$ 26,947	$ 18,963	$ 59,907	$ 38,902
General and administrative	214,377	89,507	396,375	90,749
	$ 241,324	$ 108,470	$ 456,282	$ 129,651

The weighted average assumptions used in the Black-Scholes option pricing model to determine the fair value of share-based awards granted to employees during the six months ended June 30, 2022 and 2021, respectively, were as follows:

	2022	2021
Expected stock price volatility	86.96%	97.50%
Risk-free interest rate	2.14%	1.03%
Expected term (in years)	5.96	5.77
Expected dividend yield	—	—

The following table summarizes the share-based award activity for the periods presented:

	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)
Outstanding at January 1, 2022	506,691	$ 5.68	9.3
Granted	860,058	$ 1.85	
Outstanding at June 30, 2022	1,366,749	$ 3.27	9.4
Vested and exercisable at June 30, 2022	226,492	$ 6.21	8.7
Vested and expected to vest at June 30, 2022	1,366,749	$ 3.27	9.4

The weighted average fair value of share-based awards granted during the six months ended June 30, 2022 and 2021 was $1.36 and $3.76, respectively. As of June 30, 2022, the unrecognized compensation cost related to outstanding share-based awards was $2.2 million and is expected to be recognized as expense over a weighted-average period of approximately 1.77 years.

Restricted Stock Units

The Company issues RSUs 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 Company recorded share-based compensation expense of approximately $11,000 and $15,000 in research and development expense for the three and six months ended June 30, 2021, respectively, related to RSUs. There were no RSUs outstanding as of June 30, 2022 or December 31, 2021.

(9) Commitments and Contingencies

Operating Lease

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.

As of June 30, 2022, the operating lease right-of-use asset and the operating lease liabilities were $0.1 million and $0.1 million, respectively. The weighted average discount rate used to account for the Company's operating leases under Topic 842 is the

Company's estimated incremental borrowing rate of 5.0%. The remaining term of the Company's noncancellable operating lease is 1.08 years.

Rent expense related to the Company's operating lease was approximately $23,000 and $38,000 for the three and six months ended June 30, 2022, respectively. The Company recognizes rent expense on a straight-lined basis over the lease period and accrues for rent expense incurred but not yet paid.

Future minimum lease payments under the sublease are $0.1 million at June 30, 2022.

Employee Benefit Plans

In the first quarter of 2022, the Company established a defined contribution 401(k) plan in which employees may contribute up to 100% of their salary and bonus, subject to statutory maximum contribution amounts. The Company contributes a safe harbor minimum contribution equivalent to 3% of employees' compensation. The Company generally assumes all administrative costs of the plan. For the three and six months ended June 30, 2022, the Company provided contributions of approximately $17,000 and $42,000, respectively.

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 paid Tyligand $0.8 million and issued 111,576 warrants to purchase shares of common stock at an exercise price of $7.17 per share upon successful completion of the manufacturing development plan in 2021. The warrants were cancelled in connection with the Company's IPO. In addition, $2.0 million will be payable upon the completion of scale-up of the first cumulative 100 kilograms of the Good Manufacturing Practices ("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.

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 ("BsAb") 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 remaining development and regulatory milestone payments totaling up to $54.8 million, sales milestone payments totaling up to $130.0 million, and tiered royalties of up to 12% of net sales of certain products developed under this agreement. In the second

quarter of 2022, the Company expensed $0.5 million in acquired in-process research and development related to a development milestone achieved under the agreement with Integral.

Research and Development Arrangements

In the course of normal business operations, the Company enters into agreements with universities and contract research organizations to assist in the performance of research and development activities and contract manufacturers to assist with chemistry, manufacturing, and controls related expenses. Expenditures to contract research organizations represent a significant cost in clinical development for the Company. The Company could also enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which *may* require upfront payments and long-term commitments of cash.

(10) Subsequent Event

On August 1, 2022, the Company entered into a Clinical Trial Collaboration and Supply Agreement (the “Menarini Agreement”) with Berlin-Chemie AG - Menarini Group - (“Menarini”). Pursuant to the Menarini Agreement, Menarini will provide, at no cost to the Company, elacestrant, its nonsteroidal combined selective estrogen receptor modulator and selective estrogen receptor degrader therapy, for use in combination with the Company’s investigational drug, ONA-XR, in a planned Phase 1/2 clinical trial (the “Menarini Study”). Under the Menarini Agreement, the Company will sponsor, fund and conduct the Menarini Study. There are no development, regulatory or sales milestone payments that would be owed under the Menarini Agreement. All inventions generated under the Menarini Study related to the combined use of each company’s compounds will be jointly owned by both parties

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and other financial information included in this report and our audited consolidated financial statements and related notes thereto and management's discussion and analysis of financial condition and results of operations included in our Annual Report on Form 10-K for the year ended December 31, 2021 as filed with the Securities and Exchange Commission ("SEC"), on March 23, 2022. In addition to historical information, the following discussion contains a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risks referred to under Part I, Item 1A. "Risk Factors" of our Annual Report on Form 10-K. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

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 most advanced 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 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.

On August 1, 2022, we entered into a Clinical Trial Collaboration and Supply Agreement (the "Menarini Agreement") with Berlin-Chemie AG - Menarini Group - ("Menarini"). Pursuant to the Menarini Agreement, Menarini will provide, at no cost to us, elacestrant, its nonsteroidal combined selective estrogen receptor modulator and selective estrogen receptor degrader therapy, for use in combination with our investigational drug, ONA-XR, in a planned Phase 1/2 clinical trial (the "Menarini Study"). Under the Menarini Agreement, we will sponsor, fund and conduct the Menarini Study. Under the Menarini Agreement, Menarini has agreed to manufacture and supply elacestrant at Menarini's cost and for no charge to us for use in the Menarini Study and to provide cell-free nucleic acid analysis of the anonymized blood samples of all Menarini Study patients. We will own any data and sample testing results produced in the Menarini Study. We and Menarini will jointly own any rights to inventions relating to the combined use of elacestrant and ONA-XR, while Menarini will own certain inventions solely related to elacestrant and we will own certain inventions solely related to ONA-XR. Additionally, should the Menarini Study be successful such that we or Menarini desire to pursue a Phase 3 study, the other party would be obligated to use commercially reasonable efforts to provide a reasonable supply of such study drug for a Phase 3 study at a reasonable cost. We and Menarini will form a joint development committee responsible for coordinating all activities between the parties under the Menarini Agreement. Additionally, should we receive a bona-fide third-party offer to sell, divest or license ONA-XR, we shall, subject to certain exceptions, inform Menarini of the receipt of an offer and, if Menarini timely provides proposed terms for such a transaction in writing, we shall consider such terms in good faith.

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 the fourth quarter of 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 (leterozole) 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-2023. 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 fourth quarter 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 PIK3α inhibitors, and preliminary data is expected in the fourth quarter of 2022. In

2022, WON initiated a sub-study of its Phase 2 trial in 2L/3L metastatic breast cancer that evaluates the uptake of radiolabeled progesterone (F-FFNP) via positron emission tomography (PET) imaging in breast tumors.

Our second program, CLDN6xCD3 BsAb, is an anti-CD3 x anti-Claudin 6 ("CLDN6") antigen bispecific monoclonal antibody ("BsAb") 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 reached the first development milestone under our collaboration and license agreement with Integral Molecular in the second quarter of 2022 and expect to select a candidate to support Investigational New Drug-enabling studies for CLDN6xCD3 BsAb in the fourth quarter of 2022. Beyond these two product candidates, we continue to evaluate opportunities to expand our pipeline.

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 issuance of convertible debt, convertible preferred stock and sale of common stock. Our net loss was $7.4 million for the six months ended June 30, 2022. As of June 30, 2022, we had an accumulated deficit of $36.7 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 the fourth quarter of 2023. Currently, our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures as well as 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 IPO, 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 ongoing and planned 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 most advanced product candidate ONA-XR;
- continue nonclinical studies and initiate clinical trials for our CLDN6 BsAb 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, including related upfront, milestone and royalty payments;
- 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 our 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 our ability to enroll patients. These situations, or others associated with COVID-19, could cause delays in our clinical trial plans and could increase expected costs, all of which could have a material adverse effect on our business and financial condition. At the current time, we are unable to quantify the potential effects of this pandemic on our future consolidated financial statements.

Components of Our Results of Operations

Operating Expenses

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 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 ("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 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 Income

Interest income consists of interest earned on our cash equivalents.

Interest Expense

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

Results of Operations

Comparison of the Three Months Ended June 30, 2022 and 2021

The following table sets forth our results of operations for the three months ended June 30, 2022 and 2021:

	Three months ended June 30			
	2022	2021	$ Change	% Change
Operating expenses:				
Acquired in-process research and development	$ 500,000	$ 3,087,832	$ (2,587,832)	-84 %
Research and development	1,517,243	1,333,101	184,142	14 %
General and administrative	1,990,568	604,602	1,385,966	229 %
Loss from operations	(4,007,811)	(5,025,535)	1,017,724	-20 %
Interest income (expense), net	21,296	(309)	21,605	-6992 %
Other income (expense)	4	(4,320)	4,324	-100 %
Net loss	$ (3,986,511)	$ (5,030,164)	$ 1,043,653	-21 %

Acquired In-Process Research and Development Expenses

Acquired in-process research and development expense of $0.5 million for the three months ended June 30, 2022 reflects the expense recognized related to a development milestone achieved in the second quarter of 2022 under the collaboration and licensing agreement with Integral Molecular, Inc. (“Integral”) for the development of CLDN6 BsAb for gynecologic cancer therapy.

Acquired in-process research and development expense of $3.1 million for the three months ended June 30, 2021 reflects the fair value of the initial consideration paid/issued under the collaboration and license agreement with Integral for the development of CLDN6 BsAb for gynecologic cancer therapy.

Research and Development Expenses

Research and development expenses increased by approximately $0.2 million for the three months ended June 30, 2022 as compared to the same period in 2021. The following table summarizes our research and development expenses for the three months ended June 30, 2022 as compared to the same period in 2021:

	Three months ended June 30			
	2022	2021	$ Change	% Change
ONA-XR	$ 1,000,098	$ 791,475	$ 208,623	26 %
CLDN6	71,989	308,000	(236,011)	(77)%
Personnel-related costs	417,688	222,642	195,046	88 %
Other research and development	27,468	10,984	16,484	150 %
	$ 1,517,243	$ 1,333,101	$ 184,142	14 %

The increase in ONA-XR expense of $0.2 million was primarily due to increases in contract manufacturing costs and clinical trial costs. Expenses associated with our CLDN6 program decreased from the prior period by $0.2 million primarily as a result of lower research fees incurred under the collaboration and license agreement with Integral. Personnel-related costs, which include salaries, benefits and stock compensation expense, increased by approximately $0.2 million primarily due to higher headcount over the prior year period.

General and Administrative Expenses

General and administrative expenses increased by approximately $1.4 million for the three months ended June 30, 2022 as compared to the same period in 2021. The increase was mainly due to an increase of $0.6 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 $0.7 million primarily due to higher insurance costs of $0.4 million and other costs associated with operating as a public company.

Interest Income (Expense), net

Interest income (expense), net, increased by approximately $22,000 for the three months ended June 30, 2022 as compared to the same period in 2021 primarily due to higher interest income earned as a result of higher cash and cash equivalent balances and higher interest rates.

Comparison of the Six Months Ended June 30, 2022 and 2021

The following table sets forth our results of operations for the six months ended June 30, 2022 and 2021:

	Six months ended June 30,			
	2022	**2021**	**$ Change**	**% Change**
Operating expenses:				
Acquired in progress research and development	$ 500,000	$ 3,087,832	$ (2,587,832)	-84 %
Research and development	2,868,738	1,771,840	1,096,898	62 %
General and administrative	4,082,035	1,006,181	3,075,854	306 %
Loss from operations	(7,450,773)	(5,865,853)	(1,584,920)	27 %
Interest income (expense), net	27,160	(63,294)	90,454	-143 %
Change in fair value of convertible promissory notes	—	9,317	(9,317)	-100 %
Other expense	(1,235)	(2,383)	1,148	-48 %
Net loss	$ (7,424,848)	$ (5,922,213)	$ (1,502,635)	25 %

Acquired In-Process Research and Development Expenses

Acquired in-process research and development expense of $0.5 million for the six months ended June 30, 2022 reflects the expense recognized related to a development milestone achieved in the second quarter of 2022 under the collaboration and licensing agreement with Integral for the development of CLDN6 BsAb for gynecologic cancer therapy.

Acquired in-process research and development expense of $3.1 million for the six months ended June 30, 2021 reflects the fair value of the initial consideration paid/issued under the collaboration and licensing agreement with Integral for the development of CLDN6 BsAb for gynecologic cancer therapy.

Research and Development Expenses

Research and development expenses increased by approximately $1.1 million for the six months ended June 30, 2022 as compared to the same period in 2021. The following table summarizes our research and development expenses for the six months ended June 30, 2022 as compared to the same period in 2021:

	Six months ended June 30			
	2022	**2021**	**$ Change**	**% Change**
ONA-XR expenses	$ 1,861,409	$ 1,041,253	$ 820,156	79 %
CLDN6 expenses	152,960	309,238	(156,278)	(51)%
Personnel-related costs	770,028	353,346	416,682	118 %
Other research and development	84,341	68,003	16,338	24 %
	$ 2,868,738	$ 1,771,840	$ 1,096,898	62 %

The increase in ONA-XR expense of $0.8 million was primarily due to increases in contract manufacturing costs and clinical trial costs. Expenses associated with our CLDN6 program decreased from the prior period by $0.2 million primarily as a result of lower research fees incurred under the collaboration and license agreement with Integral. Personnel-related costs, which include salaries, benefits and stock compensation expense, increased by approximately $0.4 million primarily due to higher headcount over the prior year.

General and Administrative Expenses

General and administrative expenses increased by approximately $3.1 million for the six months ended June 30, 2022 as compared to the same period in 2021. The increase was mainly due to an increase of $1.4 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 $0.8 million, professional fees and consulting services of $0.5 million, and other costs associated with operating as a public company.

Interest Income (Expense), net

Interest income (expense), net, increased by approximately $0.1 million for the six months ended June 30, 2022 as compared to the same period in 2021 primarily due to higher interest income earned as a result of higher cash and cash equivalent balances and higher interest rates. In addition, interest expense was lower for the six months ended June 30, 2022 due to the conversion of all convertible promissory notes during 2021.

Change in Fair Value of Convertible Promissory Notes

The change in fair value of convertible promissory notes was $9,000 for the six months ended June 30, 2021. This change was attributable to a decrease in the fair value of our common stock.

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 June 30, 2022, we have funded our operations through the sale of convertible debt, convertible preferred stock and common stock. As of June 30, 2022, we had $42.9 million in cash and cash equivalents and had an accumulated deficit of $36.7 million.

In October 2021, we closed an 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 the fourth quarter of 2023. 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 additional 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, the ownership interests of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. 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:

	Six months ended June 30,	
	2022	**2021**
Cash used in operating activities	$ (6,625,465)	$ (3,794,170)
Cash used in investing activities	(36,836)	(250,000)
Cash (used in) provided by financing activities	(102,071)	4,982,835
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (6,764,372)	$ 938,665

Comparison of the Six Months Ended June 30, 2022 and 2021

Operating Activities

During the six months ended June 30, 2022, we used $6.6 million of cash in operating activities. Cash used in operating activities reflected our net loss of $7.4 million and a change in our operating assets and liabilities of $0.2 million. This was partially offset by non-cash in-process research and development charges of $0.5 million and non-cash 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 six months ended June 30, 2021, we used $3.8 million of cash in operating activities. Cash used in operating activities reflected our net loss of $5.9 million and an increase in our operating assets and liabilities of $1.5 million. This was offset by non-cash in-process research and development charges of $3.1 million, the non-cash fair value measurement of warrants for services provided of $0.4 million and non-cash interest expense and share-based compensation of $0.2 million. The primary uses of cash were to fund our operations related to the development of our product candidates and fees incurred in connection with our IPO.

Investing Activities

During the six months ended June 30, 2022, we used $37,000 of cash to purchase property and equipment.

During the six months ended June 30, 2021, cash used in investing activities was attributable to the initial upfront license fee of $0.3 million related to our acquired in-process research and development.

Financing Activities

During the six months ended June 30, 2022, cash used in financing activities was $0.1 million, consisting of the payment of offering costs related to our December 2021 private placement.

During the six months ended June 30, 2021, financing activities provided $5.0 million, consisting of net proceeds from the sale of Series A preferred stock and warrants for common stock.

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

During the three and six months ended June 30, 2022, there were no material changes to our critical accounting policies and estimates from those described in our Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the SEC on March 23, 2022.

Recent Accounting Pronouncements

See Note 3 to our unaudited condensed consolidated financial statements found elsewhere in this Quarterly Report for a description of recent accounting pronouncements applicable to our condensed consolidated financial statements.

Emerging Growth Company and Smaller Reporting Company Status

In April 2012, the Jumpstart Our Business Startups Act of 2012 (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.

We also rely on other exemptions and reduced reporting requirements under the JOBS Act, including without limitation, exemption from the requirements to provide an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. We will remain an emerging growth company until the earlier to occur of (a) the last day of the fiscal year (i) following the fifth anniversary of the completion of our IPO (December 31, 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 Securities Exchange Act of 1934, as amended (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 plus the aggregate amount of gross proceeds to us as a result of our IPO is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if 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 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined in Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this Item 3.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our disclosure controls and procedures as of June 30, 2022, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – Other Information

Item 1. 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 1A. Risk Factors

Investing in our common stock involves a high degree of risk. In addition to the other information set forth in this quarterly report on Form 10-Q, you should carefully consider the factors described under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 23, 2022. There have been no material changes to the risk factors described in that report. The occurrence of any of the events or developments described in our Risk Factors could adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Exhibit No.	Exhibit Description
3.1	Amended & 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).
3.2	Amended and 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).
10.1*†	Amendment No. 2 to Consulting Agreement, dated June 17, 2022, between OncoStrategy, LLC and Context Therapeutics Inc.
10.2#	Clinical Trial Collaboration and Supply Agreement, dated August 1, 2022, by and between Context Therapeutics Inc. and Berlin-Chemie AG - Menarini Group
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.
32.1*+	Certification Pursuant to 18 U.S.C. Section 1350 of principal executive officer and principal financial officer.
101*	The following financial statements from Context Therapeutics Inc.'s Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2022, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets; (ii) Condensed Consolidated Statements of Operations; (iii) Condensed Consolidated Statement of Changes in Convertible Preferred Stock, Redeemable Common Stock and Stockholders' Deficit; (iv) Condensed Consolidated Statement of Changes in Stockholders' Equity; (v) Condensed Consolidated Statements of Cash Flows; and (vi) Notes to the Condensed Consolidated Financial Statements.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101 hereto)

* Filed herewith
† Executive Compensation Plan or Agreement
# Certain confidential information contained in this agreement has been omitted because it is both not material and is the type that the registrant treats as private or confidential

+ 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 Exchange Act, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: August 11, 2022

CONTEXT THERAPEUTICS INC.

By: /s/ Martin Lehr

Martin Lehr

Chief Executive Officer (Principal Executive Officer)

By: /s/ Jennifer Minai-Azary

Jennifer Minai-Azary

Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

AMENDMENT NO. 2 TO CONSULTING AGREEMENT

This **AMENDMENT NO. 2 TO CONSULTING AGREEMENT** (this "***Amendment***") is entered into as of the 17th day of June 2022, but effective as of the 1st day of June, 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, as amended by that Amendment No. 1 to Consulting Agreement effective as of February 1, 2022 (collectively, 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 amend the compensation for services and extend the term 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**.

   a. Section 3(a) of the Agreement shall be amended and restated as follows: "(a) **Term**. The term during which Consultant shall provide the Consulting Services hereunder (the "Term") shall commence on the date hereof and continue in full force and effect until June 30, 2024 unless earlier terminated in accordance with Section 3(b); provided, however, that the Term may be extended by written agreement of the parties."

   b. Effective as of the Amendment Effective Date, from the Amendment Effective Date through the end of the Term (as amended by this Amendment), Provider shall receive $20,000 per calendar month in arrears, provided that Consultant provides on average approximately 40 hours of Consulting Services (as defined in the Agreement) 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 is 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.

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

PROVIDER:

OncoStrategy, LLC

By: /s/ Tarek Sahmoud
Name: Tarek Sahmoud
Title: Principal & Founder

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT

This CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT (this "**Agreement**"), made as of 1 August, 2022 (the "**Effective Date**"), is by and between Context Therapeutics Inc., having a place of business at 2001 Market Street, Suite 3915, Unit# 15, Philadelphia, PA 19103 USA ("**Context**"), and Berlin-Chemie AG - Menarini Group, having a place of business at Glienicker Weg 125,12489 Berlin, Germany ("**Menarini**"). Context and Menarini are each referred to herein individually as a "Party" and collectively the "Parties".

RECITALS

A. Context owns or otherwise controls and is developing the Context Compound (as defined below) for the treatment of certain tumor types.

B. Menarini owns or otherwise controls and is developing the Menarini Compound (as defined below) for the treatment of certain tumor types.

C. Context desires to sponsor one or more clinical trials in which the Menarini Compound and the Context Compound would be dosed in combination.

D. Context and Menarini, consistent with the terms of this Agreement, desire to collaborate as more fully described herein, including by Menarini providing the Menarini Compound for the Study (as defined below).

E. Menarini grants Elacestrant License to Context under the conditions and restrictions of Elacestrant License Agreements and Context hereby agrees to abide by the conditions and restrictions of Elacestrant License Agreements.

NOW, THEREFORE, in consideration of the premises and of the following mutual promises, covenants and conditions, the Parties, intending to be legally bound, mutually agree as follows:

1. Definitions

For all purposes of this Agreement, the capitalized terms defined in this Article 1 and throughout this Agreement shall have the meanings herein specified.

1.1 "**Adverse Event**" (also known as "**AE**") means any untoward medical occurrence in a patient after administration of a pharmaceutical product, which does not necessarily have to have a causal relationship with Study treatment as further defined in the Pharmacovigilance Agreement.

1.2 "**Affiliate**" means, with respect to either Party, a firm, corporation or other entity which directly or indirectly owns or controls said Party, or is owned or controlled by said Party, or is under common ownership or control with said Party. The word "**control**" means (i) the direct or indirect ownership of fifty percent (50%) or more of the outstanding voting securities of a legal entity, or (ii) possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities, contract rights, voting rights, corporate governance or otherwise.

1.3 "**Agreement**" means this agreement, as amended by the Parties from time to time, and as set forth in the preamble.

1.4 "**Alliance Manager**" has the meaning set forth in Section 3.11.

1.5 "**Applicable Law**" means all federal, state, local, national and regional statutes, laws, rules, regulations and directives in the Territory applicable to a particular activity hereunder, including performance of clinical trials, medical treatment and the processing and protection of personal and medical data, that may be in effect from time to time, including those promulgated by the United States Food and Drug Administration ("**FDA**"), national regulatory authorities, the European Medicines Agency ("**EMA**") and any successor agency to the FDA or EMA or any agency or authority performing some or all of the functions of the FDA or EMA in any jurisdiction outside the United States or the European Union (each a "Regulatory Authority" and collectively, "**Regulatory Authorities**"), and including without limitation cGMP and GCP (each as defined below); all data protection requirements such as those specified in the EU General Data Protection Regulation 2016/679 and the regulations issued under the United States Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**"); export control and economic sanctions regulations which prohibit the shipment of United States-origin products and technology to certain restricted countries, entities and individuals; anti-bribery and anti-corruption laws pertaining to interactions with government agents, officials and representatives; laws and regulations governing payments to healthcare providers; and any United States or other country's or jurisdiction's successor or replacement statutes, laws, rules, regulations and directives relating to the foregoing.

1.6 "**Business Day**" means any day other than a Saturday, Sunday, or any public holiday in the country where the applicable obligations are to be performed.

1.7 "**Calendar Quarter**" means a three-month period beginning on January 1st, April 1st, July 1st, or October 1st.

1.8 "**Calendar Year**" means a one-year period beginning on January 1st and ending on December 31st.

1.9 "**cGMP**" means the current Good Manufacturing Practices officially published and interpreted by EMA, FDA and other applicable Regulatory Authorities that may be in effect from time to time and are applicable to the Manufacture of the Compounds.

1.10 "**Clinical Data**" means all data (including raw data) and results generated under the Study, other than Sample Testing Results.

1.11 "**Commercially Reasonable Efforts**" means the level of efforts and resources required to perform obligations under this Agreement in a sustained manner consistent with the efforts that a similarly situated pharmaceutical company would typically devote to its respective obligations under this Agreement, a study of similar potential at a similar stage of compounds development, profit potential or strategic value resulting from its own research efforts, based on conditions then prevailing.

1.12 "**Compounds**" means the Context Compound and the Menarini Compound. A "**Compound**" means the Context Compound or the Menarini Compound, as applicable.

1.13 "**Combination**" means the use or method of using the Menarini Compound and the Context Compound in concomitant or sequential administration but always administered as separate compounds.

1.14 "**Confidential Information**" means any information, Know-How or other proprietary information or materials furnished to one Party by or on behalf of the other Party pursuant to this Agreement, except to the extent that such information or materials: (a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party, as demonstrated by competent evidence; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party; (c) became generally available to the public or otherwise part of the

public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; (d) was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others; or (e) was subsequently developed by the receiving Party without use of the Confidential Information, as demonstrated by competent evidence.

1.15 "**Context**" has the meaning set forth in the preamble.

1.16 "**Context Compound**" means ONA-XR (onapristone extended-release formulation) to be provided as 10mg and 20mg film coated extended release tablets packaged in high-density polyethylene bottles and closures, with 60 tablets per bottle, with clinical use labels (or in such other form as Context reasonably deems appropriate for the Study).

1.17 "**Continuing Party**" has the meaning set forth in Section 10.1.2.

1.18 "**CTA**" means an application to a Regulatory Authority for purposes of requesting the ability to start or continue a clinical trial.

1.19 "**Data Sharing and Sample Testing Schedule**" means the schedule attached hereto as Schedule I.

1.20 "**Defending Party**" has the meaning set forth in Section 14.2.3.

1.21 "**Disposition Package**" has the meaning set forth in Section 8.7.1.

1.22 "**Dispute**" has the meaning set forth in Section 21.1.

1.23 "**Effective Date**" has the meaning set forth in the preamble.

1.24 "**Eisai**" means Eisai Co., Ltd., a corporation organized and existing under the laws of Japan, with its registered office at 6-10 Koishikawa 4-chome, Bunkyo-ku, Tokyo, 112-8088, Japan.

1.25 "**Elacestrant License**" means a license granted under the Elacestrant License Agreements.

1.26 "**Elacestrant License Agreements**" collectively means (a) License Agreement entered into by and between Eisai Co. Ltd. and Radius Health, Inc., dated June 29, 2006 and amended on February 26, 2015, and (b) License Agreement entered into by and between Radius Pharmaceuticals, Inc. and Berlin-Chemie AG – Menarini Group, dated July 23, 2020.

1.27 **"EMA**" has the meaning set forth in the definition of Applicable Law.

1.28 "**FDA**" has the meaning set forth in the definition of Applicable Law.

1.29 "**Filing Party**" has the meaning set forth in Section 10.1.2.

1.30 "**First Party**" has the meaning set forth in Section 8.17.

1.31 **"Further Transaction"** means any sale, divestment (or any other form of disposal) or license by Context to a Third Party to manufacture, develop, promote, distribute, market or sell the Context Compound or product containing the Context Compound, with respect to one or more of the countries of the world, where such transaction or deal solely involves the Context Compound (and any combination product containing the Context Compound, which combination is under Context control); provided for the purposes of clarity, the following shall not be considered a Further Transaction: (i) a sale, merger or similar transaction involving Context, as a company, to a Third Party, and (ii) the subcontracting or grant of a license to a contract manufacturer, contract salesforce organization (CSO) services, or a contract research organization for the purpose of researching, developing, manufacturing or promoting (using a CSO) the Context Compound for Context, or (iii) pre-clinical studies and clinical trials not otherwise restricted by the last sentence of Section 2.6(B).

1.32 "**GCP**" means the Good Clinical Practices officially published by EMA, FDA and the International Conference on Harmonisation of Technical Requirements for Registration of

Pharmaceuticals for Human Use (ICH) that may be in effect from time to time and are applicable to the clinical testing of the Compounds.

1.33 "**Government Official**" means: (a) any officer or employee of a government or any department, agency or instrument of a government; (b) any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (c) any officer or employee of a company or business owned in whole or part by a government; (d) any officer or employee of a public international organization such as the World Bank or United Nations; (e) any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or (f) any candidate for political office; who, when such Government Official is acting in an official capacity, or in an official decision-making role, has responsibility for performing regulatory inspections, government authorizations or licenses, or otherwise has the capacity to take decisions with the potential to affect the business of either of the Parties.

1.34 "**HIPAA**" has the meaning set forth in the definition of Applicable Law.

1.35 "**IND**" means the Investigational New Drug Application filed or to be filed with the FDA as described in Title 21 of the U.S. Code of Federal Regulations, Part 312, and the equivalent application in the jurisdictions outside the United States, including an "Investigational Medicinal Product Dossier" filed or to be filed with the Regulatory Authorities in the European Union.

1.36 "**Inventions**" means all inventions and discoveries, whether or not patentable, which are made or conceived in the performance of the Study and/or which are made or conceived by a Party through use of the Clinical Data or Sample Testing Results.

1.37 "**Joint Development Committee**" or "**JDC**" has the meaning set forth in Section 3.11.

1.38 "**Jointly Owned Invention**" has the meaning set forth in Section 10.1.1.

1.39 "**Joint Patent Application**" has the meaning set forth in Section 10.1.2.

1.40 "**Joint Patent**" means a patent that issues from a Joint Patent Application.

1.41 "**Know-How**" means any proprietary invention, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, including manufacturing, use, process, structural, operational and other data and information, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable, that is not generally known or otherwise in the public domain.

1.42 "**Liability**" has the meaning set forth in Section 14.2.1.

1.43 "**Manufacture**," "**Manufactured**," or "**Manufacturing**" means all stages of the manufacture of a Compound, including planning, purchasing, manufacture, processing, compounding, storage, filling, packaging, waste disposal, labeling, leafleting, testing, quality assurance, sample retention, stability testing, release, dispatch, and supply, as applicable.

1.44 "**Manufacturer's Release**" **or** "**Release**" means the formal quality operations of a material. Subsequent to release, a material may be used in further processing.

1.45 "**Manufacturing Costs**" means the costs of Manufacturing the applicable Compound, as calculated consistent with GAAP or IFRS and include [***].

1.46 "**Manufacturing Site**" means the facilities where a Compound is Manufactured by or on behalf of a Party, as such Manufacturing Site may change from time to time in accordance with Section 8.6 (Changes to Manufacturing).

1.47 "**Menarini**" has the meaning set forth in the preamble.

1.48 "**Menarini Compound**" means elacestrant 400 mg and 100 mg tablets, packaged in high-density polyethylene bottles with 30 tablets each without clinical trial medication label.

1.49 "**Non-Conformance**" means, with respect to a given unit of Compound an event that deviates from an approved cGMP requirement with respect to the applicable Compound, such as a procedure, Specification, or operating parameter, or that requires an investigation to assess impact to the quality of the applicable Compound

1.50 "**Non-filing Party**" has the meaning set forth in Section 10.1.2.

1.51 "**Opting-out Party**" has the meaning set forth in Section 10.1.2.

1.52 "**Other Party**" has the meaning set forth in Section 14.2.3.

1.53 "**Party**" has the meaning set forth in the preamble.

1.54 "**Permitted Use**" has the meaning set forth in Section 3.10.

1.55 "**Pharmacovigilance Agreement**" means that certain pharmacovigilance agreement entered into by the Parties prior to the initiation of the Study and regarding the Compounds and incorporated herein by reference.

1.56 "**Project Manager**" has the meaning set forth in Section 3.11.

1.57 "**Protocol**" means the written documentation that describes the Study and sets forth specific activities to be performed as part of the Study conduct, a summary of which is attached hereto as Appendix A.

1.58 "**Quality Agreement**" means that certain quality agreement as shall be entered into by the Parties prior to the commencement of the Study regarding the Menarini Compound and incorporated herein by reference.

1.59 "**Regulatory Approvals**" means any and all permissions (other than the Manufacturing approvals) required to be obtained from Regulatory Authorities and any other competent authority for the development, registration, importation, use (including in clinical trials), distribution, sale and marketing of a Compound in the United States, Europe, or other applicable jurisdictions for use in humans, including any pricing or reimbursement approvals.

1.60 "**Regulatory Authorities**" has the meaning set forth in the definition of Applicable Law.

1.61 "**Related Agreements**" means the Pharmacovigilance Agreement and the Quality Agreement.

1.62 "**Samples**" means urine, blood and tissue samples taken, in accordance with the Protocol, from patients participating in the Study.

1.63 "**Sample Testing**" means the analyses to be performed by Context in accordance with the Protocol using the applicable Samples.

1.64 "**Sample Testing Results**" means those results arising from the Sample Testing which are to be shared between Context and Menarini, as set forth in the Data Sharing and Sample Testing Schedule.

1.65 "**Second Party**" has the meaning set forth in Section 8.17.

1.66 "**Specifications**" means, with respect to a given Compound, the set of requirements for such Compound as set by each Party.

1.67 "**Study**" means the open-label, phase 1b-2 study of **EL**acestrant, in combination with **ONA**pristone in patients with advanced or metastatic estrogen receptor-positive, progesterone receptor-positive, HER2-negative breast cancer (**ELONA**), as further described in the Study Synopsis set forth in Appendix A hereto.

1.68 "**Study Completion**" has the meaning set forth in Section 3.8.

1.69 "**Sunshine Laws**" means Applicable Laws requiring collection, reporting and disclosure of POTVs to certain healthcare providers, entities and individuals. These Applicable Laws may include relevant provisions of the Patient Protection and Affordable Health Care Act of 2010 and implementing regulations thereunder.

1.70 "**Territory**" means anywhere in the world.

1.71 "**Third Party**" means any person or entity other than Menarini, Context or their respective Affiliates.

1.72 "**VAT**" "has the meaning set forth in Section 8.16.

2. Scope of the Agreement

2.1 Each Party shall contribute to the Study as set forth in this Agreement.

2.2 Each Party agrees to act in good faith in performing its obligations under this Agreement and each Related Agreement and shall notify the other Party as promptly as possible in the event of any Manufacturing delay that is likely to adversely affect supply of its Compound or Compounds as contemplated by this Agreement.

2.3 Parties' undertakings with respect to quality of the Compounds.

2.3.1 Menarini agrees to use its Commercially Reasonable Efforts to Manufacture (or have Manufactured) and supply (or have supplied) the Menarini Compound for purposes of the Study as set forth in Article 8, and Menarini hereby represents and warrants to Context that, at the time of Delivery of the Menarini Compound, such Menarini Compound shall: (A) have been Manufactured and supplied in compliance with: (i) the Specifications for the Menarini Compound; (ii) the Quality Agreement; and (iii) all Applicable Law, including cGMP and health, safety, and environmental protections, and (B) shall be free of Non-Conformance.

2.3.2 Context agrees to use its Commercially Reasonable Efforts to Manufacture (or have Manufactured) and deliver (or have delivered) the Context Compound for purposes of the Study and Context hereby represents and warrants to Menarini that, at the time of delivery of the Context Compound to subjects involved in the Study, such Context Compound shall: (A) have been Manufactured and supplied in compliance with: (i) the Specifications for the Context Compound; and (ii) all Applicable Law, including cGMP and health, safety, and environmental protections, and (B) shall be free of Non-Conformance.

2.3.3 Without limiting the foregoing, each Party is responsible for obtaining all regulatory approvals (including facility licenses) that are required to Manufacture its Compounds in accordance with Applicable Law (provided that for clarity, Context shall be responsible for obtaining Regulatory Approvals for the Study as set forth in Section 3.4).

2.4 Each Party shall have the right to delegate or subcontract any portion of its obligations solely related to the Study hereunder: (i) to its own Affiliates, without the other Party's written consent; or (ii) to Third Parties (which, in relation to the manufacture of any additional Menarini Compound or Context Compound after the Effective Date shall be with a reputable manufacturer). Each Party shall remain solely and fully liable for the performance of its subcontractors. Each Party shall ensure that each of its subcontractors performs its obligations pursuant to the terms of this Agreement, including the Appendices attached hereto. Each Party shall use Commercially Reasonable Efforts to obtain and maintain copies of documents relating to the obligations performed by such subcontractors that are held by

or under the control of such subcontractors and that are required to be provided to the other Party under this Agreement.

2.5 Other than as set forth in this Agreement, this Agreement does not create any obligation on the part of Context to provide the Context Compound for any activities other than the Study, nor does it create any obligation on the part of Menarini to provide the Menarini Compound for any activities other than the Study.

2.6 (A) Subject to paragraph (B) below, nothing in this Agreement shall (i) prohibit either Party from performing clinical studies other than the Study relating to its own Compounds, either individually or in combination with any other compound or product, in any therapeutic area, or (ii) create an exclusive relationship between the Parties with respect to any Compound (without prejudice to Section 20.2 below).

(B) Notwithstanding the foregoing, the Parties agree that Context shall not, without the prior written consent of Menarini (which consent shall be at Menarini's sole discretion), include in the Study any additional trial arms which includes any antiestrogen compounds other than the Menarini Compound. In addition, until the earlier of (i) Study completion, (ii) the termination of the Study or this Agreement, (iii) FDA providing a complete response letter ("**CRL**") to the application for approval for the Menarini Compound that does not ultimately lead to approval of the Menarini Compound within six (6) months of such initial CRL, or (iv) Menarini's breach of the terms of this Agreement, Context will not, without the prior written consent of Menarini (which consent shall be at Menarini's sole discretion), conduct a clinical trial in humans with an orally administered selective estrogen receptor degrader, other than the Menarini Compound, in patients with advanced or metastatic estrogen receptor-positive, progesterone receptor-positive, HER2-negative breast cancer.

2.7 Notwithstanding any other section to the contrary in any case, Menarini grants Elacestrant License to Context under the conditions and restrictions of Elacestrant License Agreements. Context hereby agrees to abide by the conditions and restrictions of Elacestrant License Agreements. If there is any discrepancy between the provisions of this Agreement and Elacestrant License Agreements, the provisions of Elacestrant License Agreements shall prevail and apply to the Parties.

3. Conduct of the Study

3.1 Context shall act as the sponsor of the Study and shall hold the IND relating to the Study; provided, however, that in no event shall Context file a separate IND for the Study unless required by Regulatory Authorities to do so. If a Regulatory Authority requests a separate IND for the Study, the Parties will meet to discuss an approach to address such requirement, with Context having final decision-making authority regarding such separate IND, provided that Context shall reasonably consider any input provided by Menarini.

3.2 Prior to the initiation of the Study or as may otherwise be necessary during the course of the Study, either Party shall share with the other Party any information related to the pre-clinical and clinical studies it performed regarding their respective Compound, as may be reasonably requested by the other Party in view of the evaluation of the Study.

3.3 Context agrees that the Study shall be performed in accordance with this Agreement, its obligations under the Related Agreements, the Protocol and all Applicable Law, including GCP, other than any Study activities to be performed by Menarini for which Menarini shall ensure that such Study activities are performed in accordance with this Agreement, its obligations under the Related Agreements, and all Applicable Law, including GCP. In the event that any Regulatory Authority, ethics committee or institutional review board has

questions related to the Protocol or the conduct of the Study that relate to the Menarini Compound, Menarini will provide reasonable assistance in responding to such questions.

3.4 Context agrees that all its Study activities shall be in compliance with all directions from, and that have been agreed with, any Regulatory Authority and/or ethics committee with jurisdiction over the Study. Further, Context shall ensure that all Regulatory Approvals from any Regulatory Authority and/or ethics committee with jurisdiction over the Study are obtained prior to initiating performance of the Study (in particular and to the extent applicable, Context will follow the FDA Guidance on co-development of two or more investigational drugs). Context shall participate in and, if required, lead any and all discussions with any Regulatory Authority regarding the Study, provided, however, that Menarini shall have the right (but no obligation) to participate in any such discussions. Menarini grants to Context a non-exclusive, non-transferable (except in connection with a permitted assignment, sublicense or subcontract) "right of reference" (as defined in 21 CFR 314.3(b)), or similar "right of reference" as defined in applicable regulations in the relevant part of the Territory, with respect to Menarini's Regulatory Approvals for the Menarini Compound, as necessary for Context to prepare, submit and maintain Regulatory Approvals for the Study. Further, Menarini shall provide to Context a cross-reference letter or similar communication to the applicable Regulatory Authority to effectuate such right of reference.

3.5 Notwithstanding anything to the contrary in this Agreement, neither Party shall have any right to access the other Party's CMC Data (as hereinafter defined) with respect to its Compounds unless it is requested or required by the Regulatory Authority. If necessary, each Party shall authorize FDA and other applicable Regulatory Authorities to cross-reference the U.S. and EU Regulatory Approvals of its Compound to provide data access to the other Party solely to the extent necessary to support conduct of the Study. If the cross-references to such Regulatory Approvals are not deemed sufficient by a Regulatory Authority in any given country, then such Party shall file the complete CMC components of the Common Technical Document for its Compound (the "**CMC Data**") with such Regulatory Authority, with a letter of authorization for the other Party to cross-reference the CMC Data for the review of the CTA; however, the other Party shall have no right to directly access the CMC Data. If direct access to CMC Data of the other Party is required for any regulatory filing submission, the Parties will discuss in good faith a potential solution; however in the absence of an agreement, the Parties shall refrain from using the CMC Data for any such filing.

3.6 In addition to the foregoing, Menarini shall use its Commercially Reasonable Efforts to: (i) provide the first tranche of Menarini Compound described in Appendix B to Context no later than [***] days from the written order from Context, and (ii) provide such other documents and information as may be requested by a Regulatory Authority, to the extent such documents and information are reasonably available to Menarini.

3.7 Context shall maintain reports and all related documentation in good scientific manner and in compliance with Applicable Law. Each Party shall provide to the other all Study information and documentation reasonably requested by such other Party to enable it to (i) comply with any of its legal and regulatory obligations, or any request by any Regulatory Authority, in each case, to the extent related to the Study or, subject to Section 3.4 and Section 3.5 above, such Party's Compounds, (ii) conduct the Sample Testing (in the case of Context), (iii) satisfy any contractual obligation to a subcontractor engaged pursuant to Section 2.4, and (iv) in the case of Menarini, determine whether the Study has been performed by Context in accordance with this Agreement.

3.8 Context shall own all Clinical Data. Context hereby grants Menarini a worldwide, perpetual, fully paid up, royalty free, sublicensable limited license to use the Clinical Data and Sample

Testing Results for the Permitted Use as set forth in Section 3.10. Context shall provide to Menarini copies of all Clinical Data, in electronic form or other mutually agreeable alternate form, and on the timelines specified in the Data Sharing\ and Sample Testing Schedule (if applicable) or upon mutually agreeable timelines and a complete copy of the Clinical Data shall be provided to Menarini no later than [***] days following Study Completion. To the extent applicable, each Party shall provide to the other Party with pharmacokinetics data regarding their respective Compounds on the timelines specified in the Data Sharing and Sample Testing Schedule (if applicable) or upon mutually agreeable timelines. "**Study Completion**" shall be deemed to occur upon lock of the Study database. Context shall ensure that all patient authorizations and consents required under HIPAA or any other similar Applicable Law in connection with the Study permit such sharing of Clinical Data with Menarini.

3.9 Subject to Section 3.8, Context shall own all Sample Testing Results, whether the testing is conducted by or on behalf of Context and/or Menarini. Context shall provide to Menarini the Sample Testing Results for the Sample Testing conducted by or on behalf of Context, in electronic form or other mutually agreeable alternate form, and on the timelines specified in the Data Sharing and Sample Testing Schedule or other mutually agreed timelines. Likewise, Menarini shall not perform any Sample Testing without the prior written consent of Context. Menarini shall provide to Context the Sample Testing Results for the Sample Testing conducted by or on behalf of Menarini, in electronic form or other mutually agreeable alternate form, and on the timelines specified in the Data Sharing and Sample Testing Schedule or other mutually agreed timelines.

3.10 Except to the extent otherwise agreed in writing and signed by authorized representatives of each Party, each Party shall use the Clinical Data and Sample Testing Results for the purposes of (i) publications in compliance with Section 12, (ii) further research, development and exploitation of the Context Compound (in the case of Context as the using Party), including seeking and maintaining Regulatory Approval of the Context Compound (including label extensions), (iii) further research, development and exploitation of the Menarini Compound (in the case of Menarini as the using Party), including seeking and maintaining Regulatory Approval of the Menarini Compound (including label extensions) and (iv) filing and prosecuting patent applications for Inventions and enforcing any resulting patents (collectively, the "**Permitted Use**"). The Parties agree to provide sufficient quantities of their Compounds for interference testing in bioanalytical or proprietary assays in order to confirm, as applicable, that their Compound does not interfere with the other Party's assay performance. Initial experiments may be performed to determine impact to assay performance and will follow a validated protocol and/or standard operating procedure.

3.11 Joint Development Committee. The Parties shall form a joint development team (the "**Joint Development Committee**" or "**JDC**") made up of an equal number of representatives of Context and Menarini, which shall initially be set as two (2) representatives from and selected by each Party, which shall have responsibility for coordinating all activities between the Parties under, and pursuant to, this Agreement. Each Party shall designate a project manager (the "**Project Manager**") who may or may not be part of the JDC and who shall be responsible for implementing and coordinating activities and facilitating the exchange of scientific information between the Parties with respect to the Study. The JDC shall meet as soon as practicable after the Effective Date and then no less than twice yearly, and more often as reasonably considered necessary at the request of either Party, to provide an update on Study progress. Prior to any such meeting, the Context Project Manager shall provide an update in writing to the Menarini Project Manager, which update shall contain

information about overall Study progress, recruitment status, interim analysis (if results are available), final analysis and other information relevant to the conduct of the Study. In addition to a Project Manager, each Party shall designate an alliance manager (the "**Alliance Manager**"), who may or may not be the Project Manager and/or a member of the JDC, and who shall endeavor to ensure clear and responsive communication between the Parties and the effective exchange of information and shall serve as the primary point of contact for any issues arising under this Agreement. The Alliance Managers shall have the right to attend all JDC meetings and may bring to the attention to the JDC any matters or issues either of them reasonably believes should be discussed and shall have such other responsibilities as the Parties may mutually agree in writing. In the event that an issue arises, and the Alliance Managers cannot or do not, after good faith efforts, reach agreement on such issue, the issue shall be elevated to the Chief Medical Officer for Context and the Chief Medical Officer for Menarini. If the Parties cannot agree, Context shall have final decision making rights on all operational issues and regulatory strategies relating to the Study, except that Context may not make changes to the Study which may materially impact the Menarini Compound without the written consent of Menarini, which shall not be unreasonably withheld, conditioned or delayed; provided that, in all cases, such consent or written explanation for why such consent is being withheld, conditioned or delayed shall be provided within [***] days of Context's request for Menarini's consent; and provided further that if Menarini fails to provide such written explanation within such fifteen [***] day period, then Menarini shall be deemed to have provided its consent.

3.12 Each Party shall also appoint a supply chain representative to hold telephone discussions at a mutually agreed-upon frequency to review the quantities of Menarini Compound and Context Compound needed for the Study (in accordance with Article 8 and Appendix B) and any other supply chain issues that may arise during the Study.

3.13 A Party may change its representatives on the JDC and its Project Manager and Alliance Manager by giving the other Party written notice thereof.

3.14 Context shall provide Menarini with (i) an electronic draft of the final Study report for Menarini to provide comments to Context within [***] days of receipt of such draft final Study report and (ii) the final version of the final Study report promptly after it is issued. Context shall consider in good faith any comments provided by Menarini on the draft of the final Study report and shall not include any statements relating to the Menarini Compound which have not been approved by Menarini, approval of which shall not be unreasonably withheld, conditioned or delayed.

3.15 Notwithstanding anything in this Agreement to the contrary, but without prejudice to Section 2.6 and Section 20.2, each Party acknowledges and agrees that the other Party may have present or future business activities or opportunities, including business activities or opportunities with Third Parties, involving antiestrogen compounds, in the case of Context, or antiprogesterone compounds, in the case of Menarini, or other similar products, programs, technologies or processes. Accordingly, each Party acknowledges and agrees that nothing in this Agreement shall be construed as a representation or inference that the other Party will not develop for itself, or enter into business relationships with other Third Parties regarding, any products, programs, studies (including combination studies), technologies or processes that are similar to or that may compete with the Combination or any other product, program, technology or process, including antiestrogens or antiprogesterones, provided that the Clinical Data, Sample Testing Results, Jointly Owned Inventions, and Confidential Information are not used or disclosed in connection therewith in violation of this Agreement.

3.16 Nothing in this Agreement, but without prejudice to Section 20.2, shall prohibit or restrict a Party from licensing, assigning or otherwise transferring to an Affiliate or Third Party its rights to its Compound and the related Clinical Data, Confidential Information (not including any Confidential Information solely owned by the other Party), Sample Testing Results or Jointly Owned Inventions; provided, however, that in the case of any such license, assignment or transfer, the licensee, assignee or transferee shall agree in writing to use such Clinical Data, Confidential Information, Sample Testing Results and Jointly Owned Inventions only for the Permitted Use and any other use expressly permitted by this Agreement and to otherwise be bound by the terms of this Agreement.

4. Protocol and Related Documents

4.1 A summary of the initial Protocol, entitled "Protocol Summary", has been agreed to by the Parties as of the Effective Date, and is attached as Appendix A. Context shall have the final decision regarding the contents of the Protocol; provided, however, that any material changes to the Protocol materially impacting the Menarini Compound shall require Menarini's prior written consent, not to be unreasonably withheld, conditioned or delayed. Any such proposed changes will be sent in writing to Menarini's Project Manager and Menarini's Alliance Manager. Menarini will provide such consent, or a written explanation for why such consent is being withheld, within [***] days of receiving a copy of Context's requested changes; provided that if Menarini fails to provide such written explanation within such [***] day period, then Menarini shall be deemed to have consented to such change or changes.

4.2 Context shall prepare the patient informed consent form for the Study (which shall include any required consent for the Sample Testing) in consultation with Menarini (it being understood and agreed that the portion of the informed consent form relating to the Menarini Compound will be timely provided to Context by Menarini). Any changes to such form that relate to the Menarini Compound shall be subject to Menarini's review and prior written consent, not to be unreasonably withheld, conditioned or delayed. Any such proposed changes will be sent in writing to Menarini's Project Manager and Menarini's Alliance Manager. Menarini will provide such consent, or a written explanation for why such consent is being withheld, within [***] days of receiving a copy of Context's requested changes; provided that if Menarini fails to provide such written explanation within such [***] day period, then Menarini shall be deemed to have consented to such change or changes.

4.3 Within a reasonable time after the Effective Date, the Parties shall enter into an agreement related to the collection of financial disclosure information from "clinical investigators" involved in the Study and the certification and/or disclosure of the same in accordance with all Applicable Law, including, but not limited to, Part 54 of Title 21 of the United States Code of Federal Regulations (Financial Disclosure by Clinical Investigators) and related FDA guidance documents. Among other things, such agreement will provide (a) for Context to track and collect from all "clinical investigators" involved in the Study either separate certification and/or disclosure forms for each of Context and Menarini (which for clarity, Menarini shall provide Context with such certification and/or disclosure form to be sent to "clinical investigators") or one (1) "combined" certification and/or disclosure form for both Context and Menarini and (b) that Context will be responsible for preparing and submitting the Financial Disclosure Module 1.3.4 components to the FDA for any Regulatory Approvals in connection with the Study. For purposes of this Section 4.3, the term "clinical investigators" shall have the meaning set forth in Part 54.2(d) of Title 21 of the United States Code of Federal Regulations.

4.4 Within a reasonable time after the Effective Date, the Parties shall negotiate in good faith and enter into a Quality Agreement and a Pharmacovigilance Agreement. For clarity, transfer of the Menarini Compound and the initiation of the Study cannot take place before the Quality Agreement and the Pharmacovigilance Agreement are in effect.

4.5 *Sunshine Laws*.

4.5.1 For purposes of compliance with reporting obligations under Sunshine Laws, as between the Parties, Context represents that it is not, as of the Effective Date and to the best of its knowledge, subject to reporting obligations under the Sunshine Laws. Therefore, as between the Parties, and to the extent they are required by law, Menarini will report payments or other transfers of value ("**POTV**") made by Context or any Third Party contract research organization used to conduct the Study related to the conduct of the Study and any applicable associated contractor engagements as required under the Sunshine Laws for the Study. Menarini shall request delayed publication for any reported POTV for the Study as permitted under the Sunshine Laws and if consistent with Menarini's normal business practices. In the event that Context becomes responsible for reporting POTV for studies sponsored by it in a given country during the term of this Agreement, Context shall provide written notification to Menarini and the Parties will meet to confer to discuss how they wish to handle reporting thereafter. Interpretation of the Sunshine Laws for purposes of reporting any POTV by a Party shall be in such Party's sole discretion so long as the interpretation complies with Applicable Law.

4.5.2 Context (i) will provide (to the extent in the possession of Context), or will utilize Commercially Reasonable Efforts to obligate and ensure that each Third Party contract research organization used to conduct the Study and other applicable Third Party contractors for the Study provides, Menarini with any information requested by Menarini as Menarini may reasonably determine is necessary for Menarini to comply with its reporting obligations under Sunshine Laws (with such amounts paid to, or at the direction of, healthcare providers, teaching hospitals and/or any other persons for whom POTVs must be reported under Sunshine Laws to be reported to Menarini within a reasonable time period specified by Menarini) and (ii) will reasonably cooperate with, and will utilize Commercially Reasonable Efforts to obligate and ensure that each Third Party contract research organization used to conduct the Study and other applicable Third Party contractors for the Study reasonably cooperates with, Menarini in connection with its compliance with such Sunshine Laws. The form in which Context provides any such information shall be mutually agreed but sufficient to enable Menarini to comply with its reporting obligations and Menarini may disclose any information that it believes is necessary to comply with Sunshine Laws. Without limiting the foregoing, Menarini shall have the right to allocate POTVs in connection with this Agreement in any required reporting under Sunshine Laws in accordance with its normal business practices. These obligations shall survive the expiration and termination of this Agreement to the extent necessary for Menarini to comply with Sunshine Laws. Context shall not be required to provide any information to Menarini that is subject to disclosure pursuant to Context's own obligations under the Sunshine Laws.

5. Adverse Event Reporting

Context will be solely responsible for compliance with all Applicable Law pertaining to safety reporting for the Study and related activities. Prior to the initiation of the Study, the Parties will have executed the Pharmacovigilance Agreement to ensure the exchange of relevant safety data and Adverse Event reporting within appropriate timeframes and in an appropriate format to enable the Parties to fulfill local and international regulatory reporting obligations and to facilitate appropriate safety reviews.

6. Term and Termination

6.1 The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect until completion of all of the obligations of the Parties hereunder or until terminated by either Party pursuant to this Article 6.

6.2 In the event that Menarini reasonably and in good faith believes that the Menarini Compound is being used in the Study in an unsafe manner and notifies Context in writing of the grounds for such belief, and Context fails to promptly incorporate (subject to approval by applicable Regulatory Authorities or Institutional Review Boards) changes into the Protocol reasonably requested by Menarini to address such issue or to otherwise reasonably and in good faith address such issue, Menarini may terminate this Agreement and the supply of the Menarini Compound effective upon written notice to Context and upon the safe transition of patients out of the Study.

6.3 Either Party may terminate this Agreement if the other Party commits a material breach of this Agreement, and such material breach continues for thirty (30) days after receipt of written notice thereof from the non-breaching Party; provided that if such material breach cannot reasonably be cured within thirty (30) days, the breaching Party shall be given a reasonable period of time to cure such breach.

6.4 If either Party determines in good faith, based on a review of the Clinical Data, Sample Testing Results or other Study-related Know-How or other information, that the Study may unreasonably affect patient safety, such Party shall promptly notify the other Party of such determination. The Party receiving such notice may propose modifications to the Study to address the safety issue identified by the other Party and, if the notifying Party agrees, shall act to immediately implement such modifications; provided, however, that after discussions, if the Parties cannot agree on a plan to address the concerns then the notifying Party need not wait for the other Party to propose modifications and may instead terminate this Agreement immediately upon written notice to such other Party. If the Parties agree to cease the Study, the Parties shall reasonably cooperate towards an orderly wind-down of the Study in a manner medically necessary to safely transition patients out of the Study.

6.5 In the event that any Regulatory Authority takes any action, or raises any objection that substantively functions, (i) to suspend or terminate the Study or (ii) that prevents a Party from supplying, in the case of Context, the Context Compound and, in the case of Menarini, the Menarini Compound, for purposes of the Study, then the Parties shall meet promptly to discuss such matter in good faith and determine a reasonable approach to such matter. If after discussions, the Parties cannot agree on a plan to address the concerns and such matter is still unresolved, then either Party may terminate this Agreement immediately upon written notice to such other Party; provided, however, that the Parties shall reasonably cooperate towards an orderly wind-down or completion of the Study in a manner medically necessary to safely transition patients out of the Study. Additionally, if either Party reasonably believes that the Study data shows (e.g., through an interim analysis or other

data read out) evidence of lack of efficacy and/or futility of the Study and if such Party is therefore considering terminating the Study, then such Party shall notify the other Party and both Parties shall discuss in good faith. If the Parties agree that the Study shows evidence of lack of efficacy and/or futility of the Study, then either Party may terminate this Agreement, provided that the Parties shall reasonably cooperate towards an orderly wind-down of the Study in a manner medically necessary to safely transition patients out of the Study. If the Parties are in disagreement on the possible evidence of lack of efficacy or futility of the Study, then the Parties shall mutually appoint a third-party expert ("**Arbitrator**") in the field of the Study who shall advise on the matter, and the decision of the Arbitrator shall be final and binding upon the Parties. The Arbitrator shall decide without any particular procedure but after reasonably hearing information presented by the Parties. The costs of such Arbitrator shall be equally (50%/50%) borne by the Parties, and if the Arbitrator finally determines that the Study shows evidence of lack of efficacy and/or futility of the Study such that a reasonable and prudent company would decide to terminate such Study, either Party may terminate this Agreement and the Parties shall reasonably cooperate towards an orderly wind-down of the Study in a manner medically necessary to safely transition patients out of the Study.

6.6 In the event that this Agreement is terminated for any reason other than a termination by Context for Menarini's material breach pursuant to Section 6.3, Context shall, at Menarini's sole discretion, promptly either return or destroy all unused Menarini Compound pursuant to Menarini's instructions. If Menarini requests that Context destroy the unused Menarini Compound, Context shall provide written certification of such destruction. For clarity, in the event this Agreement is terminated for any reason, then Context shall have the continuing right to use any Menarini Compound in its possession solely to wind down the Study.

6.7 Either Party shall be entitled to terminate this Agreement immediately upon written notice to the other Party, if such other Party materially fails to perform any of its obligations under Section 13.3 or materially breaches any representation or warranty contained in Section 13.3. Additionally, should: (i) it be documentarily evidenced that the Study budget is exceeding or is anticipated to exceed the estimated budget amount by more than [***] of the amount set forth in the initial statement of work (covering the entire Study as described in the Study Synopsis in Appendix A) between Context and the primary contract research organization engaged by Context to perform the Study (the "**Primary CRO**"); and (ii) Context reasonably determines not to cover such additional costs and expenses, then, if Context intends to terminate the Study, Context shall notify Menarini in writing with such reasonable details and documentary evidence and the Parties shall discuss in good faith a potential solution, and if the Parties are unable to find a solution within [***] days of Context's notice to Menarini regarding this matter, then Context may terminate the Study and this Agreement effective upon written notice to Menarini, provided that further to such termination, the Parties shall reasonably cooperate towards an orderly wind-down of the Study in a manner medically necessary to safely transition patients out of the Study. The non-terminating Party shall have no claim against the terminating Party for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Section 6.7.

6.8 The provisions of this Section 6.8 and Sections 3.5, 3.7, 3.8, 3.9, 3.10, 6.4 (with respect to the cooperation in winding down the Study), 6.5 (with respect to the cooperation in winding down the Study), 6.6, 6.7 (no claim for termination), 6.9, 6.10, 13.2, 13.4, 14.2 (Indemnification),14.3 (Limitation of Liability), and Articles 1 (Definitions), 5 (Adverse Event Reporting), 7 (Costs of Study), 9 (Confidentiality), 10 (Intellectual Property), 11 (Reprints; Rights of Cross-Reference), 12 (Press Releases and Publications), 15 (Use of Name), 20.1

and 20.2, to the extent provided therein (Additional Obligations), 21 (Dispute Resolution and Jurisdiction), 22 (Notices), 23 (Relationship of the Parties) and 25 (Construction) shall survive the expiration or termination of this Agreement; provided, however, that in the event Menarini terminates this Agreement pursuant to Sections 6.4 or 6.5 (and Context continues the Study), or Context terminates this Agreement pursuant to Section 6.3 for Menarini's breach of contract, then Menarini's rights contained in Section 3.8, 20.2 and Article 11, shall not survive the termination of this Agreement.

6.9 Termination of this Agreement shall be without prejudice to any claim or right of action of either Party against the other Party for any prior breach of this Agreement.

6.10 Upon termination of this Agreement, each Party and its Affiliates shall promptly return to the other Party or destroy any Confidential Information of the other Party (other than Clinical Data, Sample Testing Results, and Inventions) furnished to the receiving Party by the other Party, except that the receiving Party shall have the right to retain one copy for record-keeping purposes.

7. Costs of Study

The Parties agree that (i) Menarini shall provide the Menarini Compound for use in the Study, as described in Article 8, at no cost to Context; (ii) Context shall bear all other costs associated with the conduct of the Study, including that Context shall provide the Context Compound for use in the Study; and (iii) Menarini shall provide cfNA analysis of the anonymized blood samples of all Study patients and shall bear the costs of testing, as further described in Appendix C (which shall be considered Clinical Data and/or Sample Testing Results, as appropriate), provided that Context shall be responsible for shipments of the anonymized blood samples and shall bear all costs associated with such shipments, as further described in Appendix C. The Parties shall use Commercially Reasonable Efforts so that the anonymized blood samples cannot be related to a specific individual patient by Context. Should the Parties determine and/or reasonably believe that the anonymized blood samples may be related by Context to a specific individual patient, then the Parties shall work together to take such reasonable steps and enter into appropriate data processing agreement(s) compliant with Applicable Laws regarding such samples.

For the avoidance of doubt, Context will not be required to reimburse Menarini for any costs or expenses incurred by Menarini or its Affiliates in connection with the Study, and Menarini will not be required to reimburse Context for any costs or expenses incurred by Context or its Affiliates in connection with the Study.

8. Supply and Use of the Compound

8.1 *Supply of the Compounds*. Appendix B (the "**Supply Agreement**") sets out the quantities of the Menarini Compound that Menarini shall use its Commercially Reasonable Efforts to supply, or cause to be supplied, and the timelines for such supply, in each case, for use in the Study, including any extensions thereto. In the event that Context determines that the quantities of the Menarini Compounds set forth in the Supply Agreement are not sufficient to complete the Study (due, for example, to the addition of Study Sites or countries, or subject withdrawal from the Study) or any extension of the Study (due, for example, to patients having a durable response beyond the initial Study timeframe), Context shall so notify Menarini, and the Parties shall discuss in good faith regarding additional quantities of Menarini Compounds to be provided and the schedule on which such additional quantities may be provided. Each Party shall also provide to the other Party a contact person for the

supply of its Compound or Compounds under this Agreement. Notwithstanding the foregoing, or anything to the contrary herein, in the event that either Party is not supplying Compound in accordance with the terms of this Agreement, or is allocating under Section 8.10, then the other Party shall have no obligation to supply its Compound or Compounds or may allocate proportionally.

8.2 *Minimum Shelf-Life Requirements*. Each Party shall use Commercially Reasonable Efforts to supply its Compound or Compounds hereunder with an adequate remaining shelf life at the time of Delivery to meet the Study requirements in accordance with Appendix B.

8.3 *Provision of Compounds*.

8.3.1 Menarini will use its Commercially Reasonable Efforts to deliver, at its own cost, the Menarini Compound to Context's, or its designee's, location as specified by Context in the written order ("**Delivery**" with respect to such Menarini Compound). Title and risk of loss for the Menarini Compound shall transfer from Menarini to Context at Delivery. All costs associated with the subsequent transportation, warehousing and distribution of Menarini Compound shall be borne by Context. Context will, or will cause its designee to: (i) take delivery of the Menarini Compound supplied hereunder; (ii) subsequently label and pack (in accordance with Section 8.4) and promptly ship the Menarini Compound to the Study sites, in compliance with cGMP, GCP and other Applicable Law; and (iii) provide, from time to time at the reasonable request of Menarini, the following information: any applicable chain of custody forms; in-transport temperature recorder(s); records and receipt verification documentation; such other transport or storage documentation as may be reasonably requested by Menarini (to the extent within Context's possession or control); and usage and inventory reconciliation documentation related to the Menarini Compound.

8.3.2 Context is solely responsible, at its own cost, for supplying (including all Manufacturing, acceptance and release testing) the Context Compound for the Study, and the subsequent handling, storage, transportation, warehousing and distribution of the Context Compound supplied hereunder. Context shall ensure that all such activities are conducted in compliance with cGMP, GCP and other Applicable Law. For purposes of this Agreement, the "**Delivery**" of a given quantity of the Context Compound shall be deemed to occur when such quantity is packaged for shipment to a Study site.

8.4 *Labeling and Packaging; Use, Handling and Storage*.

8.4.1 Menarini shall provide the Menarini Compound to Context in the U.S. in such form as reasonably requested by Context and reasonably approved by the JDC, and Context shall be responsible for labeling, packaging, and leafleting such Menarini Compound in accordance with the Study requirements and otherwise in accordance with all Applicable Law, including cGMP, GCP, and health, safety and environmental protections.

8.4.2 Context shall (i) use the Menarini Compound solely for purposes of performing the Study; (ii) not use the Menarini Compound in any manner inconsistent with this Agreement or for any commercial purpose; and (iii) use, store, transport, handle and dispose of the Menarini Compound in compliance with the Quality Agreement and Applicable Laws. Context shall not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying information, structure or ideas of the Menarini Compound, and in particular shall not analyze the Menarini Compound by physical, chemical or biochemical means except as necessary to perform its obligations under this Agreement.

8.5 *Product Specifications*. A certificate of analysis and safety data sheet shall accompany each shipment of the Menarini Compound to Context as shall be further clarified in the Quality Agreement. Upon request, Context shall provide Menarini with a certificate of analysis covering each shipment of Context Compound used in the Study.

8.6 *Changes to Manufacturing*. Each Party may make changes from time to time to its Compound or the Manufacturing Site in compliance with the Quality Agreement (with respect to the Menarini Compound) and this Agreement (with respect to the Context Compound) and as prior discussed in the JDC.

8.7 Product Testing; Noncompliance

8.7.1 After Manufacturer's Release. After Manufacturer's Release of Menarini Compound and concurrently with Delivery of the Compound to Context, Menarini shall provide Context with such certificates and documentation as are described in the Quality Agreement ("**Disposition Package**"). Context shall take all steps necessary to determine that the Context Compound or Menarini Compound, as applicable, is suitable for release before making such Context Compound or Menarini Compound, as applicable, available for human use, and Menarini shall provide cooperation or assistance as reasonably requested by Context in connection with such determination with respect to the Menarini Compound. Context shall be responsible for storage and maintenance of Menarini Compound until it is tested and/or released, which storage and maintenance shall be in compliance with the Specifications for the applicable Menarini Compound, and Applicable Law, and shall be responsible for any failure of the Menarini Compound to meet the Specifications to the extent caused by shipping, storage, or handling conditions after Delivery to Context hereunder.

8.7.2 *Non-Conformance*.

a. In the event that either Party becomes aware that any Compound may have a Non-Conformance, despite testing and quality assurance activities (including any activities conducted by the Parties under Sections 8.7.1 (After Manufacturer's Release)), such Party shall notify the other Party upon identification of the Non-Conformance. The Parties shall investigate any Non-Conformance in accordance with Section 8.9 (Investigations) and any discrepancy between them shall be resolved in accordance with Section 8.8 (Resolution of Discrepancies).

b. In the event that any proposed or actual shipment of Menarini Compound (or portion thereof) shall be agreed to have a Non-Conformance at the time of Delivery to Context, then unless otherwise agreed to by the Parties, Menarini shall promptly replace such Menarini Compound as is found to have a Non-Conformance (with respect to Menarini Compound that has not yet been administered in the course of performing the Study). Unless otherwise agreed to by the Parties in writing, the sole and exclusive remedies of Context with respect to any Menarini Compound that is found to have a Non-Conformance at the time of Delivery shall be (i) prompt replacement of such Menarini Compound as set forth in this Section 8.7.2(b), and (ii) indemnification under Section 14.2 (to the extent applicable); provided, for clarity, that Context shall not be deemed to be waiving any rights under Section 8.15. In the event that Menarini Compound is lost or damaged after Delivery, the Parties shall discuss a replacement supply at reasonable cost (which shall not exceed Menarini's direct cost of goods of the Menarini Compound, including shipment costs plus [***]) and reasonable timelines. For the avoidance of doubt, Menarini shall have no obligation to provide replacement Menarini Compound for any Menarini Compound supplied hereunder other than such Menarini Compound as has been agreed or determined to have a Non-Conformance at the time of Delivery to Context. Menarini shall be responsible for any costs incurred by Context in connection

with the return or destruction of any Menarini Compound supplied hereunder that is found to have a Non-Conformance caused by Menarini.

c. Context shall be responsible for, and Menarini shall have no obligations or liability with respect to, any Context Compound supplied hereunder that is found to have a Non-Conformance. Context shall replace any Context Compound as is found to have a Non-Conformance (with respect to Context Compound that has not yet been administered in the course of performing the Study). Unless otherwise agreed to by the Parties in writing, the sole and exclusive remedies of Menarini with respect to any Context Compound that is found to have a Non-Conformance at the time of Delivery shall be (i) replacement of such Context Compound as set forth in this Section 8.7.2(c), and (ii) indemnification under Section 14.2 (to the extent applicable); provided, for clarity, that Menarini shall not be deemed to be waiving any rights under Section 8.15.

8.8 *Resolution of Discrepancies*. Disagreements regarding any determination of Non-Conformance by Context shall be resolved by representatives of both Parties.

8.9 *Investigations*. The process for investigations of any Non-Conformance shall be handled in accordance with each Party's procedures.

8.10 *Shortage: Allocation*. In the event that a Party's Compound is in short supply as a result of a Manufacturing disruption, Manufacturing difficulties or other similar event - in each case, for causes beyond such Party's reasonable control - such that a Party reasonably believes in good faith that it will not be able to fulfill its supply obligations hereunder with respect to such Compound, such Party will provide prompt written notice to the other Party thereof (including the shipments of Compound hereunder expected to be impacted and the quantity of its Compound that such Party reasonably determines it will be able to supply) and the Parties will promptly discuss such situation (including how the quantity of Compound that such Party is able to supply hereunder will be allocated within the Study). In such event, the Party experiencing such shortage shall (i) use its Commercially Reasonable Efforts to remedy the situation giving rise to such shortage and to take action to minimize the impact of the shortage on the Study, and (ii) allocate to the other Party an amount of Compound at least proportionate to the total amount of the Compound shipments hereunder expected to be impacted by the shortage divided by the total demand for the Compound for the impacted time period.

8.11 *Records*. Each Party shall maintain complete and accurate records in all material respects pertaining to its Manufacture of its Compound or Compounds supplied hereunder.

8.12 *Quality*. Quality matters related to the Manufacture of the Menarini Compound shall be governed by the terms of the Quality Agreement in addition to the relevant quality provisions of this Agreement. Quality matters related to the Manufacture of the Context Compound shall be governed by the relevant quality provisions of this Agreement.

8.13 *Quality Control*. Each Party shall implement and perform operating procedures and controls for sampling, stability and other testing of its Compound or Compounds, and for validation, documentation and release of its Compound or Compounds and such other quality assurance and quality control procedures as are required by the Specifications and cGMPs, and (with respect to the Menarini Compound) the Quality Agreement.

8.14 *Audits and Inspections*. No routine GMP and/or GCP audits will be performed, provided that senior quality management of both Parties may agree to hold any such audit or inspection. To the extent allowed by any agreement(s) with a Third Party, the GMP and/or GCP documentation, GMP and/or GCP reports, and CAPA plans from the Context manufacturing of any Context Compound to be used in the Study shall be shared with Menarini upon

reasonable request (such request not to occur more than once in any twelve (12) month period). Parties shall bear their own costs of such audits.

8.15 *Recalls*. Recalls of the Menarini Compound shall be governed by the terms of the Quality Agreement. Recalls of the Context Compound shall be addressed in accordance with the applicable regulations and laws and as Context otherwise deems appropriate.

8.16 *VAT*. It is understood and agreed between the Parties that any payments made, and any other consideration given under this Agreement are each exclusive of any value added or similar tax ("**VAT**"), which shall be added thereon as applicable and at the relevant rate. Subject to Section 8.17, where VAT is properly charged by the supplying Party and added to a payment made or other consideration provided (as applicable) under this Agreement, the Party making the payment or providing the other consideration (as applicable) will pay the amount of VAT properly chargeable only on receipt of a valid tax invoice from the supplying Party issued in accordance with the laws and regulations of the country in which the VAT is chargeable. Each Party agrees that it shall provide to the other Party any information and copies of any documents within its control to the extent reasonably requested by the other Party for the purposes of (i) determining the amount of VAT chargeable on any supply made under this Agreement, (ii) establishing the place of supply for VAT purposes, or (iii) complying with its VAT reporting or accounting obligations.

8.17 Where one Party or its Affiliate (the "**First Party**") is treated as making supply of goods or services in a particular jurisdiction (for VAT purposes) for non-cash consideration, and the other Party or its Affiliate (the "**Second Party**") is treated as receiving such supply in the same jurisdiction, thus resulting in an amount of VAT being properly chargeable on such supply, the Second Party shall only be obliged to pay to the First Party the amount of VAT properly chargeable on such supply (and no other amount). The Second Party shall pay such VAT to the First Party on receipt of a valid VAT invoice from the First Party (issued in accordance with the laws and regulations of the jurisdiction in which the VAT is properly chargeable). The Parties agree to (i) use their reasonable endeavors to determine and agree the value of the supply that has been made and, as a result, the corresponding amount of VAT that is properly chargeable, and (ii) provide to each other any information or copies of documents in their control as are reasonably necessary to evidence that such supply will take, or has taken, place in the same jurisdiction (for VAT purposes).

9. Confidentiality

9.1 Subject to Section 13.3.8, Menarini and Context agree to hold in confidence any Confidential Information provided by the other Party, and neither Party shall use Confidential Information of the other Party except for the performance of the Study and for the Permitted Use and any other use expressly permitted by this Agreement. Neither Party shall, without the prior written permission of the other Party, disclose any Confidential Information of the other Party to any Third Party except to the extent disclosure (i) is required by Applicable Law; (ii) is pursuant to the terms of this Agreement; or (iii) is necessary for the conduct of the Study, and in each case ((i) through (iii)) provided that the disclosing Party shall provide reasonable advance notice to the other Party before making such disclosure. For the avoidance of doubt: (A) Context may, without Menarini's consent, disclose Confidential Information to clinical trial sites and clinical trial investigators performing the Study, the data safety monitoring and advisory board relating to the Study, the Third Party clinical research organization(s) supporting Context with the Study, and Regulatory Authorities working with Context on the Study, in each case to the extent necessary for the performance of the Study

and provided that such persons (other than governmental entities) are bound by an obligation of confidentiality at least as stringent as the obligations contained herein and further provided that Context shall remain liable towards Menarini for any unauthorized use or disclosure of the Confidential Information by these subjects; and (B) Menarini may, without Context's consent, disclose, on a need to know basis (and, if applicable, only to the extent required by any contractual obligations), Confidential Information to its, its Affiliates and Menarini Compound licensors, directors, officers, employees and consultants to the extent necessary for the performance of its obligations or exploitation of its rights hereunder, provided that Menarini shall remain liable to Context for any unauthorized use or disclosure of the Confidential Information by any of these parties.

9.2 Inventions that constitute Confidential Information and are jointly owned by the Parties shall constitute the Confidential Information of both Parties.

a. Menarini shall have the right to (i) use Clinical Data and Sample Testing Results in connection with its independent development, commercialization or other exploitation of any proprietary Menarini compound including the Menarini Compound (alone or in combination with the Context Compound and/or other pharmaceutical agents) without the consent of, or any obligation to account to, Context; and (ii) disclose such Confidential Information to Third Parties consistent with Section 3.10 and Articles 10, 11, 12 and 20.2.

b. Context shall have the right to (i) use its Confidential Information, Clinical Data and Sample Testing Results, as well as any Sample Testing Results that may arise from Menarini performing such testing, in connection with its independent development, commercialization or other exploitation of any proprietary Context compound including the Context Compound (alone or in combination with the Menarini Compound and/or other pharmaceutical agents) without the consent of, or any obligation to account to, Menarini; and (ii) disclose such Confidential Information to Third Parties consistent with Section 3.10 and Articles 10, 11, 12 and 20.2.

9.3 Inventions that constitute Confidential Information and are solely owned by one Party shall constitute the Confidential Information of that Party. Context may use and disclose to Third Parties any Context solely owned Confidential Information for any purpose without obligation or accounting to Menarini. Similarly, Menarini may use and disclose to Third Parties any Menarini solely owned Confidential Information for any purpose without obligation or accounting to Context.

9.4 All Confidential Information containing personal identifiable data shall be handled in accordance with all data protection and privacy laws, rules, and regulations applicable to such Party.

9.5 The obligations of confidentiality in this Section 9 shall remain in full force and effect until each piece of Confidential Information falls in the public domain, through no breach of this Section 9 by any of the Parties.

10. Intellectual Property

10.1 *Joint Ownership and Prosecution*.

10.1.1 Subject to Sections 10.2 and 10.3, as between the Parties, all rights to all Inventions invented after the Effective Date relating to the combined use of the Menarini Compound and the Context Compound (each a "**Jointly Owned Invention**") shall belong jointly to Menarini and Context. For those countries where a specific license is required for a joint owner of a Jointly Owned Invention to practice such Jointly Owned

Invention in such countries, (i) Context hereby grants to Menarini a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up license, transferable and sublicensable, under Context's right, title and interest in and to all Jointly Owned Inventions to use such Jointly Owned Inventions for the Permitted Use and any other use expressly permitted by this Agreement, and (ii) Menarini hereby grants to Context a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up license, transferable and sublicensable, under Menarini's right, title and interest in and to all Jointly Owned Inventions to use such Jointly Owned Inventions for the Permitted Use and any other use expressly permitted by this Agreement. For clarity, the terms of this Agreement do not provide Menarini or Context with any rights, title or interest or any license to the other Party's background intellectual property except as expressly provided for herein and necessary for the Parties to conduct the Study. For further clarity, any license to the other Party's background intellectual property granted by either Party to the other Party hereunder shall be non-exclusive, royalty-free, non-transferrable, non-sublicensable, and to be exploited only to the extent strictly necessary for the conduct of the Study. For the avoidance of doubt and except as expressly provided herein, (i) Context's right to exploit each Jointly Owned Invention shall not otherwise provide Context any rights to the Menarini Compound, and (ii) Menarini's right to exploit each Jointly Owned Invention shall not otherwise provide Menarini any rights to the Context Compound.

10.1.2 Promptly following the Effective Date, patent representatives of each of the Parties shall meet (in person, videoconference, or by telephone) to discuss the patenting strategy for any Jointly Owned Inventions which may arise under this Agreement. In particular, the Parties shall discuss which Party will file a patent application (including any provisional, substitution, divisional, continuation, continuation in part, reissue, renewal, reexamination, extension, supplementary protection certificate and the like) in respect of any Jointly Owned Invention (each, a "**Joint Patent Application**") and whether the Parties wish to appoint Joint Patent Counsel. In any event, the Parties shall consult and reasonably cooperate with one another in the preparation, filing, prosecution (including prosecution strategy) and maintenance of such patent application and shall equally share the expenses associated with the Joint Patent Applications. In the event that one Party (the "**Filing Party**") wishes to file a patent application for a Jointly Owned Invention and the other Party (the "**Non-filing Party**") does not want to file any patent application for such Jointly Owned Invention or does not want to file in a particular country, the Non-filing Party shall execute such documents and perform such acts at the Filing Party's expense as may be reasonably necessary to effect an assignment of such Jointly Owned Invention to the Filing Party (in such country or all countries, as applicable) in a timely manner to allow the Filing Party to prosecute such patent application. Likewise, if a Party (the "**Opting-out Party**") wishes to discontinue the prosecution and maintenance of a Joint Patent Application, the other Party, at its sole option (the "**Continuing Party**"), may continue such prosecution and maintenance. In such event, the Opting-out Party shall execute such documents and perform such acts at the Continuing Party's expense as may be reasonably necessary to effect an assignment of such Joint Patent Application to the Continuing Party (in such country or all countries, as applicable) in a timely manner to allow the Continuing Party to prosecute and maintain such patent application. Any Joint Patent Application or Jointly Owned Invention so assigned shall thereafter be owned solely by the Continuing Party or Filing Party (as applicable), and except as otherwise set forth herein, the Opting-out Party or Non-filing Party (as applicable) shall have no right to practice under such Joint

Patent Application or any patent claiming such Jointly Owned Invention in the applicable country or countries and, for the avoidance of doubt, any such patent, when issued, shall not be a Joint Patent.

10.1.3 Except as expressly provided in Sections 3.10 10.1.2 and in furtherance and not in limitation of Section 9.1, each Party agrees to make no patent application based on the other Party's Confidential Information, and to give no assistance to any Third Party for such application, without the other Party's prior written authorization.

10.1.4 Menarini shall have the first right to initiate legal action to enforce all Joint Patents against infringement, and to protect all Jointly Owned Inventions from misappropriation, by any Third Party where such infringement or misappropriation results from the development or sale of an antiestrogen, or to defend any declaratory judgment action relating thereto, at its sole expense. In the event that Menarini fails to initiate or defend such action within [***] days after being first notified of such infringement or misappropriation, Context shall have the right to do so at its sole expense. Context shall have the first right to initiate legal action to enforce all Joint Patents against infringement and to protect all Jointly Owned Inventions from misappropriation, by any Third Party where such infringement or misappropriation results from the development or sale of an antiprogesterone, or to defend any declaratory judgment action relating thereto, at its sole expense. In the event that Context fails to initiate or defend such action within [***] after being first notified of such infringement, Menarini shall have the right to do so at its sole expense. In the event that legal action to enforce Joint Patents will involve infringement or misappropriation resulting from the development or sale of a molecule or molecules that is/are or include(s) both an antiestrogen and an antiprogesterone, the Parties shall work together to coordinate such action and shall share the costs and expenses of such litigation equally. For clarity, if the alleged infringer is selling or intending to sell only one of either an antiestrogen or an antiprogesterone, then the foregoing obligation to share the costs and expenses of such litigation shall not apply.

10.1.5 If one Party brings any prosecution or enforcement action or proceeding against a Third Party with respect to any Joint Patent, the second Party agrees to be joined as a party plaintiff where necessary and to give the first Party reasonable assistance and authority to file and prosecute the suit. The costs and expenses of the Party bringing suit under this Section 10.1.5 shall be borne by such Party, and any damages or other monetary awards recovered shall be shared as follows: (i) the amount of such recovery actually received by the Party controlling such action shall be first applied to the out-of-pocket costs of the Party controlling the action; (ii) the remaining balance shall next be applied to the out-of-pocket costs of the Party incurred in such action; and then (iii) any remaining proceeds shall be divided evenly between Menarini and Context. A settlement or consent judgment or other voluntary final disposition of a suit under this Section 10.1.5 may not be entered into without the consent of the Party not bringing the suit.

10.2 *Inventions Owned or Otherwise Controlled by Menarini*. Notwithstanding Section 10.1, the Parties agree that, as between the Parties, all rights to Inventions relating to the Menarini Compound other than Inventions relating to the combined use of the Menarini Compound and the Context Compound (including, but not limited to, (a) the composition of matter of the Menarini Compound, (b) a method of manufacture or formulation of the Menarini Compound as a monotherapy, and/or (c) the use or a method of use of the Menarini Compound as a monotherapy or as used with other agents, antibodies or compounds (other than an Invention pertaining, whether generically or specifically, to the composition of matter, method of manufacture or formulation, or the use or a method of use of both the Context Compound and the Menarini Compound)) are the exclusive property of Menarini. Menarini shall be

entitled to file in its own name relevant patent applications and to own resultant patent rights for any such Invention. For the avoidance of doubt, any Invention generically encompassing the Menarini Compound (and not any Context proprietary compound including the Context Compound) within its scope, even where the Menarini Compound is not disclosed per se, is the exclusive property of Menarini. For clarity, nothing in this Agreement shall be construed to grant Context any right or license under the patents and know-how owned or otherwise controlled by Menarini with respect to the Menarini Compound other than the limited rights expressly granted herein.

10.3 *Inventions Owned by Context*. Notwithstanding Section 10.1, the Parties agree that all rights to Inventions relating to the Context Compound other than Inventions relating to the combined use of the Menarini Compound and the Context Compound (including but not limited to (a) the composition of matter of the Context Compound, (b) a method of manufacture or formulation of the Context Compound as a monotherapy, and/or (c) a method of use of the Context Compound as a monotherapy or as used with other agents, antibodies or compounds (other than an Invention pertaining, whether generically or specifically, to the composition of matter, method of manufacture or formulation, or a method of use of both the Context Compound and the Menarini Compound)) are the exclusive property of Context. Context shall be entitled to file in its own name relevant patent applications and to own resultant patent rights for any such Invention. For the avoidance of doubt, any Invention generically encompassing the Context Compound (and not any Menarini proprietary compound including the Menarini Compound) within its scope, even where the Context Compound is not disclosed per se, is the exclusive property of Context.

10.4 Notwithstanding any provision of this Article 10 to the contrary, the Parties agree that all Inventions invented after the Effective Date relating to the Menarini Compound shall be subject to provisions of the Elacestrant License Agreements. In the event of any inconsistency between the Elacestrant License Agreements and this Agreement, the terms of the Elacestrant License Agreements shall prevail and apply to the Parties. Without limiting the foregoing, the Parties agree that all Inventions invented after the Effective Date relating to the Menarini Compound shall be promptly disclosed to Eisai.

11. Reprints; Rights of Cross-Reference

Consistent with applicable copyright and other laws, each Party may use, refer to, and disseminate reprints of scientific, medical, and other published articles and materials from journals, conferences and/or symposia relating to the Study which disclose the name of a Party, provided such use does not constitute an endorsement of any commercial product or service by the other Party.

12. Press Releases and Publications

12.1 The Parties will mutually agree (not to be unreasonably withheld, conditioned or delayed) on the content and timing of any press release with respect to this Agreement or the Study; provided that Context may make public disclosures concerning this Agreement and/or the Study as required by Applicable Law or the rules of any exchange on which its securities are traded.

12.2 To the extent required by Applicable Law or in accordance with Context's policies, Context will register the Study with the Clinical Trials Registry located at www.clinicaltrials.gov. Context is committed to timely publication of the results following Study Completion, after taking appropriate action to secure intellectual property rights (if any) arising from the Study.

The publication of the results of the Study will be in accordance with the Protocol. Menarini agrees not to publish any results of the Study involving the Context Compound prior to the timely publication of such Study results by Context.

12.3 Each Party shall use reasonable efforts to publish or present scientific papers dealing with the Study in accordance with accepted scientific practice. Each Party may issue a press release related to any scientific presentation or publication regarding the Study in a form mutually agreed to by the Parties (not to be unreasonably withheld, conditioned or delayed) or as otherwise required by Applicable Law.

12.4 The Parties agree that prior to submission of the results of the Study for publication or presentation or any other dissemination of results including oral dissemination, the publishing Party shall invite the other to comment on the content of the material to be published or presented according to the following procedure:

(i) At least [***] days prior to submission for publication of any paper, letter, or any other publication, or [***] days prior to submission for presentation of any abstract, poster, talk or any other presentation, the publishing Party shall provide to the other Party the full details of the proposed publication or presentation in an electronic version (email attachment). Upon written request from the other Party, the publishing Party agrees not to submit data for publication/presentation for an additional [***] days in order to allow for actions to be taken to preserve rights for patent protection.

(ii) The publishing Party shall give reasonable consideration to any request by the other Party made within the periods mentioned in clause (i) above to modify the publication and the Parties shall work in good faith and in a timely manner to resolve any issue regarding the content for publication.

(iii) The publishing Party shall remove all Confidential Information of the other Party before finalizing the publication.

12.5 Context agrees to identify Menarini and acknowledge Menarini's support in any press release and any other publication or presentation of the results of the Study.

13. Representations and Warranties; Disclaimers

13.1 Each of Menarini and Context represents and warrants to the other that it has the full right and authority to enter into this Agreement and that this Agreement (i) constitutes a legal and valid obligation binding upon such Party, enforceable in accordance with its terms and (ii) does not conflict with any provision of any agreement such Party is otherwise a party to.

13.2 Context does not undertake that the Study shall lead to any particular result, nor is the success of the Study guaranteed. Neither Party accepts any responsibility for any use that the other Party may make of the Clinical Data nor for advice or information given in connection therewith.

13.3 *Anti-Corruption*.

13.3.1 In performing their respective obligations hereunder, the Parties acknowledge that the corporate policies of Menarini and Context and their respective Affiliates require that each Party's business be conducted within the letter and spirit of the law. By signing this Agreement, each Party agrees to conduct the business contemplated herein in` a manner which is consistent with all Applicable Law, including the U.S. Foreign Corrupt Practices Act, good business ethics, and its ethics and other corporate policies, and to abide by the spirit of the other Party's applicable ethics and compliance guidelines which may be provided by such other Party from time to time.

13.3.2 Specifically, each Party agrees that it has not, and covenants that it, its Affiliates, and its and its Affiliates' directors, employees, officers, and anyone acting on its behalf, will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorize, ratify or offer to make, or take any action in furtherance of, any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting it in obtaining or retaining business for it or the other Party, or in any way with the purpose or effect of public or commercial bribery.

13.3.3 Each Party shall not contact, or otherwise knowingly meet with, any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement, without the prior written approval of the other Party, except where such meeting is consistent with the purpose and terms of this Agreement and in compliance with Applicable Law.

13.3.4 Each Party represents that: (i) it has no impediment to enter into the transaction contemplated in this Agreement; (ii) it is not excluded, debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for government programs; and (iii) it has not and will not use in any capacity the services of any person or Subcontractor debarred under Applicable Law with respect to activities to be performed under this Agreement.

13.3.5 Each Party represents and warrants that except as disclosed to the other in writing prior to the commencement of this Agreement: (i) it does not have any interest which directly or indirectly conflicts with its proper and ethical performance of this Agreement; (ii) it shall maintain arm's length relations with all Third Parties with which it deals for or on behalf of the other in performance of this Agreement; and (iii) it has provided complete and accurate information and documentation to the other Party, the other Party's Affiliates and its and their personnel in the course of due diligence conducted by the other Party for this Agreement, including disclosure of any officers, employees, owners or persons directly or indirectly retained by such Party in relation to the performance of this Agreement who are Government Officials or relatives of Government Officials. Each Party shall make all further disclosures as necessary to the other Party to ensure the information provided remains complete and accurate throughout the term of this Agreement. Subject to the foregoing, each Party agrees that it shall not hire or retain any Government Official to assist in its performance of this Agreement, with the sole exception of conduct of or participation in clinical trials under this Agreement, provided that such hiring or retention shall be subject to the completion by the hiring or retaining Party of a satisfactory anti-corruption and bribery (e.g., FCPA) due diligence review of such Government Official. Each Party further covenants that any future information and documentation submitted to the other Party as part of further due diligence or a certification shall be complete and accurate.

13.3.6 Each Party shall have the right during the term of this Agreement, and for a period of two (2) years following termination of this Agreement, to conduct an investigation and audit of the other Party's activities, books and records, to the extent they relate to that other Party's performance under this Agreement, to verify compliance with the terms of this Section 13.3. Such other Party shall cooperate fully with such investigation or audit, the scope, method, nature, and duration of which shall be at the sole reasonable discretion of the Party requesting such audit.

13.3.7 Each Party shall ensure that all transactions under the Agreement are properly and accurately recorded in all material respects on its books and records and that each document upon which entries in such books and records are based is complete and accurate in all material respects. Each Party further represents, warrants, and covenants that all books, records, invoices and other documents relating to payments and expenses under this Agreement are and shall be complete and accurate and reflect in reasonable detail the character and amount of transactions and expenditures. Each Party must maintain a system of internal accounting controls reasonably designed to ensure that no off-the-books or similar funds or accounts will be maintained or used in connection with this Agreement.

13.3.8 Each Party agrees that in the event that the other Party believes in good faith that there has been a possible violation of any provision of Section 13.3, such other Party may make full disclosure of such belief and related information needed to support such belief at any time and for any reason to any competent government bodies and its agencies, and to whoever such Party determines in good faith has a legitimate need to know.

13.3.9 Each Party shall comply with its own ethical business practices policy and any Corporate Integrity Agreement to which it is subject, and shall conduct its Study-related activities in accordance with Applicable Law. Each Party agrees to ensure that all of its employees involved in performing its obligations under this Agreement are made specifically aware of the compliance requirements under this Section 13.3. In addition, each Party agrees to ensure that all such employees have either participated in compliance training conducted by such Party or such employees have been informed of such Party's policies regarding anti-bribery and corruption, prior to his/her performance of any obligations or activities under this Agreement. Each Party further agrees to certify its continuing compliance with the requirements under this Section 13.3 on a periodic basis during the term of this Agreement in such form as may be reasonably requested by the other Party.

13.4 EXCEPT AS EXPRESSLY PROVIDED HEREIN, CONTEXT MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE CONTEXT COMPOUND, AND ANY WARRANTY THAT THE CONTEXT COMPOUND DOES NOT INFRINGE THIRD PARTIES INTELLECTUAL PROPERTY RIGHTS, AND MENARINI MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE MENARINI COMPOUNDS, AND ANY WARRANTY THAT THE MENARINI COMPOUND DOES NOT INFRINGE THIRD PARTIES INTELLECTUAL PROPERTY RIGHTS.

14. Insurance: Indemnification: Limitation of Liability

14.1 *Insurance*. Without limiting its obligations and liability under this Agreement, each Party shall effect and maintain, at its own expense, with reputable insurance companies, a General Third Party Liability and Product Liability Insurance policy with a limit of liability not lower than $[***] ([***] US Dollars) for any one occurrence or series of occurrences arising out of any one event or series of events.

Context shall or shall procure that the sponsor of the Study, purchase a Clinical Trial Liability Insurance policy extended to product liability risks, covering all subjects participating in the

Study. Such Clinical Trial Insurance policy shall be fully compliant with local laws and regulations applicable in the country where the Study is performed. Any deductibles, policy exclusions or uncovered risks will remain at the sole costs and expenses of the Party which subscribed the policy.

Context shall use Commercially Reasonable Efforts to include in its contract with the Primary CRO that such Primary CRO shall maintain a professional liability insurance policy with limits of liability not lower than $[***] ([***] US Dollars).

Notwithstanding the foregoing, either Party shall maintain such insurance coverage during the term of this Agreement and, thereafter, for a minimum of 5 (five) years after the expiration or termination of this Agreement.

Upon request of a Party, the other Party shall provide the requesting Party with a certificate of insurance issued by the insurer or by the broker which shall include the details of its insurance policy, including, at least, the name of the insurer, the insured business activity, the policy number, the effective date, the expiration date and the limits of liability applied.

If either Party fails to maintain in force any of its own insurance policies as above, the other Party shall have the right (but not the obligation) to maintain any relevant insurance coverage by paying the relevant premiums in place of the defaulting Party, with the right to be fully reimbursed by the Party which has failed to maintain the policies required under this Agreement.

14.2 *Indemnification*.

14.2.1 *Indemnification by Menarini*. Menarini agrees to defend, indemnify and hold harmless Context, its Affiliates, and its and their employees, directors, subcontractors and agents from and against any loss, damage, reasonable costs and expenses (including reasonable attorneys' fees and expenses) incurred in connection with any claim, proceeding, or investigation by a Third Party arising out of this Agreement or the Study (a "**Liability**"), to the extent that such Liability (A) was caused by (i) negligence or willful misconduct on the part of Menarini (or any of its Affiliates, or its and their employees, directors, subcontractors or agents); (ii) a breach on the part of Menarini of any of its representations and warranties or any other covenants or obligations of Menarini under this Agreement; or (iii) a breach of Applicable Law by Menarini ; or (B) is determined to be attributable to the Menarini Compound, including any infringement of Third Parties intellectual property rights deriving from the Menarini Compound.

14.2.2 *Indemnification by Context*. Context agrees to defend, indemnify and hold harmless Menarini, its Affiliates, and its and their employees, directors, subcontractors and agents from and against any Liability to the extent that such Liability (A) was caused by (i) negligence or willful misconduct on the part of Context (or any of its Affiliates, or its and their employees, directors, subcontractors or agents); (ii) a breach on the part of Context of any of its representations and warranties or any other covenants or obligations of Context under this Agreement; or (iii) a breach of Applicable Law by Context; or (B) is determined to be attributable to the Context Compound, including any infringement of Third Parties intellectual property rights deriving from the Context Compound.

14.2.3 *Procedure*. The obligations of Context and Menarini under this Section 14.2 are conditioned upon the delivery of written notice to Context or Menarini, as the case might be, of any potential Liability within a reasonable time after a Party becomes aware of such potential Liability. A Party will have the right to assume the defense of

any suit or claim related to the Liability (using counsel reasonably satisfactory to the other Party) if it has assumed responsibility for the suit or claim in writing. The other Party may participate in (but not control) the defense thereof at its sole cost and expense. The Party controlling such defense (the "**Defending Party**") shall keep the other Party (the "**Other Party**") advised of the status of such action, suit, proceeding or claim and the defense thereof and shall reasonably consider recommendations made by the Other Party with respect thereto. The Defending Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Other Party, which shall not be unreasonably withheld, conditioned or delayed. The Defending Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Other Party from all liability with respect thereto or that imposes any liability or obligation on the Other Party without the prior written consent of the Other Party. The Defending Party shall have no liability for any settlement entered into by the Other Party without the Defending Party's prior written consent.

14.2.4 *Study Patients*. Menarini shall not offer compensation on behalf of Context to any Study subject or bind Context to any indemnification obligations in favor of any Study `subject. Likewise, Context shall not offer compensation on behalf of Menarini to any Study subject or bind Menarini to any indemnification obligations in favor of any Study subject.

14.3 *LIMITATION OF LIABILITY*. IN NO EVENT SHALL EITHER PARTY (OR ANY OF ITS AFFILIATES OR SUBCONTRACTORS) BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS OR DAMAGES FOR LOST OPPORTUNITIES), WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF THIS AGREEMENT. NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, IN NO EVENT SHALL THE LIABILITY OF EITHER PARTY HEREUNDER BE LIMITED OR EXCLUDED IN CASE OF: (i) FRAUD, GROSS NEGLIGENCE OR WILFUL MISCONDUCT, (ii) THIRD PARTY CLAIMS INDEMNIFIABLE UNDER SECTION 14.2 ABOVE, (iii) DAMAGES ARISING OUT OF, OR RELATED TO, A PARTY'S BREACH OF ITS OBLIGATIONS UNDER THIS AGREEMENT TO USE, DISCLOSE, LICENSE, ASSIGN OR OTHERWISE TRANSFER SAMPLE TESTING RESULTS, CLINICAL DATA, CONFIDENTIAL INFORMATION AND JOINTLY-OWNED INVENTIONS.

15. Use of Name

Except as expressly provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark, or logo of the other Party for any purpose in connection with the performance of this Agreement. To the extent required, or Context determines may be necessary (in its sole discretion), to be disclosed by Context in connection with any filings with the Securities and Exchange Commission, any regulatory agency or similar regulatory or exchange frameworks, Context shall have the right to include in such filings such information relating to this Agreement and/or a copy of this Agreement, without notice to Menarini.

16. Force Majeure

If in the performance of this Agreement, one of the Parties is prevented, hindered, or delayed by reason of any cause beyond such Party's reasonable control (e.g., war, riots, pandemic, fire, strike, governmental laws, etc.), such Party shall be excused from performance to the extent that it is necessarily prevented, hindered, or delayed ("**Force Majeure**"). The nonperforming Party will notify the other Party of such Force Majeure within ten (10) days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance will be of no greater scope and no longer duration than is necessary and the non-performing Party will use Commercially Reasonable Efforts to remedy its inability to perform.

17. Entire Agreement; Modification

This Agreement, together with the Related Agreements, constitutes the sole, full and complete agreement by and between the Parties with respect to the subject matter of this Agreement, and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded by this Agreement. No amendments, changes, additions, deletions, or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the Parties hereto.

18. Assignment and Sub-Contracting

Other than as provided for in Section 2.4, neither Party shall assign or transfer this Agreement without the prior written consent of the other Party; provided, however, that either Party may assign all or any part of this Agreement without the other Party's consent (i) to a Third Party that merges with, consolidates with or acquires substantially all of the assets or voting control of the assigning Party or (ii) to a Third Party that acquires all the rights of the assigning Party to the Menarini Compound, in the case of the Menarini Compound, or the Context Compound, in the case of Context, or (iii) to one or more of its Affiliates', and any and all rights and obligations of either Party may be exercised or performed by its Affiliates, provided that such Affiliates agree to be bound by this Agreement. Any breach by a Party's Affiliate, or merging/acquiring entity pursuant to section (i) or (ii) of the preceding sentence, of any such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's merging/acquiring entity or Affiliate. Each Party shall remain primarily liable for any acts or omissions of its Affiliates.

19. Invalid Provision

If any provision of this Agreement is held to be illegal, invalid, or unenforceable, the remaining provisions shall remain in full force and effect and will not be affected by the illegal, invalid, or unenforceable provision. In lieu of the illegal, invalid or unenforceable provision, the Parties shall negotiate in good faith to agree upon a reasonable provision that is legal, valid, and enforceable to carry out as nearly as practicable the original intention of the entire Agreement.

20. Additional Obligations

20.1 Should a Party reasonably determine that the Study was successful such that a subsequent clinical trial with the Combination, including additional, expansion or registrational study (the "**Phase 3 Study**") could reasonably be performed, such Party shall notify the other Party's Alliance Manager. Promptly after receipt of such notice, the Parties shall meet to discuss in good faith (i) the potential design and cost sharing for such Phase 3 Study; and (ii) the Protocol for such Phase 3 Study. Should the Parties fail to agree on the terms for such Phase 3 Study, and should one Party (the "**Phase 3 Party**") wish to pursue a Phase 3 Study,

the other Party shall nevertheless use Commercially Reasonable Efforts to provide (i) the Menarini Compound (in such case where Context is the Phase 3 Party) or the Context Compound (in such case where Menarini is the Phase 3 Party) at reasonable cost (which shall not exceed the non-Phase 3 Party's direct cost of goods for the Compound, including shipment costs plus [***]) and in such quantities and pursuant to such reasonable timelines as the Phase 3 Party reasonably deems necessary, and (ii) a "right of reference" as necessary for the Phase 3 Party to prepare, submit and maintain regulatory submissions related to the Phase 3 Study and related Regulatory Approvals. The Phase 3 Party shall consider in good faith all comments to the Protocol that the other Party may provide, and the Phase 3 Party shall not insert in the Protocol anything that may materially impact the Menarini Compound (in such case where Context is the Phase 3 Party) or the Context Compound (in such case where Menarini is the Phase 3 Party) without the other Party's prior written consent, not to be unreasonably withheld, conditioned or delayed, unless a particular change is required by Applicable Laws or an applicable IRB/ethics committee. Additionally, the Phase 3 Party shall give the other Party access to the entire documentation of the Phase 3 Study and shall permit the other Party to interact with any Regulatory Authority with respect to the Phase 3 Study. In any event (regardless if an agreement on Phase 3 Study is achieved between the Parties), the Parties shall discuss in good faith the potential for a mutually beneficial exploitation of the Phase 3 Study results and data.

20.2 If at any time prior to three (3) months after the database lock of the Study Context receives a bona-fide written offer from a Third Party regarding a potential Further Transaction, Context shall notify Menarini in writing of Context's receipt of such offer ("**Further Transaction Notice**"), without any obligation to provide any details regarding the terms of, or party(ies), to such Third-Party offer; provided however, that no such notice shall be required if providing such notice (i) would result in conflict with any Applicable Law (including the rules of any exchange on which Context's securities are traded), or (ii) may require public disclosure pursuant to Applicable Law or the rules of any exchange on which Context's securities are traded (pursuant to written advice obtained by Context external legal counsel which advice shall be shared with Menarini in such a way and to the extent providing such advice to Menarini does not waive Context's attorney-client privilege). After receipt of the Further Transaction Notice, if Menarini desires to pursue a Further Transaction, then Menarini shall promptly notify Context in writing that sets forth the proposed terms for such Further Transaction ("**Menarini Response**"), which Context shall consider in good faith. In no event shall Context share the results generated under the Study with any Third Party in connection with any intended potential Further Transaction until such results have been publicly disclosed in accordance with the terms of this Agreement. Furthermore, in no event shall Menarini share the results generated under the Study with any Third Party (other than its licensors) until such results have been publicly disclosed in accordance with the terms of this Agreement. Any obligations of Context set forth in this Section 20.2 shall immediately terminate upon (i) Menarini's breach of any terms of this Agreement, (ii) FDA providing a complete response letter ("**CRL**") to the application for approval for the Menarini Compound that does not ultimately lead to approval of the Menarini Compound within six (6) months of such initial CRL, (iii) the termination or expiration of this Agreement, or termination of the Study, (iv) Menarini's failure to provide the Menarini Response setting forth reasonable terms (as Context determines in its sole discretion) within [***] days of Menarini's receipt of a Further Transaction Notice, or (v) Menarini and Context's failure to come to definitive terms regarding a transaction within [***] days of Menarini's receipt of a Further Transaction Notice.

21. Governing Law

21.1 The Parties shall attempt in good faith to settle all disputes arising out of or in connection with this Agreement in an amicable manner. Any claim, dispute or controversy arising out of or relating to this Agreement, including the breach, termination, or validity hereof or thereof (each, a "**Dispute**"), shall be governed by and construed in accordance with the substantive laws of the State of New York, without giving effect to its choice of law principles. The Parties hereby consent to the exclusive jurisdiction and venue in the state or federal courts located in New York City, Southern District, New York to resolve any dispute which cannot be resolved amicably by the Parties.

21.2 Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed or maintained notwithstanding any ongoing discussions between the Parties.

21.3 Menarini acknowledges that it is aware (and any representative who receives Confidential Information has or will be advised) that federal and state securities laws prohibit any person who has material non-public information about a company or its securities from purchasing or selling securities of such company, or from communicating such information to other persons, under circumstances in which it is foreseeable that such person may purchase or sell such securities. Menarini covenants to refrain from using or communicating material non-public information provided by or on behalf of Context in violation of such securities laws.

22. Notices

All notices or other communications that are required or permitted hereunder shall be in writing and delivered personally, sent by electronic mail (and promptly confirmed by personal delivery or overnight courier), or sent by internationally recognized overnight courier addressed as follows:

If to Context, to:

Context Therapeutics Inc.
2001 Market Street,
Suite 3915, Unit#15
Philadelphia, PA 19103 USA
Attn: Martin Lehr, Chief Executive Officer
Email: [***]

with a required copy to:

Context Therapeutics Inc.
2001 Market Street,
Suite 3915, Unit#15
Philadelphia, PA 19103 USA
Attn: Alex Levit, Chief Legal Officer
Email: [***]
Attn: Context's Alliance Manager

If to Menarini, to:

Berlin-Chemie AG
Glienicker Weg 125, 12849 Berlin
Attn: President of the Board of Directors

Email: [***]

with a required copy to:

Berlin-Chemie AG
Glienicker Weg 125, 12849 Berlin
Attn: Head of Legal Department
Email: [***]
Attn: Menarini's Alliance Manager
Email: [***]

23. Relationship of the Parties

The relationship between the Parties is and shall be that of independent contractors, and does not and shall not constitute a partnership, joint venture, agency, or fiduciary relationship. Neither Party shall have the authority to make any statements, representations, or commitments of any kind, or take any actions, which are binding on the other Party, except with the prior written consent of the other Party to do so. All persons employed by a Party will be the employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

24. Counterparts and Due Execution

This Agreement and any amendment may be executed in two (2) or more counterparts (including by way of electronic transmission), each of which shall be deemed an original, but all of which together shall constitute one and the same instrument, notwithstanding any electronic transmission, storage, and printing of copies of this Agreement from computers or printers. When executed by the Parties, this Agreement shall constitute an original instrument, notwithstanding any electronic transmission, storage, and printing of copies of this Agreement from computers or printers. For clarity, signatures transmitted via PDF shall be treated as original signatures.

25. Construction

Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, the use of any gender will be applicable to all genders, and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein shall be deemed to be followed by the phrase "without limitation" or like expression. The term "will" as used herein means shall. References to "Article," "Section" or "Appendix" are references to the numbered sections of this Agreement and the appendices attached to this Agreement, unless expressly stated otherwise. Except where the context otherwise requires, references to this "Agreement" shall include the appendices attached to this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction will be applied against either Party hereto.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the respective representatives of the Parties have executed this Agreement as of the Effective Date.

Context Therapeutics Inc.

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

Berlin-Chemie AG

By: /s/ Dr. Attilio Sebastio
Name: Dr Attilio Sebastio
Title: Chief Financial Officer

By: /s/ Dr. Luca Lastrucci
Name: Dr. Luca Lastrucci
Title: Chairman of the Executive Board

[***]

[***]

Schedule I

DATA SHARING AND SAMPLE TESTING SCHEDULE

[***]

Appendix C

TESTING OF cfNA IN BLOOD SAMPLES

[***]

EXHIBIT 31.1

CERTIFICATION

I, Martin Lehr, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: August 11, 2022

/s/ Martin Lehr

Martin Lehr
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Jennifer Minai-Azary, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: August 11, 2022

/s/ Jennifer Minai-Azary

Jennifer Minai-Azary
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

STATEMENT PURSUANT TO 18 U.S.C. § 1350

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), 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 Quarterly Report on Form 10-Q for the period ended June 30, 2022, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report") fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

(2) The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

	/s/ Martin Lehr
Date: August 11, 2022	Martin Lehr Chief Executive Officer (Principal Executive Officer)
	/s/ Jennifer Minai-Azary
Date: August 11, 2022	Jennifer Minai-Azary Chief Financial Officer (Principal Financial Officer)

"This certification accompanies the Form 10-Q 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-Q), irrespective of any general incorporation language contained in such filing."