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 September 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 November 4, 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 Company-sponsored trial and 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 and other economic uncertainties 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 and ability to seek additional capital in the future through equity and/or debt financings, partnerships, collaborations, or other sources and the availability and terms 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 U.S. Securities and Exchange Commission ("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 ONA-XR and CLDN6 BsAb. 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

	September 30, 2022 (Unaudited)	December 31, 2021 (Note 3)
Assets		
Current assets:		
Cash and cash equivalents	$ 39,427,118	$ 49,635,197
Prepaid expenses and other current assets	2,512,076	1,620,164
Total current assets	41,939,194	51,255,361
Operating lease right-of-use asset	73,752	—
Property and equipment, net	30,762	—
Other assets	39,313	—
Restricted cash	—	50,389
Total assets	$ 42,083,021	$ 51,305,750
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,494,995	$ 1,826,294
Accrued expenses and other current liabilities	2,438,319	1,207,121
Operating lease liability - current	78,197	—
Total current liabilities	4,011,511	3,033,415
Total liabilities	4,011,511	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 September 30, 2022 and December 31, 2021	15,966	15,966
Additional paid-in capital	78,589,142	77,510,809
Accumulated deficit	(40,533,598)	(29,254,440)
Total stockholders' equity	38,071,510	48,272,335
Total liabilities and stockholders' equity	$ 42,083,021	$ 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 September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Acquired in-process research and development	$ —	$ —	$ 500,000	$ 3,087,832
Research and development	2,077,566	739,598	4,946,304	2,511,438
General and administrative	1,970,521	828,464	6,052,556	1,834,645
Loss from operations	(4,048,087)	(1,568,062)	(11,498,860)	(7,433,915)
Interest income (expense), net	192,245	(1,261)	219,405	(64,555)
Change in fair value of convertible promissory notes	—	—	—	9,317
Other income	1,532	126,531	297	124,148
Net loss	$ (3,854,310)	$ (1,442,792)	$ (11,279,158)	$ (7,365,005)
Net loss per common share, basic and diluted	$ (0.24)	$ (4.00)	$ (0.71)	$ (20.74)
Weighted average shares outstanding, basic and diluted	15,966,053	361,067	15,966,053	355,087

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)
Fair value of warrants issued for services	—	—	—	—	—	—	—	—	371,895	—	371,895
Share-based compensation expense, including vesting of restricted stock and issuance of common stock	—	—	—	—	—	—	6,262	6	161,817	—	161,823
Net loss	—	—	—	—	—	—	—	—	—	(1,442,792)	(1,442,792)
Balance at September 30, 2021	2,212,543	$ 14,641,005	2,624,324	$ 6,341,288	16,666	$ 82,330	348,531	$ 348	$ 2,948,294	$ (26,162,575)	$ (23,213,933)

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
Share-based compensation expense	—	—	276,521	—	276,521
Net loss	—	—	—	(3,854,310)	(3,854,310)
Balance at September 30, 2022	15,966,053	$ 15,966	$ 78,589,142	$ (40,533,598)	$ 38,071,510

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

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

	Nine months ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (11,279,158)	$ (7,365,005)
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	732,803	306,699
Depreciation and amortization expense	6,074	—
Non-cash interest expense	—	64,555
Change in fair value of convertible promissory notes	—	(9,317)
Reduction in the carrying amount of operating lease right-of-use asset	56,736	—
Gain on extinguishment of debt	—	(125,577)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(891,912)	(9,707)
Other assets	(39,313)	—
Accounts payable	(229,228)	(179,199)
Accrued expenses and other current liabilities	1,576,728	20,021
Operating lease liability	(52,291)	—
Cash used in operating activities	(9,619,561)	(3,837,803)
Cash flows from investing activities:		
Acquired in-process research and development	(500,000)	(250,000)
Purchase of property and equipment	(36,836)	—
Cash used in investing activities	(536,836)	(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
Payment of offering costs related to initial public offering	—	(816,917)
Cash (used in) provided by financing activities	(102,071)	4,165,918
Net (decrease) increase in cash, cash equivalents and restricted cash	(10,258,468)	78,115
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	$ 39,427,118	$ 419,152
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 and accrued expenses	$ —	$ 1,004,856
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 $40.5 million as of September 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 $39.4 million as of September 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 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 September 30, 2022, and its results of operations for the three and nine months ended September 30, 2022 and 2021 and cash flows for the nine months ended September 30, 2022 and 2021. Operating results for the three and nine months ended September 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 condensed 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 September 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 consist 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 condensed consolidated 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:

	September 30,	
	2022	2021
Series Seed convertible preferred stock	—	2,624,324
Series A convertible preferred stock	—	2,212,543
Stock options	1,341,504	436,437
Unvested restricted stock awards	—	33,397
Warrants	5,860,000	480,415
	7,201,504	5,787,116

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:

	September 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)	$ 1,921,341	$ 1,921,341	$ —	$ —

	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:

	September 30, 2022	December 31, 2021
Compensation and benefits	$ 564,989	$ 436,990
Research and development costs	1,801,041	339,072
Professional fees	12,000	345,530
Other	60,289	85,529
Total	$ 2,438,319	$ 1,207,121

(6) Convertible Promissory Notes and Other Debt

Senior Convertible Notes

The Company previously issued certain convertible promissory notes to various investors which were converted into Senior Convertible Notes (the “Senior Convertible Notes”, and 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 Stock. The Company recorded a non-cash credit of $9,000 in the condensed consolidated statement of operations for the nine months ended September 30, 2021 related to the decrease in fair value of the Senior Convertible Notes. For the nine months ended September 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 for a loan in an aggregate principal amount of $0.1 million (the “Loan”) pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security (CARES) Act 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. The outstanding principal balance of the Loan of $0.1 million was forgiven in July 2021 and was recognized as a gain on extinguishment of debt within other income in the condensed consolidated statements of operations during the three and nine months ended September 30, 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 sheets as of December 31, 2021. The liability was reclassified into additional paid-in capital in March 2022 upon the issuance of the warrants.

At September 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 Performance 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 September 30, 2022, 546,535 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 August 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 nine months ended September 30, 2022 and 2021:

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Research and development	$ 14,349	$ 17,775	$ 74,256	$ 56,677
General and administrative	262,172	133,300	658,547	224,049
	$ 276,521	$ 151,075	$ 732,803	$ 280,726

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 nine months ended September 30, 2022 and 2021, respectively, were as follows:

	2022	2021
Expected stock price volatility	87.02%	97.50%
Risk-free interest rate	2.17%	1.03%
Expected term (in years)	5.95	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	890,058	$ 1.85	
Forfeited	(55,245)	$ 2.52	
Outstanding at September 30, 2022	1,341,504	$ 3.27	9.1
Vested and exercisable at September 30, 2022	275,061	$ 5.90	8.5
Vested and expected to vest at September 30, 2022	1,341,504	$ 3.27	9.1

The weighted average fair value of share-based awards granted during the nine months ended September 30, 2022 and 2021 was $1.38 and $3.76, respectively. As of September 30, 2022, the unrecognized compensation cost related to outstanding share-based awards was $1.9 million and is expected to be recognized as expense over a weighted-average period of approximately 2.25 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 $10,000 and $25,000 in research and development expense for the three and nine months ended September 30, 2021, respectively, related to RSUs. There were no RSUs outstanding as of September 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 September 30, 2022, the operating lease right-of-use asset and the operating lease liabilities were $74,000 and $78,000, 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 0.83 years.

Rent expense related to the Company's operating lease was approximately $23,000 and $60,000 for the three and nine months ended September 30, 2022, respectively. The Company recognizes rent expense on a straight-line basis over the lease period and accrues for rent expense incurred but not yet paid.

Future minimum lease payments under the sublease are $80,000 at September 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 nine months ended September 30, 2022, the Company provided contributions of approximately $12,000 and $54,000, respectively.

Collaboration Agreement with Tyligand Bioscience

In March 2020, the Company entered into a process development agreement (the "Tyligand Process Development Agreement") 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 Process Development Agreement, Tyligand was solely responsible for the design and optimization of an improved manufacturing process for ONA-XR. Upon completion of specific performance-based milestones, Tyligand and the Company entered into a license agreement (the "Tyligand License Agreement" and, together with the Tyligand Process Development Agreement, the "Tyligand Agreements") whereby Tyligand was granted the exclusive right to ONA-XR and is solely responsible for the development and commercialization of ONA-XR in China, Hong Kong and Macau (the "Territory"). The Company retains rights in the rest of the world 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 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, granted 418,559 shares of Series A Stock with a fair market value of approximately $2.8 million, and expensed these costs 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 approximately $55 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 November 7, 2022, the Company entered into a Development and Manufacturing Services Agreement (the "Lonza Development Agreement"), with Lonza Sales AG ("Lonza Sales") and Lonza AG (collectively, "Lonza"). Under the terms of the Lonza Development Agreement, Lonza will provide services relating to the development and manufacture of the Company's anti-claudin 6 bispecific monoclonal antibody product (the "Product") in accordance with the project plan attached to the Lonza Development Agreement and any other work as may be agreed to between the Company and Lonza. The Lonza Development Agreement will terminate upon the completion of the agreed upon services, unless earlier terminated by the Company or Lonza for uncured material breaches, insolvency of the other party, or if a party determines that it is not possible to complete the services for material scientific or material technical reasons.

In addition, on November 7, 2022, the Company entered into a License Agreement (the "Lonza License Agreement") with Lonza Sales. Under the terms of the Lonza License Agreement, to the extent incorporated into the Product, Lonza granted the Company a non-exclusive license to use certain proprietary Lonza intellectual property and systems for the Company to develop, manufacture and commercially exploit the Product.

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.

Our first program, ONA-XR, is being advanced across various investigator-sponsored trials and a Company-sponsored trial:

- An ongoing Phase 2 investigator-sponsored trial is being conducted in collaboration with Jefferson Health to evaluate ONA-XR in combination with anastrozole to treat women with progesterone receptor positive ("PR+") endometrial adenocarcinoma who have failed front line therapy with a platinum/taxane-based chemotherapy regimen. As of September 30, 2022, we note the following:
  - The trial has enrolled 12 of 25 planned patients.
  - The preliminary 4-month progression free survival ("PFS") rate was 77.7%, based on nine evaluable patients.
  - Three patients received treatment for greater than 12 months.
  - Overall, seven patients remain in the trial.
  - There have been no treatment-related serious adverse events reported.

  This trial is ongoing and updated trial results are expected in mid-2023.
- An ongoing Phase 2 investigator-sponsored basket trial is being conducted in collaboration with Memorial Sloan Kettering Cancer Center to evaluate ONA-XR in combination with anastrozole to treat women with PR+ recurrent gynecologic cancers. As of September 30, 2022, we note the following:
  - Cohort 1, which treats patients with PR+ recurrent granulosa cell tumors with ONA-XR as a single agent, completed accrual to stage 1 and has shown a 12-month PFS rate of 20.1% and a Clinical Benefit Rate (stable disease) of 35.7%. Two patients continued on active treatment for greater than 18 months. One patient remains on trial.
  - Cohort 4, which treats patients with PR+ recurrent granulosa cell tumors with ONA-XR in combination with anastrozole, enrolled 14 patients in stage 1 and will expand to stage 2 when greater than or equal to one response is observed. Seven patients remain on trial.
  - There have been no treatment-related serious adverse events reported.

  This trial is ongoing and updated trial results are expected in mid-2023.
- An ongoing Phase 2 investigator-sponsored trial is being conducted in collaboration with Wisconsin Oncology Network to evaluate ONA-XR in combination with fulvestrant in second line or third line advanced or metastatic estrogen receptor positive ("ER+"),PR+,HER2- breast cancer (the "SMILE" trial). This trial is intended to evaluate potential ONA-XR plus fulvestrant drug synergy after treatment failure of CDK4/6 and/or PIK3α inhibitors, with initial clinical data expected in December 2022.
- The SMILE trial will also evaluate radiolabeled progesterone ("^{18}F-FFNP") distribution in PR target tissues and quantify available PR binding sites via positron emission tomography (PET)/computed tomography (CT) imaging in breast tumors when co-treated with ONA-XR. Data is expected in 2023.

- 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, we will conduct a Phase 1b/2 study of elacestrant in combination with ONA-XR in patients with advanced or metastatic ER+,PR+,HER2- breast cancer (the “ELONA” trial). 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 the ELONA trial. Under the Menarini Agreement, we will sponsor, fund and conduct the ELONA trial, and Menarini has agreed to manufacture and supply elacestrant at Menarini's cost and for no charge to us for use in the ELONA trial and to provide cell-free nucleic acid analysis of the anonymized blood samples of all ELONA trial patients.
- In November 2022, we initiated the ELONA trial, with Phase 1b data expected in the fourth quarter of 2023.

The observations from the ongoing clinical trials noted above are based on information available as of September 30, 2022. These trials are still actively enrolling patients and these preliminary clinical findings may materially fluctuate on a month-to-month basis as the trials progress and may not be representative of results after all patients complete the respective trial and all data is collected and analyzed. Further, this data is subject to continuing audit and verification procedures that will not be complete until the conclusion of the respective trial and therefore the interim data is subject to change.

Our second program, CLDN6xCD3 bispecific antibody, is being advanced toward an Investigational New Drug Application ("IND") submission. 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 or expressed at very low levels in normal adult tissues. We reached the first development milestone under our collaboration and license agreement with Integral Molecular ("Integral") in the second quarter of 2022. We expect to select a candidate to support Investigational New Drug ("IND")-enabling studies for CLDN6xCD3 BsAb in December 2022 and an IND submission is planned in the first quarter of 2024.

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 $11.3 million for the nine months ended September 30, 2022. As of September 30, 2022, we had an accumulated deficit of $40.5 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 first quarter of 2024. 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 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 will continue to incur significant 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 and 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 previously outstanding convertible promissory notes of the Company were converted as of February 2021.

Results of Operations

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

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

	Three months ended September 30,			
	2022	**2021**	**$ Change**	**% Change**
Operating expenses:				
Research and development	$ 2,077,566	$ 739,598	$ 1,337,968	181 %
General and administrative	1,970,521	828,464	1,142,057	138 %
Loss from operations	(4,048,087)	(1,568,062)	(2,480,025)	158 %
Interest income (expense), net	192,245	(1,261)	193,506	(15345)%
Other income	1,532	126,531	(124,999)	(99)%
Net loss	$ (3,854,310)	$ (1,442,792)	$ (2,411,518)	167 %

Research and Development Expenses

Research and development expenses increased by approximately $1.3 million for the three months ended September 30, 2022 as compared to the same period in 2021. The following table summarizes our research and development expenses for the three months ended September 30, 2022 as compared to the same period in 2021:

	Three months ended September 30,			
	2022	**2021**	**$ Change**	**% Change**
ONA-XR	$ 1,422,477	$ 331,872	$ 1,090,605	329 %
CLDN6	299,686	207,398	92,288	44 %
Personnel-related costs	331,263	199,216	132,047	66 %
Other research and development	24,140	1,112	23,028	2071 %
	$ 2,077,566	$ 739,598	$ 1,337,968	181 %

The increase in ONA-XR expense of $1.1 million was primarily due to an increase of $0.6 million in contract manufacturing costs and an increase of $0.4 million in clinical trial costs, mostly as a result of preparing to initiate our Phase 1b/2 ELONA trial. Personnel-related costs, which include salaries, benefits and stock compensation expense, increased by approximately $0.1 million, primarily due to higher headcount over the prior year period.

General and Administrative Expenses

General and administrative expenses increased by approximately $1.1 million for the three months ended September 30, 2022 as compared to the same period in 2021. The increase was primarily due to an increase of $0.4 million in compensation and share-based compensation as a result of an increase in our general and administrative headcount and changes to compensation arrangements, higher insurance costs of $0.4 million and $0.3 million of other costs associated with operating as a public company.

Interest Income (Expense), net

Interest income (expense), net, increased by approximately $0.2 million for the three months ended September 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.

Other Income

Other income of $0.1 million for the three months ended September 30, 2021 was primarily due to the recognition of a gain on extinguishment of debt as a result of the forgiveness of our outstanding Paycheck Protection Program loan in July 2021.

Comparison of the Nine Months Ended September 30, 2022 and 2021

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

	Nine months ended September 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	4,946,304	2,511,438	2,434,866	97 %
General and administrative	6,052,556	1,834,645	4,217,911	230 %
Loss from operations	(11,498,860)	(7,433,915)	(4,064,945)	55 %
Interest income (expense), net	219,405	(64,555)	283,960	(440)%
Change in fair value of convertible promissory notes	—	9,317	(9,317)	(100)%
Other income	297	124,148	(123,851)	(100)%
Net loss	$ (11,279,158)	$ (7,365,005)	$ (3,914,153)	53 %

Acquired In-Process Research and Development Expenses

Acquired in-process research and development expense of $0.5 million for the nine months ended September 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.

Acquired in-process research and development expense of $3.1 million for the nine months ended September 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.

Research and Development Expenses

Research and development expenses increased by approximately $2.4 million for the nine months ended September 30, 2022 as compared to the same period in 2021. The following table summarizes our research and development expenses for the nine months ended September 30, 2022 as compared to the same period in 2021:

	Nine months ended September 30,			
	2022	**2021**	**$ Change**	**% Change**
ONA-XR expenses	$ 3,283,887	$ 1,423,277	$ 1,860,610	131 %
CLDN6 expenses	452,646	523,462	(70,816)	(14)%
Personnel-related costs	1,101,291	545,583	555,708	102 %
Other research and development	108,480	19,116	89,364	467 %
	$ 4,946,304	$ 2,511,438	$ 2,434,866	97 %

The increase in ONA-XR expenses of $1.9 million was primarily due to an increase of $1.1 million in contract manufacturing costs and an increase of $0.5 million in clinical trial costs, mostly as a result of preparing to initiate our Phase

1b/2 ELONA trial. Personnel-related costs, which include salaries, benefits and stock compensation expense, increased by approximately $0.6 million, primarily due to higher headcount over the prior year period.

General and Administrative Expenses

General and administrative expenses increased by approximately $4.2 million for the nine months ended September 30, 2022 as compared to the same period in 2021. The increase was mainly due to an increase of $1.8 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 due to higher insurance costs of $1.3 million and $0.9 million of other costs associated with operating as a public company.

Interest Income (Expense), net

Interest income (expense), net, increased by approximately $0.3 million for the nine months ended September 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 nine months ended September 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 $9,317 for the nine months ended September 30, 2021. This change was attributable to a decrease in the fair value of our common stock.

Other Income

Other income of $0.1 million for the nine months ended September 30, 2021 was primarily due to the recognition of a gain on extinguishment of debt as a result of the forgiveness of our outstanding Paycheck Protection Program loan in July 2021.

Liquidity and Capital Resources

Overview

Since our inception, we have not recognized any revenue and have incurred operating losses and negative cash flows from our operations. We have not yet commercialized any product and we do not expect to generate revenue from sales of any products for several years, if at all. Since our inception through September 30, 2022, we have funded our operations through the sale of convertible debt, convertible preferred stock and common stock. As of September 30, 2022, we had $39.4 million in cash and cash equivalents and had an accumulated deficit of $40.5 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 first quarter of 2024. We have based these estimates on assumptions that may prove to be imprecise, and we could utilize our available capital resources sooner than we expect.

Funding Requirements

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

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

- the scope, timing, progress and results of discovery, preclinical development, laboratory testing and clinical trials for our product candidates;

- the costs of manufacturing our product candidates for clinical trials and in preparation for regulatory approval and commercialization;
- the extent to which we enter into 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 stockholders 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:

	Nine months ended September 30,	
	2022	**2021**
Cash used in operating activities	$ (9,619,561)	$ (3,837,803)
Cash used in investing activities	(536,836)	(250,000)
Cash (used in) provided by financing activities	(102,071)	4,165,918
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (10,258,468)	$ 78,115

Comparison of the Nine Months Ended September 30, 2022 and 2021

Operating Activities

During the nine months ended September 30, 2022, we used $9.6 million of cash in operating activities. Cash used in operating activities reflected our net loss of $11.3 million partially offset by in-process research and development charges of $0.5 million, non-cash share-based compensation of $0.7 million, and a change in our operating assets and liabilities of $0.4 million. The primary uses of cash were to fund our operations related to the development of our product candidates.

During the nine months ended September 30, 2021, we used $3.8 million of cash in operating activities. Cash used in operating activities reflected our net loss of $7.4 million, a gain of $0.1 million from the extinguishment of debt and an increase in our operating assets and liabilities of $0.2 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 of $0.4 million and non-cash interest expense and share-based compensation of $0.4 million. The primary uses of cash were to fund our operations related to the development of our product candidates.

Investing Activities

During the nine months ended September 30, 2022, cash used in investing activities was primarily attributable to the payment of a development milestone of $0.5 million under the collaboration and licensing agreement with Integral for the development of CLDN6 BsAb for gynecologic cancer therapy. In addition, we used $37,000 of cash to purchase property and equipment.

During the nine months ended September 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 nine months ended September 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 nine months ended September 30, 2021, financing activities provided $4.2 million, primarily consisting of net proceeds of $5.0 million from the sale of Series A preferred stock and warrants for common stock, partially offset by the payment of $0.8 million of offering costs related to our IPO.

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 nine months ended September 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 $1.235 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 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 until either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 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 September 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 September 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. Other than as set forth below, 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.

The passage of the Inflation Reduction Act of 2022 may negatively impact our ability to sell our product candidates, if approved, profitably.

On August 16, 2022, the Inflation Reduction Act of 2022, or the IRA, was passed, which among other things, allows for The Centers for Medicare & Medicaid Services to negotiate prices for certain single-source drugs and biologics reimbursed under Medicare Part B and Part D, beginning with ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. The legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated “maximum fair price” under the law or for taking price increases that exceed inflation. The legislation also caps Medicare beneficiaries’ annual out-of-pocket drug expenses at $2,000. The effect of the IRA on our business and the healthcare industry in general is not yet known.

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

Because we are filing this Quarterly Report on Form 10-Q within four business days after the triggering event, we are making the following disclosure under this Item 5 instead of filing a Current Report on Form 8-K under Item 1.01, Entry into a Material Definitive Agreement:

Development and Manufacturing Services Agreement

On November 7, 2022, Context Therapeutics Inc. (the “Company”) entered into a Development and Manufacturing Services Agreement (the “Lonza Development Agreement”), with Lonza Sales AG (“Lonza Sales”) and Lonza AG (collectively, “Lonza”). Under the terms of the Lonza Development Agreement, Lonza will provide services relating to the development and manufacture of the Company’s anti-claudin 6 bispecific monoclonal antibody product (the “Product”) in accordance with the project plan attached to the Lonza Development Agreement and any other work as may be agreed to between the Company and Lonza. The Lonza Development Agreement will terminate upon the completion of the agreed upon

services, unless earlier terminated by the Company or Lonza for uncured material breaches, insolvency of the other party, or if a party determines that it is not possible to complete the services for material scientific or material technical reasons.

The Company can terminate certain services under the Lonza Development Agreement, but in addition to payment for certain non-cancellable commitments, the Company would be required to pay a cancellation fee, such fee to be determined depending on the timing of such notice prior to the commencement of the related services.

The License Development Agreement requires the Company to obtain a license from Lonza prior to receipt of the Product or in vivo clinical studies or any other commercial use or sale of the Product, which the Company entered into concurrently with the License Development Agreement, as further described below. Additionally, should the Company desire to either manufacture the Product itself or have it manufactured by a third party, the Company would be required to obtain Lonza's consent (not to be unreasonably withheld, conditioned or delayed) and would need to enter into a separate technology transfer agreement with Lonza for a non-exclusive license to the extent necessary to manufacture, have manufactured and supply the Product at a licensing fee up to £750,000.

The Lonza Development Agreement also contains customary representations, warranties, indemnification and other obligations of the Company and Lonza.

License Agreement

On November 7, 2022, the Company entered into a License Agreement (the "Lonza License Agreement") with Lonza Sales. Under the terms of the Lonza License Agreement, to the extent incorporated into the Product, Lonza granted the Company a non-exclusive license to use certain proprietary Lonza intellectual property and systems for the Company to develop, manufacture and commercially exploit the Product.

The Company shall pay certain royalties and annual payments in respect of the manufacturing and sale of Product, which amounts shall be determined by the party manufacturing the Product and ranges from a potential annual payment of up to less than $500,000 and a royalty on net sales from 0% up to a low single digit percentage. The royalty payments and annual payments would be reduced in certain circumstances, including should the valid claims for any such patent rights not exist in the country in which such Product is being sold, and the royalty payments would expire upon the later of the expiration of the licensed patents in the country in which such Product is being sold, the expiration of the licensed patents in the country in which such Product is being manufactured, and ten years from the first commercial sales of the Product in such country of sale.

The Lonza License Agreement continues until terminated, and the Company or Lonza may terminate the Lonza License Agreement for uncured material breaches or insolvency of the other party. The Company can unilaterally terminate the Lonza License Agreement with prior written notice to Lonza, and Lonza can also unilaterally terminate the Lonza License Agreement upon certain actions by the Company.

The Lonza License Agreement also contains customary representations, warranties, indemnification and other obligations of the Company and Lonza.

The foregoing description of the Lonza Development Agreement and Lonza License Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Lonza Development Agreement and Lonza License Agreement, which will be filed as exhibits to a subsequent filing with the Securities and Exchange Commission (the "Commission"), as permitted by the rules of the Commission.

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#	Clinical Trial Collaboration and Supply Agreement, dated August 1, 2022, by and between Context Therapeutics Inc. and Berlin-Chemie AG - Menarini Group (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q (File No. 001-40654), as filed with the SEC on August 11, 2022).
10.2*	Amendment No. 3 to Process Development Agreement & Amendment No. 1 to License, Development, Manufacturing & Marketing Agreement, dated November 7, 2022, between Context Therapeutics LLC and Tyligand Bioscience (Shanghai) Limited.
10.3*#	Development and Manufacturing Services Agreement, dated November 7, 2022, between Lonza Sales AG, Lonza AG and Context Therapeutics Inc.
10.4*#	License Agreement, dated November 7, 2022, between Lonza Sales AG and Context Therapeutics Inc.
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 September 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
# 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: November 9, 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. 3 TO PROCESS DEVELOPMENT AGREEMENT & AMENDMENT NO. 1 TO LICENSE, DEVELOPMENT, MANUFACTURING & MARKETING AGREEMENT

This **AMENDMENT NO. 3 TO PROCESS DEVELOPMENT AGREEMENT** (the "***Development Amendment***") **and AMENDMENT NO. 1 TO LICENSE, DEVELOPMENT, MANUFACTURING & MARKETING AGREEMENT** (the "***License Amendment***", and collectively with the Development Amendment, this "***Amendment***") is effective as of this 7th day of November 2022 (the "***Amendment Effective Date***"), and is entered into by and between Tyligand Bioscience (Shanghai) Limited, having its registered office at Floor 1 (West Lobby and Auxiliary Room), 4 and 5, Tower 12 (No.1), No. 3728, Jinke Road, Shanghai Pilot Free Trade Zone of PRC ("***Tyligand***") and Context Therapeutics LLC, a Delaware limited liability company having its registered office at 2001 Market Street, Suite 3915, Unit#15, Philadelphia, PA 19103 ("***Context***"). Tyligand and Context are sometimes referred to herein individually as a "***Party***" and collectively as the "***Parties***."

RECITALS

WHEREAS, Tyligand and Context entered into that certain Process Development Agreement, effective as of the 6th day of March 2020, as amended by Amendment No. 1 effective as of the 21st day of April 2021, and as amended by Amendment No. 2 effective as of the 3rd day of June 2021 (as amended, the "***Development Agreement***"), which outlines the rights and obligations of Tyligand and Context with respect to the conduct of certain services to be performed by Tyligand;

WHEREAS, due to the Successful Completion (as defined in the Development Agreement) of Tyligand's process development efforts, the Parties also entered into that certain License, Development, Manufacturing & Marketing Agreement on the 23rd day of August 2021 (the "***License Agreement***"), for Tyligand's development and commercialization of the Compound (as defined in the License Agreement) in the Territory (as defined in the License Agreement);

WHEREAS, the Parties intend to enter into the Development Amendment to recognize and agree that the provisions in Sections 3.1 (Milestones), 3.2 (Royalty), 3.6 (Method of Payments) and 3.7 (Conflict) in ARTICLE III, CONSIDERATION of the Development Agreement shall survive the Term (as defined in Section 10.1 of the Development Agreement);

WHEREAS, the Parties intend to enter into the License Amendment to (i) amend and restate Section 1.52 in ARTICLE 1 DEFINITIONS of the License Agreement, (ii) amend and restate Section 4.2.1 (Grant Back) in ARTICLE 4 IMPROVEMENT of the License Agreement, and (iii) recognize and agree that the provisions in Section 4.2.1 (Grant Back) in ARTICLE 4 IMPROVEMENT and Section 9.1 (Term) in ARTICLE 9 TERM AND TERMINATION of the License Agreement shall survive the expiration of the License Agreement subject to terms and conditions thereof;

NOW THEREFORE, in order to avoid any confusion, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, wish to enter into this Amendment and 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 Development Agreement or License Agreement, as applicable.

Development Amendment

2. **Amendment to Section 10.7 of the Development Agreement**. Effective as of the Amendment Effective Date, Section 10.7 of the Development Agreement is hereby amended and restated as follows:

> "10.7 Survival. Subject to terms and conditions of this Agreement, the termination or expiration of this Agreement shall not affect the survival and continuing validity and enforceability of provisions herein expressed to survive and operate following such expiration or termination, including Sections 3.1, 3.2, 3.6 and 3.7, and Article VI through Article XI."

License Amendment

3. **Amendment to Section 1.52 of the License Agreement**. Effective as of the Amendment Effective Date, Section 1.52 of the License Agreement is hereby amended and restated as follows:

> "**"Tyligand Know-How"** means all Know-How that relate solely and directly to the Compound or the Product which becomes Controlled by Tyligand or its Affiliates, sublicensees or contractors."

4. **Amendment to Section 4.2.1 of the License Agreement**. Effective as of the Amendment Effective Date, Section 4.2.1 of the License Agreement is hereby amended and restated as follows:

> "4.2.1 Grant Back. Subject to terms and conditions of this Agreement, Tyligand hereby grants Context an exclusive, fully-paid up, royalty-free license (which shall become perpetual and irrevocable upon the expiration of this Agreement or the earlier termination of this Agreement by Context pursuant to Section 9.2.1, 9.2.2, or 9.2.3 or by Tyligand pursuant to Section 9.2.4), with the right to grant sublicenses, to any Improvement and Tyligand Know-How resulting from the activities undertaken by Tyligand or its Affiliates or sublicensees related to the Compound, related to the Product, or pursuant to this Agreement, whether patentable or non-patentable, for Context and its Affiliates and sublicensees to (i) make, have made, use, research, develop, commercialize, sell, offer to sell, import and export the Compound or any improvements thereto outside the Territory, and (ii) make, have made, use, research, develop, import and export the Compound, Product or any improvements thereto inside or outside the Territory for use, research, development, sale and commercialization outside the Territory."

5. **Amendment to Section 9.4 of the License Agreement**. Effective as of the Amendment Effective Date, the following sentence shall be added at the end of Section 9.4:

> "Tyligand further acknowledges and agrees that subject to terms and conditions of this Agreement, Sections 4.2.1 and 9.1 of this Agreement shall survive any termination or expiration of this Agreement."

General Terms

6. **Entire Agreement**. Each Party acknowledges that this Amendment, together with the Development Agreement and License Agreement, as applicable, constitutes the entire agreement of the Parties with respect to the subject matter hereof.

7. **Full Force and Effect**. Except as expressly amended hereby, all of the other terms and conditions of the Development Agreement and License Agreement, as applicable, shall remain unchanged and in full force and effect in accordance with their original terms.

8. **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.

CONTEXT:	**TYLIGAND:**
Context Therapeutics LLC	**Tyligand Bioscience (Shanghai) Limited**
By: /s/ Martin Lehr Name: Martin Lehr	By: /s/ Tony Zhang Name: Tony Y. Zhang
Title: Chief Executive Officer	Title: Chief Executive Officer

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

Development and Manufacturing Services Agreement

between

Lonza Sales AG

and

Lonza AG

and

Context Therapeutics Inc.

THIS DEVELOPMENT AND MANUFACTURING SERVICES AGREEMENT is made the 7th day of November 2022 ("Effective Date")

BETWEEN

1. LONZA SALES AG, of Muenchensteinerstrasse 38, Ch-4002 Basel, Switzerland;
2. LONZA AG, of Muenchensteinerstrasse 38, Ch-4002 Basel, Switzerland; and
3. CONTEXT THERAPEUTICS INC., of 2001 Market Street, Suite 3915, Unit 15, Philadelphia, PA 19103 ("Customer").

Lonza AG and Lonza Sales AG together or individually referred to as "**Lonza**" as applicable.

Recitals

WHEREAS, Customer is engaged in the development and research of certain products and requires assistance in the development and manufacture of a certain product;

WHEREAS, Lonza and its Affiliates have among other things expertise in the evaluation, development and manufacture of biologic products;

WHEREAS, Customer wishes to engage Lonza for Services relating to the development and manufacture of the Product as described in this Agreement; and

WHEREAS, Lonza, or its Affiliate, is prepared to perform such Services for Customer on the terms and subject to the conditions set out herein.

NOW, THEREFORE, in consideration of the mutual promises contained herein, and for other good and valuable consideration, the parties intending to be legally bound, agree as follows:

1. Definitions and Interpretation

"Affiliate" means any company, partnership or other entity which directly or indirectly Controls, is Controlled by or is under common Control with the relevant Party. "Control" means the ownership of more than fifty percent (50%) of the issued share capital or the legal power to direct or cause the direction of the general management and policies of the relevant Party.

"Agreement" means this agreement incorporating all Appendices and Project Plans, as amended from time to time by written agreement of the Parties.

"Applicable Laws" means all relevant U.S. and European Union federal, state and local laws, statutes, rules, and regulations, which are applicable to a Party's activities hereunder, including the applicable regulations and guidelines of any Regulatory Authority together with amendments thereto.

"Approval" means the first marketing approval by the FDA or EMA of Product from the Facility for commercial supply.

"Background Intellectual Property" means any Intellectual Property either: (i) owned or controlled by a Party or any of its Affiliates prior to the Effective Date; or (ii)

developed or acquired by a Party or any of its Affiliates independently from the performance of the Services hereunder during the Term of this Agreement. Lonza Information and the Manufacturing Process shall form part of, and be included in, Lonza's Background Intellectual Property. Customer's Background Intellectual Property shall exclude any Intellectual Property licensed (whether under this or any other agreement) to Customer or any Affiliate of Customer by Lonza or any Affiliate of Lonza.

"Batch" the Product derived from a single run of the Manufacturing Process.

"Batch Record" means the executed version of a given Master Batch Record pertaining to a given Batch

"Binding Order" means a binding order on the Parties made in accordance with Clause 6.1.

"Cancellation Fee" has the meaning given in Clause 6.2.

"Capital Equipment" means those certain pieces of new equipment described in the Project Plan which are to be acquired and paid for on terms to be agreed in accordance with this Agreement.

"Cell Bank" means the Customer's Cell Bank or cell stock of rodent and/or human cell line in accordance with the Project Plan.

"Cell Bank Storage" means the storage of Customer's Cell Bank in accordance with Clause 2.11 of this Agreement.

"Cell Line" means the cell line, particulars of which are set out in the applicable Project Plan.

"Certificate of Analysis" means a document prepared by Lonza listing tests performed by Lonza or approved External Laboratories, the Specification and test results.

"Certificate of Compliance" means a document prepared by Lonza: (i) listing the manufacturing date, unique Batch number and concentration of Product in such Batch; and (ii) certifying that such Batch was manufactured in accordance with the Master Batch Record and cGMP, if applicable.

"cGMP" means those laws and regulations applicable in the United States, the European Union and the European Economic Area, the United Kingdom, Switzerland and any other countries the Parties may mutually agree upon in writing, relating to the manufacture of medicinal products for human use, including current good manufacturing practices as specified in the ICH guidelines, including ICH Q7A "ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients", US Federal Food

Drug and Cosmetic Act at 21CFR (Chapters 210, 211, 600 and 610) and the Guide to Good Manufacturing Practices for Medicinal Products as promulgated under European Directives 2001/83/EC and 2003/94/EC. For the avoidance of doubt, Lonza's operational quality standards are defined in internal cGMP policy documents.

"cGMP Drug Product Batch" means a Batch of Drug Product which is required under the Project Plan to be manufactured in accordance with cGMP.

"cGMP Drug Substance Batch" means a Batch of Drug Substance which is required under the Project Plan to be manufactured in accordance with cGMP.

"Change" means any change to the Services, pricing, Project Plan or scope of work incorporated into a written amendment to the Agreement in accordance with Clause 16.5 or effected in accordance with the Quality Agreement.

"Commencement Date" means the date of removal of the vial of cells from frozen storage for the production of a Batch or, in the case of other Services, the date of commencement of such Services.

"Confidential Information" means Customer Information and/or Lonza Information, as the context requires.

"Corruption Laws" means all anti-bribery and anti-corruption laws and regulations in the US, UK and EU including but not limited to the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010, and the Organization for Economic Co-operation and Development Convention on Combating Bribery and Foreign Public Officials in International Business Transactions.

"Customer Information" means all technical and other information that is proprietary to Customer or any Affiliate of Customer (including any and all Customer know-how and trade secrets and Customer Background Intellectual Property) or not known to Lonza and/or not in the public domain relating to the Cell Line, Customer's business, and the Product, in each case from time to time supplied by or on behalf of the Customer to Lonza. Customer Information shall exclude any Lonza Information provided (whether under this or any other agreement) to Customer or any Affiliate of Customer by Lonza or any Affiliate of Lonza in connection with the Services.

"Customer Materials" means any Raw Materials, components of Product, or other materials of any nature, in each case provided by or on behalf of Customer.

"Delivery" shall have the meaning set out at Clause 7.1.

"Development Work" means all activities other than the manufacture of Pilot Batches and cGMP Batches.

"Drug Product" means the formulation of the Drug Substance in its final dosage form to be manufactured by Lonza under the terms of this Agreement.

"Drug Substance" means the Product in bulk drug substance form.

"EMA" means the European Medicines Agency, or any successor agency thereto.

"External Laboratories" means any Third Party instructed by Lonza, with Customer's prior written consent, to conduct certain activities not customarily performed by Lonza which are required to complete the Services.

"Facility" means: (i) in respect of development and manufacturing of Pilot Drug Substance Batches and/or cGMP Drug Substance Batches, Lonza's facility in Slough, UK, Visp, Switzerland, Singapore, and/or Hayward, California, USA; (ii) in respect of Pilot Drug Product Batches and/or cGMP Drug Product Batches at a Lonza facility as may be agreed by the Parties.

"Failed Drug Product Batch" shall have the meaning set out in Clause 7.5.3.

"Failed Drug Substance Batch" shall have the meaning set out in Clause 7.4.3.

"FDA" means the United States Food and Drug Administration, or any successor agency thereto.

"GDPR" means the European Union General Data Privacy Regulations.

"GS" means the glutamine synthetase expression system of which Lonza is the proprietor.

"GS Licence" means a licence granted by Lonza in respect of the use of GS.

"Handling Fee" means (i) the procurement and handling fee of [***] percent ([***]%) of the acquisition cost of Raw Materials by Lonza that is charged to the Customer in addition to the cost of such Raw Materials and (ii) for the management and handling of activities performed by the External Laboratories, a fee of [***] percent ([***]%) of the cost that is charged to the Customer in addition to the charge for such External Laboratories.

“Intellectual Property” means: (i) inventions (whether or not patentable), patents, trade secrets, copyrights, trademarks, trade names and domain names, rights in designs, rights in computer software, database rights, rights in confidential information (including know-how) and any other intellectual property rights, in each case whether registered or unregistered; (ii) all applications (or rights to apply) for, and renewals or extensions of, any of the rights described in the foregoing sub-clause (i); and (iii) all rights and applications that are similar or equivalent to the rights and application described in the foregoing sub-clauses (i) and (ii), which exist now, or which come to exist in the future, in any part of the world.

“International Trade Restrictions” means all applicable United States, United Nations, and European Union export control, trade, and financial sanctions laws, rules, and regulations.

“Latent Defect” means any instance where a Drug Substance or Drug Product Batch fails to comply with Specification, and which could not be discovered by reasonable and customary observation or inspection pursuant to Clauses 7.4.1 and 7.5.1.

“Lonza Information” means all information that is proprietary to Lonza or any Affiliate of Lonza and that is maintained in confidence by Lonza or any Affiliate of Lonza and that is disclosed by Lonza or any Affiliate of Lonza to Customer under or in connection with this Agreement, including any and all Lonza know-how and trade secrets and Lonza Background Intellectual Property and Lonza Operating Documents.

“Lonza Operating Documents” means the corporate standards, standard operating procedures, standard manufacturing procedures, Lonza-customized manufacturing procedures developed prior to the Effective Date or outside the scope of this Agreement, electronic programs and files, raw material specifications, protocols, Lonza validation documentation, and supporting documentation used by Lonza, such as, without limitation, environmental monitoring, for operation and maintenance of the Facility and Lonza equipment used in the process of producing the Product. Lonza Operating Documents shall be regarded as Lonza Information.

“Lonza Responsibility” means a failure solely due to Lonza’s negligence, intentional misconduct, or material breach of its obligations hereunder. Lonza Responsibility shall not include any failure due to a biological reason.

"Manufacturing Process" means, as the context requires: (i) the production process for the manufacture of Drug Substance; and/or (ii) the production process for the manufacture of Drug Product from Drug Substance, in each instance pursuant to the Services hereunder as such process may be improved or modified from time to time by agreement of the Parties in writing. For clarity, the Manufacturing Process (to the extent not incorporating any Customer Intellectual Property, Customer Information and/or Customer Background Intellectual Property) shall be Lonza's Background Intellectual Property.

"Master Batch Record" means the document which defines the manufacturing methods, test methods and other procedures, directions and controls associated with the manufacture and testing of Product.

"New Customer Intellectual Property" has the meaning given in Clause 10.2.

"New Lonza Intellectual Property" has the meaning given in Clause 10.3.

"Party" means each of Lonza and Customer and, together, the "Parties".

"Pilot Drug Product Batch" means a Batch of Drug Product which is designated as a pilot Batch and which shall not comply with cGMP and is not required to meet the Specification.

"Pilot Drug Substance Batch" means a Batch of Drug Substance which is designated as a pilot Batch and which shall not comply with cGMP and is not required to meet the Specification.

"Price" means the price for the Batches (including Pilot Drug Substance Batches, Pilot Drug Product Batches, cGMP Drug Substance Batches and cGMP Drug Product Batches), Services and Products as set out in the applicable Project Plan (the Price excludes the cost of the Raw Materials and the Handling Fee).

"Product" means the Product identified in the Project Plan.

"Project Plan" means the plan describing the Services to be performed by Lonza under this Agreement, including any update and amendment of the Project Plan to which the Parties may agree from time to time. The Project Plan are incorporated into and shall be an integral part of this Agreement. The initial Project Plan is attached hereto as Appendix A.

"Quality Agreement" means the quality agreement, which shall be attached hereto as Appendix C, setting out the

responsibilities of the Parties in relation to quality as required for compliance with cGMP. The Quality Agreement is incorporated into and shall be an integral part of this Agreement.

"Raw Materials" means all ingredients, solvents, primary packaging materials, filter, single-use liquid-paths and other components of the Product required to perform the Manufacturing Process or Services set forth in the bill of materials detailing the same ("Raw Materials" includes Resins and single use bags, but excludes any consumables or wearables).

"Regulatory Authority" means the FDA, EMA and any other similar regulatory authorities as may be agreed upon in writing by the Parties.

"Release" has the meaning given in Clause 7.1.

"Resin" means the chromatographic media and UF membranes intended to refine or purify the Product, as specified in the Master Batch Record.

"Services" means all or any part of the services to be performed by Lonza (including, process and analytical method transfer, process development, process optimization, validation, clinical and commercial manufacturing of Batches, as well as quality control and quality assurance activities) under this Agreement, particulars of which are set out in the Project Plan.

"Services Data" means any and all data obtained by Lonza or any Affiliate, contractor or External Laboratories of Lonza in the course of performing the Services.

"Specifications" means the specifications of the Product as specified in the applicable Project Plan or as otherwise agreed in writing between the Parties, which may be agreed and amended from time to time in accordance with this Agreement.

"Specification (Drug Product)" means the specification of the Drug Product with regard to sterility and fill volume only as specified in the applicable Project Plan or as otherwise agreed in writing between the Parties.

"Stage of Work" means the individual stages of the Services as set out in the Project Plan.

"Storage Requirements" means the Cell Bank storage requirements as set out in the Project Plan or as agreed between the Parties in writing.

"Subcontractors" means any Third Party selected and approved by Lonza which Lonza instructs to perform any part of the Service which Lonza customarily offers to customers.

"Term" has the meaning given in Clause 14.1.

"Third Party" means any party other than Customer, Lonza and their respective Affiliates.

In this Agreement references to the Parties are to the Parties to this Agreement, headings are used for convenience only and do not affect its interpretation, references to a statutory provision include references to the statutory provision as modified or re-enacted or both from time to time and to any subordinate legislation made under the statutory provision, references to the singular include the plural and vice versa, and references to the word "including" are to be construed without limitation.

2. Performance of Services

2.1. Lonza AG, Lonza Sales AG, and Affiliates.

2.1.1 Lonza AG shall be independently accountable for the performance of the Services under this Agreement performed or to be performed by Lonza in Switzerland and such performance shall be subject to the terms of this Agreement. Lonza Sales AG shall have no responsibility with respect to the performance of said Services and Lonza AG shall under no circumstance be deemed a subcontractor of Lonza Sales AG.

2.1.2 Lonza Sales AG shall be independently accountable for the performance of the Services under this Agreement performed or to be performed by Lonza outside of Switzerland and such performance shall be subject to the terms of this Agreement. Lonza AG shall have no responsibility with respect to the performance of Services by Lonza Sales AG and Lonza Sales AG shall under no circumstance be deemed a subcontractor of Lonza AG.

2.1.3 Lonza AG, Lonza Sales AG, or any of their respective Affiliates may execute a Project Plan or Statement of Work with Customer pursuant to this Agreement and submit invoices to Customer under such Project Plan or Statement of Work. In such circumstances all references in this Agreement to Lonza shall be deemed to be applicable to the relevant Affiliate of Lonza with respect to that particular Project Plan or Statement of Work. Such Affiliate shall be entitled to enforce this Agreement with respect to such Project Plan or Statement of Work in its own name as an intended third party beneficiary and the Affiliate shall be solely liable to Customer (under the terms of this Agreement) for any obligations and liabilities undertaken pursuant to such Project Plan or Statement of Work.

2.2. Customer hereby retains Lonza to perform the Services set out in the Project Plan. Subject to the provisions of Clause 2, Lonza shall itself and through its Affiliates, diligently carry out the Services set out in the Project Plan and use commercially reasonable efforts to perform the Services without any material defect and according to the estimated timelines set out in the Project Plan. Owing to the unpredictable nature of the biological processes involved in the Services, the timescales set down for the performance of the Services are estimated only. Lonza shall retain appropriately qualified and trained personnel with the requisite knowledge and experience to perform the Services in accordance with this Agreement.

2.3. Subcontracting and External Laboratories. Lonza may subcontract or delegate any of its rights or obligations under this Agreement to perform the Services and Lonza

shall be responsible for the acts and omissions of its Subcontractors. Lonza may engage an External Laboratory to provide some of the Services and Lonza shall be responsible for the acts and omissions of such External Laboratories chosen or nominated by Lonza. Lonza shall not be responsible for services performed by, nor for any acts and/or omissions whatsoever of, any Subcontractors or External Laboratories chosen or nominated by Customer.

2.4. Supply of Customer Information and Customer Materials. If Customer is providing Customer Background Intellectual Property, Customer Information, Customer Materials, the Cell Line, and/or other information or materials that may be reasonably required to be provided by or on behalf of Customer to Lonza and/or its Affiliates for Lonza and/or its Affiliates to perform the Services to Lonza, the Parties agree that they shall work together to transfer (as described in the Project Plan) the Customer Background Intellectual Property, Customer Information, Customer Materials, the Cell Line, and/or other information or materials that may be reasonably required to be provided by or on behalf of Customer to Lonza and/or its Affiliates or Lonza and/or its Affiliates to perform the Services to the Facility, including implementing the technology transfer plan set out in the Project Plan. Customer shall fully support such technology transfer as reasonably requested by Lonza. Customer shall (by such date as agreed between the Parties) supply to Lonza all such relevant Customer Background Intellectual Property, Customer Information, Customer Materials, the Cell Line, and/or other information or materials that may be reasonably required to be provided by or on behalf of Customer to Lonza and/or its Affiliates for Lonza and/or its Affiliates to perform the Services. Lonza shall not be responsible for any delays arising out of Customer's failure to provide such Customer Background Intellectual Property, Customer Information, Customer Materials, the Cell Line, and/or other information and/or materials reasonably required to be provided by or on behalf of Customer for Lonza to perform and/or its Affiliates the Services, and any unreasonable delay shall be deemed a cancellation and Customer shall pay the Cancellation Fee in respect of such cancelled Services and shall pay for all additional reasonable costs and expenses arising out of such delay.

2.5. Pilot Drug Substance Batches and Pilot Drug Product Batches. Lonza shall manufacture, or procure the manufacture of, the Pilot Drug Substance Batch(es) and the Pilot Drug Product Batch(es) in accordance with the Project Plan, but shall have no obligation to meet Specifications or Specification (Drug Product) or comply with cGMP in relation to the Pilot Drug Substance Batch(es) or the Pilot Drug Product Batch(es) (and Lonza makes no warranty in this regard). Customer shall have the right to make whatever use of the Pilot Drug Substance Batch(es) and the Pilot Drug Product Batch(es) as it shall determine, provided that Customer pays Lonza for such Pilot Drug Substance Batch(es) and Pilot Drug Product Batch(es), and such use is not for human use and does not violate any laws. Unless Lonza and Customer agree otherwise, all Pilot Drug Substance Batches and Pilot Drug Product Batches shall be promptly shipped to Customer.

2.6. Prior to commencement of cGMP manufacturing pursuant to Clause 2.7, Lonza shall review the process assumptions. If there is a material difference in the process assumptions as compared with the results demonstrated during the manufacture of the applicable Pilot Drug Substance Batch(es) or Pilot Drug Product Batch(es), the Parties shall meet to discuss in good faith the consequences of such changes**.**

2.7. cGMP Drug Substance Batches and cGMP Drug Product Batches. Lonza will, in accordance with the terms of this Agreement and the Quality Agreement and subject to Clause 2.7.3:

2.7.1. Manufacture and Release to Customer cGMP Drug Substance Batches in accordance with cGMP and which meet the applicable Specifications, together with a Certificate of Analysis;

2.7.2. Manufacture cGMP Drug Product Batches in accordance with cGMP and which meet the Specifications (Drug Product), and shall Release the cGMP Drug Product Batches together with a Certificate of Analysis if such cGMP Drug Product Batch meets the applicable Specifications (provided that Lonza's liability for such cGMP Drug Product shall be as set out in Clause 2.7.3 below);

2.7.3. In each case (clause 2.7.1 and 2.7.2), Lonza shall use reasonable commercial endeavours to meet the Specifications and Specification (Drug Product), provided that Lonza shall not charge the Customer for: (i) any cGMP Drug Substance Batches failing to meet Specification; or (ii) any cGMP Drug Product Batch failing to meet the Specification (Drug Product), if, in each case due to Lonza's negligence or failure to use commercially reasonable endeavours. For clarity, if a cGMP Drug Product Batch meets the Specifications (Drug Product) but no other applicable Specifications, then Customer shall be required to pay for such cGMP Drug Product Batch notwithstanding the fact that it only met the Specification (Drug Product) and not any other Specifications. Notwithstanding the foregoing, Lonza shall not be responsible for any failure to meet the Specifications and the Specification (Drug Product) in respect of, and Customer shall pay for:

(a) the first [***] cGMP Drug Substance Batches and the first [***] cGMP Drug Product Batches manufactured; and/or

(b) in respect of the [***] cGMP Drug Substance Batch and the [***] cGMP Drug Product Batch manufactured following any material change in the Manufacturing Process agreed to or requested by Customer.

However, Lonza shall comply with its performance obligations set out in Clause 2.2 and shall in relation to all cGMP Batches of Product be responsible for meeting such Specifications as may be agreed in writing prior to commencement of the Services in respect of the following:

(a) For cGMP Drug Substance Batches:

I. Bioburden;

II. Mycoplasmas;

III. In Vitro tests (3 cell lines);

IV. Endotoxins; and

V. Minute virus of mice (MVM)

(b) For cGMP Drug Product Batches: Specification (Drug Product).

2.7A Lonza shall not have any obligation to comply with cGMP nor achieve any Specifications with regard to the Development Work or any other non-manufacturing services.

2.7B Prior to Customer's submission of any information to the Regulatory Authority related in any way to Lonza or the Services provided under this Agreement (including information related to a Regulatory Authority's request for additional information or an inspection, and Customer's answer or other response thereto), Customer shall provide to Lonza, for Lonza's review, copies thereof.

2.8. Raw Materials. Lonza shall procure all required Raw Materials as well as consumables other than those Raw Materials that are Customer Materials. Customer shall be responsible for payment for all consumables and Raw Materials (together with the Handling Fee).

2.9. Promptly following the Effective Date the Customer shall supply to Lonza the Customer Information, together with full details of any known hazards relating to the Cell Line, and the Customer Materials, their storage and use. On review and approval by Lonza's safety committee of this Customer Information and hazards information, the Cell Line (if applicable), the Customer Materials, Customer Background Intellectual Property, and any other necessary Intellectual Property shall be provided to Lonza (or, as the case may be, rights thereto shall be secured by Customer and conveyed to Lonza) at Lonza's reasonable request.

2.10. GS Licence. Where the Cell Line uses GS, the Customer acknowledges that it will require a GS Licence from Lonza prior to receipt of the Product or in vivo clinical studies or any other commercial use or sale of the Product. The terms of such GS Licence shall be negotiated in good faith.

2.11. Cell Bank Storage.

2.11.1. Cell Bank Storage shall commence at a time agreed between the Parties and shall continue, unless otherwise terminated in accordance with Clause 2.11.5, for [***] years (the "Initial Storage Term"). Thereafter, if Customer wishes Lonza to continue Cell Bank Storage, the Parties shall enter into a separate agreement. Lonza shall store the Cell Bank in accordance with the Storage Requirements and Lonza shall not transfer the Cell Bank to a Third Party (other than an Affiliate of Lonza) without Customer's prior written consent. Lonza reserves the right to perform testing of the Cell Bank which Lonza requires for QA, regulatory or safety purposes.

2.11.2. Cell Banks stored at Lonza shall at all times remain Customer's property (subject always to the terms of any other agreements or licences with Lonza, and subject to any Third Party Intellectual Property rights), save that the Cell Bank shall be subject to a lien in respect of any sums owed under any agreement by Customer to Lonza.

2.11.3. Notwithstanding any other provisions of this Agreement, the price of Cell Bank Storage is calculated and shall be payable on a [***] month basis. Payment shall be made before Cell Bank Storage commences, and thereafter, [***] months prior to each anniversary of such commencement. Customer shall not be entitled to any refund in respect of any partial use of Cell Bank Storage. The initial price for Cell Bank Storage is set out in the Project Plan and shall be subject to review in accordance with Clause 8.8. If Customer does not pay for Cell Bank Storage by the due date, Lonza shall not be obliged to continue the Cell Bank Storage and Customer shall be required within [***] days of Lonza's written notice to arrange collection and shipping of the Cell Bank.

2.11.4. Lonza shall use reasonable endeavours to protect the Cell Bank from destruction, theft or loss during Cell Bank Storage. Notwithstanding any other provision of this Agreement, risk of loss or damage to the Cell Bank shall remain with Customer at all times. Notwithstanding Clause 12.5, other than in instances of gross negligence, the total aggregate liability of Lonza and its Affiliates for all claims (whether in contract, tort, negligence, breach of statutory duty, under indemnity, for any strict liability or otherwise) in connection with or arising out of Cell Bank Storage shall not exceed in the aggregate an amount equal to [***] the total Price paid by Customer for Cell Bank Storage for the Initial Storage Term.

2.11.5. Either Party may terminate the Cell Bank Storage on giving [***] months prior written notice to the other. Customer shall not be entitled to any refunds in respect of any unused element of Cell Bank Storage for any such termination initiated by Customer.

2.11.6. Upon termination of this Agreement or termination of the Cell Bank Storage pursuant to Clause 2.11.5 above and, in either case, upon payment of all sums due to Lonza, Customer shall either arrange for collection of the Cell Bank or instruct Lonza to destroy it. If the Customer has not collected the Cell Bank within [***] days from the date of termination of this Agreement or termination of the Cell Bank Storage, Lonza shall upon giving Customer a further [***] days written notice, arrange for the Cell Bank to be destroyed, in which case Customer shall pay Lonza the reasonable costs of such destruction.

3. Project Management

3.1 Project Plans. As at the date of this Agreement, the initial Project Plan is set out in Appendix A. Each Project Plan shall include a description of the Services to be provided, the Product to be manufactured, (including draft Specifications (Drug Product)), a schedule for completion of the Project Plan, pricing details, and such other information as is necessary for the relevant Services. In the event of a conflict between the terms of a Project Plan and the terms of this Agreement, the terms of this Agreement will govern. If the Parties agree any additional work to be added to the Project Plan under and subject to this Agreement ("Additional Work") it shall be subject to price and terms to be agreed in writing. Once the Additional Work has been added, the pricing for such Additional Work shall be subject to review in accordance with the provisions of Clause 8.8. If Customer wishes Lonza to perform a new project it shall notify Lonza and Lonza shall decide whether or not it is able to accept such new project. If Lonza has capacity for, and is willing to accept such new project the Parties shall negotiate a new Project Plan (which shall be subject to the terms of this Agreement and attached hereto as an Appendix) for such project. Lonza shall not be obligated to perform any services on any additional project unless and until a new Project Plan is agreed and signed by the Parties.

3.2 Project Management. With respect to each Project Plan, each party will appoint a project manager who will be responsible for overseeing the Project Plan.

3.3 Person in Plant. Customer shall be permitted to have, at no additional cost, [***] employee or consultant at the Facility as reasonably requested by Customer, at any time during the Manufacturing Process for the purpose of observing, reporting on, and consulting as to the performance of the Services as may be approved in writing in advance by Lonza (such approval not to be unreasonably withheld, conditioned or delayed). Such employee or consultant shall be subject to and agree to abide by confidentiality obligations and Lonza's customary practices, operating procedures and security procedures regarding persons in plant, and such employee or consultant agrees to comply with all instructions of Lonza's employees at the Facility. Customer's employee(s) or consultant(s) working at the Facility shall be and remain employees or consultant(s) of Customer, and Customer shall be solely responsible for the payment of compensation for such Customer employee (including applicable federal, state and local withholding, and other payroll taxes, workers' compensation insurance, health insurance, and other similar statutory and fringe benefits) or consultant. Customer covenants and agrees to maintain workers' compensation benefits and employers' liability insurance as required by applicable laws with respect to all Customer employees working at the Facility.

4. Quality

4.1 Responsibility for quality assurance and quality control of Product shall be allocated between Customer and Lonza as set forth in the Quality Agreement and in Lonza's standard operating procedures. If there is a conflict between the terms and conditions of this Agreement and the Quality Agreement, the terms and conditions of the Quality Agreement shall prevail for matters relating solely to the quality and disposition of the Product, and this Agreement shall prevail for all other matters. If the Quality Agreement is not in place at the Effective Date, Lonza and Customer

commit to enter into the Quality Agreement in a timely manner, but in no event later than the commencement of cGMP manufacturing.

4.2 Provisions regarding inspections by Regulatory Authorities and audits shall be set out in the Quality Agreement.

4.3 Records. Lonza will maintain accurate records for the production of the Product, as required by Applicable Laws. Lonza will retain possession of the Master Batch Record and Batch Records and Lonza Operating Documents and will make copies of the Master Batch Record and Batch Records available to Customer (in each case excluding any Lonza Information and Lonza Background Intellectual Property). Lonza Operating Documents will remain Lonza Information. Lonza will make Lonza Operating Documents available during site visits by Customer but Customer will not be permitted to make copies of and/or remove Lonza Operating Documents from the Lonza site. In connection with a filing for Regulatory Approval of the Product, Lonza will provide the Lonza Operating Documents and any Lonza Information directly to the Regulatory Authority.

5. Insurance

Each Party shall for itself and all of its applicable Affiliates, during the Term and for [***] years after [***], obtain and maintain at its own cost and expense from a qualified insurance company, comprehensive general liability insurance in the amount of at least [***] US Dollars per claim made and [***] US Dollars in the annual aggregate. In addition, Customer shall during the Term and for [***] years after [***], obtain and maintain at its own cost and expense from a qualified insurance company, product liability coverage in the amount of at least [***] US Dollars per claim made and in the annual aggregate. Each Party shall provide the respective other Party with a certificate of such insurance upon reasonable request.

6. Ordering and Cancellation

6.1 Binding Commitment. The Parties' binding commitment in respect of the Services is set out in the Project Plan and this shall be regarded as a Binding Order. Any additional or inconsistent terms or conditions of any Customer purchase order, acknowledgement and/or similar standardised form given and/or received pursuant to this Agreement shall have no effect and such terms and conditions are hereby rejected.

6.2 Cancellation. If Customer wishes to cancel any Stage of Work then it shall notify Lonza in writing and Customer shall be liable to pay (other than as set forth in Section 14.3(e)) a cancellation fee (a "Cancellation Fee") as follows:

6.2.1 Development Work: If Customer provides written notice of cancellation of any Development Work Customer shall pay for any of the cancelled Development Work Lonza performed prior to the date of notification of cancellation and for any of such cancelled Development Work which would (were it not for the cancellation) have been performed during the period of [***] days post cancellation notification.

6.2.2 Pilot Drug Substance Batch(es) / Pilot Drug Product Batch(es): If Customer provides written notice of cancellation of any Pilot Drug Substance Batch and/or any Pilot Drug Product Batch less than or equal to [***] months prior to the Commencement Date of such Pilot Drug Substance Batch or Pilot Drug Product Batch or at any time after, then a Cancellation Fee of [***] percent ([***]%) of the Price of each such Pilot Drug Substance Batch(es) and [***] percent ([***]%) of the Price of each such Pilot Drug Product Batch(es) cancelled is payable. If Customer provides written notice of cancellation of any Pilot Drug Substance Batch and/or any Pilot Drug Product Batch more

than [***] months prior to the Commencement Date of such Pilot Drug Substance Batch or Pilot Drug Product Batch, then [***] is payable.

6.2.3 cGMP Drug Substance Batches: If Customer provides written notice of cancellation of any cGMP Drug Substance Batch of Product:

(a) less than or equal to [***] months prior to the Commencement Date of such cGMP Drug Substance Batch or at any time after, then a Cancellation Fee of [***] percent ([***]%) of the applicable Price of each such cGMP Drug Substance Batch cancelled is payable;

(b) more than [***] months but less than or equal to [***] months prior to the Commencement Date of one or more such cGMP Drug Substance Batches, then a Cancellation Fee of [***] percent ([***]%) of the Price of each such cGMP Drug Substance Batch cancelled is payable.

(c) more than [***] months prior to the Commencement Date of one or more such cGMP Drug Substance Batches, then [***] is payable.

6.2.4 cGMP Drug Product Batches: If Customer provides written notice of cancellation of any cGMP Drug Product Batch to Lonza:

(a) less than or equal to [***] months prior to the Commencement Date of one or more such cGMP Drug Product Batch or at any time after, then a Cancellation Fee of [***] percent ([***]%) of the Price of each such cGMP Drug Product Batch cancelled is payable;

(b) more than [***] months but less than or equal to [***] months prior to the Commencement Date of one or more such cGMP Drug Product Batches, then a Cancellation Fee of [***] percent ([***]%) of the Price of each such cGMP Drug Product Batch cancelled is payable.

(c) more than [***] months prior to the Commencement Date of one or more such cGMP Drug Product Batches, then [***] is payable.

6.2.5 Mitigation of Batch Cancellation. Following the cancellation of a Batch pursuant to Clauses 6.2.2, 6.2.3 or 6.2.4, Lonza will use commercially reasonable efforts to secure a replacement batch for a new project (but excluding any batch and/or project then under contract with Lonza) for the cGMP manufacturing capacity, and for the same dates and duration that would have been occupied by the cancelled Batch. If Lonza is successful in securing such a replacement batch, the applicable Cancellation Fee for the cancelled Batch may be reduced accordingly by an amount equal to [***] percent ([***]%) of the production fees associated with such replacement but in no event shall such reduction exceed the Price of the cancelled Batch.

6.2.6 Payment of Cancellation Fees. Cancellation Fees and the amounts payable pursuant to Clause 6.2.7 shall be payable following Lonza's efforts to mitigate subject to Clause 6.2.5, but in any event no later than [***] days following the applicable written notice of cancellation, provided Lonza shall promptly refund Customer for any such payment(s) should Lonza's mitigation efforts be successful.

6.2.7 Additional Costs. In addition to any Cancellation Fee, Customer shall pay for all costs associated with the cancelled Service and/or Batch that Lonza has incurred, or is irrevocably committed to pay, including the cost of any External Laboratories (and the applicable Handling Fee) and Raw Materials and Resins (and the applicable Handling Fee) which Lonza has purchased or in respect to which Lonza has become irrevocably committed and which cannot be reused or returned to the supplier for a full refund; provided Lonza shall promptly refund Customer for any partial refund Lonza may receive.

Upon cancellation of any part of the Services and/or any Batch, all Raw Materials and External Laboratories fees shall be paid for by Customer within [***] days of invoice and, with respect to Raw Materials, at Customer's option will either be: (a) delivered to Customer; or (b) disposed of by Lonza.

7. Delivery and Acceptance

7.1 Delivery. All Product shall be delivered [***] (as defined by Incoterms® 2020) [***] ("Delivery" or "Delivered"). Lonza shall deliver to Customer the Certificate of Analysis and such other documentation as is reasonably required to meet all applicable regulatory requirements of the Regulatory Authorities (the "Release") not later than the date of Delivery of Batches. With respect to any Customer Materials, title and risk of loss shall remain with the Customer and shall not transfer to Lonza. With respect to Product, title and risk of loss shall transfer to Customer upon [***] in accordance with this provision. Risk of loss to Product during shipping between Lonza Facilities shall be Lonza's.

7.2 If requested in writing by Customer, Lonza will (acting as agent of Customer for such purpose) arrange the transportation of Product [***]. All additional costs and expenses of whatever nature reasonably incurred by Lonza in arranging such transportation and insurance shall be charged to Customer in addition to the Price. Transportation of Product shall be at the sole risk of [***] who shall be deemed to have full knowledge of the carrier's terms and conditions of carriage. Customer shall, as appropriate, observe, perform and be subject to the carriage terms in relation to the transportation of the Product. Where Lonza has made arrangements for the transportation of Product, Customer shall diligently examine the Product as soon as practicable after receipt. Notice of all claims (time being of the essence) arising out of: (a) visible damage to or total or partial loss of Product in transit shall be given in writing to Lonza and the carrier within [***] days of receipt by Customer; (b) non-Delivery shall be given in writing to Lonza within [***] days after the date of the despatch notice; or (c) with respect to a Latent Defect Sections 7.4.1 and 7.5.1 shall apply. Customer shall make damaged Product and associated packaging materials available for inspection and shall comply with the requirements of any insurance policy covering the Product notified by Lonza to Customer.

7.3 Storage. Customer shall arrange for shipment and take delivery of such Batch from the Facility, at [***] expense, within [***] days after issue of the invoice under clause 8.5.2 or pay the storage costs set out in the applicable project plan. Lonza shall provide storage on a bill and hold basis for such Batch(es) at no charge for up to [***] days; provided that any additional storage beyond [***] days will be subject to availability and, if available, will be charged to Customer at Lonza's then current standard rates and will be subject to a separate agreement. In addition to Clause 8.3, Customer shall be responsible for all value added tax (VAT) and any other applicable taxes, levies, import, duties and fees of whatever nature imposed as a result of any storage. Notwithstanding anything to the contrary contained in this Agreement, in no event shall Lonza be required to store any Batch for more than [***] calendar days after issue of the invoice under clause 8.5.2. Within [***] business days following a written request from Lonza, Customer shall provide Lonza with a letter in form satisfactory to Lonza confirming the bill and hold status of each stored Batch.

7.4 Acceptance/Rejection of cGMP Drug Substance Batches.

7.4.1 Promptly following Release of cGMP Drug Substance Batch(es) (whether or not the cGMP Drug Substance Batch was actually shipped to Customer or was stored at Lonza or shipped to another Lonza Facility for manufacture of the cGMP Drug Product Batch), which was required pursuant to the terms of this Agreement to meet Specifications, Customer shall inspect such cGMP Drug Substance Batch(es) and shall have the right to test any such cGMP Drug Substance Batches to determine compliance with the Specifications.

Lonza shall provide samples of the Drug Substance Batch to Customer or Customer's designated testing lab within [***] business days of Lonza's receipt of Customer's request for such samples. Customer shall notify Lonza in writing of any rejection of a cGMP Drug Substance Batch (which was required to meet the Specifications) based on any claim that it fails to meet Specifications within [***] days of Release, after which time all unrejected cGMP Drug Substance Batches shall be deemed accepted. Notwithstanding the foregoing should any cGMP Drug Substance Batch Released hereunder have a Latent Defect, Customer shall notify Lonza of such Latent Defect within [***] days after Customer becomes aware of such Latent Defect and in any event no later than [***] months after delivery of the applicable Batch; provided that such Latent Defect was not reasonably detectable by inspection within [***] days of Release.

7.4.2 If Lonza believes that a cGMP Drug Substance Batch, which was required by the terms of this Agreement to meet Specifications, has been incorrectly rejected, Lonza may require that Customer provides samples to Lonza for testing. Lonza may retain and test such samples. If there is a discrepancy between Customer's and Lonza's test results such that Lonza's test results fall within the relevant Specifications, or there exists a dispute between the Parties over the extent to which such failure is attributable to a given Party, the Parties shall appoint an independent laboratory promptly to review records, test data and perform comparative tests and/or analyses on samples of the cGMP Drug Substance Batch that allegedly fails to conform to Specifications. Such independent laboratory shall be mutually agreed upon by the Parties. The independent laboratory's results shall be in writing and shall be final and binding save for manifest error. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the Party against whom the independent laboratory rules.

7.4.3 If it is determined (by the Parties or the independent laboratory) that a rejected cGMP Drug Substance Batch (where such cGMP Drug Substance Batch was required pursuant to the terms of this Agreement to have been compliant with cGMP and/or met the Specifications) failed to conform with the Specifications (such Batch being a "Failed Drug Substance Batch"), then to the extent this was solely a Lonza Responsibility, Lonza shall, at Customer's discretion, either:

(i) refund Customer the amount paid by Customer in respect of such Failed Drug Substance Batch and associated Raw Materials, to the extent paid by Customer; or

(ii) schedule a replacement cGMP Drug Substance Batch to be manufactured (the timing of which shall be subject always to available capacity in the Facility, provided Lonza shall use reasonable efforts to expedite any such timing), and Customer shall pay for such replacement cGMP Drug Substance Batch and Raw Materials and Resins used therein (and any money it paid towards the Failed Drug Substance Batch shall be credited to the Price of such replacement cGMP Drug Substance Batch).

7.5 Acceptance/Rejection of cGMP Drug Product Batches.

7.5.1 Promptly following Delivery of cGMP Drug Product Batch(es) (whether or not the cGMP Drug Product Batch was actually shipped to Customer or was stored at Lonza), which was required pursuant to the terms of this Agreement to meet Specification (Drug Product) Customer shall inspect such cGMP Drug Product Batch(es) and shall have the right to test any such cGMP Drug Product Batches to determine compliance with the Specification (Drug Product). Customer shall notify Lonza in writing of any rejection of a

cGMP Drug Product Batch which was required pursuant to the terms of this Agreement to meet Specification (Drug Product) based on any claim that it fails to meet Specification (Drug Product) within [***] days of Release Delivery, after which time all unrejected cGMP Drug Product Batches shall be deemed accepted. Customer may not reject any cGMP Drug Product Batch on the grounds that it fails any Specifications other than Specification (Drug Product), and Customer must pay for all such cGMP Drug Product Batches, provided that they meet the Specification (Drug Product). Notwithstanding the foregoing should any cGMP Drug Product Batch Released hereunder have a Latent Defect, Customer shall notify Lonza of such Latent Defect within [***] days after Customer becomes aware of such Latent Defect and in any event no later than [***] months after delivery of the applicable Batch; provided that such Latent Defect was not reasonably detectable by inspection within [***] days of Release.

7.5.2 If Lonza believes that a cGMP Drug Product Batch which was required pursuant to the terms of this Agreement to meet Specification (Drug Product) has been incorrectly rejected, Lonza may require that Customer provides samples to Lonza for testing. Lonza may retain and test such samples. If there is a discrepancy between Customer's and Lonza's test results such that Lonza's test results show that the cGMP Drug Product Batch meet the relevant Specification (Drug Product), or there exists a dispute between the Parties over the extent to which such failure is attributable to a given Party the Parties shall appoint an independent laboratory promptly to review records, test data and perform comparative tests and/or analyses on samples of the cGMP Drug Product Batch that allegedly fails to conform to Specification (Drug Product). Such independent laboratory shall be mutually agreed upon by the Parties. The independent laboratory's results shall be in writing and shall be final and binding save for manifest error. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the Party against whom the independent laboratory rules.

7.5.3 If it is determined (by the Parties or the independent laboratory) that a rejected cGMP Drug Product Batch (where such cGMP Drug Product Batch, was required pursuant to the terms of this Agreement to have been compliant with cGMP and/or met the Specification (Drug Product)) failed to conform with the Specification (Drug Product) (such Batch being a "Failed Drug Product Batch"), then to the extent this was solely a Lonza Responsibility, Lonza shall, at Customer's discretion, either:

(i) refund Customer the amount paid by Customer in respect of such Failed Drug Product Batch and associated Raw Materials, to the extent paid by Customer; or

(ii) schedule a replacement cGMP Drug Product Batch to be manufactured (the timing of which shall be subject always to available capacity in the Facility, provided Lonza shall use reasonable efforts to expedite any such timing), and Customer shall pay for such replacement cGMP Drug Product Batch and Raw Materials and Resins used therein (and any money it paid towards the Failed Drug Product Batch shall be credited to the Price of such replacement cGMP Drug Product Batch).

For clarity in the event that a cGMP Drug Product Batch meets the Specifications (Drug Product) but not any other Specifications, Customer must still pay in full for such cGMP Drug Product Batch. Customer may only reject a cGMP Drug Product Batch on the grounds that it failed to meet cGMP or the Specification (Drug Product) in each case solely due to a Lonza Responsibility (notwithstanding that such cGMP Drug Product Batch may not meet any other Specifications).

7.6 Except if due to Lonza's gross negligence, nothing in Clause 7.4 or 7.5 shall oblige Lonza to replace or refund any Drug Substance material produced by a cGMP Drug Substance Batch (or manufacture an additional cGMP Drug Substance Batch) or any other drug substance that may be required to produce any replacement cGMP Drug Product Batch. Clauses 7.4 and 7.5 shall always be subject to the provisions of Clauses 12.4 and 12.5.

7.7 Customer acknowledges and agrees that its sole remedy with respect to a Failed Drug Substance Batch and/or Failed Drug Product Batch that is a Lonza Responsibility is as set forth in Clauses 7.4 and 7.5. Accordingly, other than if due to Lonza's gross negligence or intentional breach, Customer hereby waives all other remedies at law or in equity regarding the foregoing claims. Except if due to Lonza's gross negligence Lonza shall not be responsible for (i) the cost of Raw Materials (except to the extent set forth in Clauses 7.4.3 and 7.5.3), Customer Materials, Drug Substance required for the manufacture of a cGMP Drug Product Batch, and/or (ii) starting materials consumed in any Failed Drug Substance Batch or Failed Drug Product Batch.

7.8 The Parties further agree that in the event that any Batch is a Failed Drug Substance Batch or a Failed Drug Product Batch and such failure is caused by any defect in any Customer Information, Customer Material, Cell Line, Customer Background Intellectual Property, and/or any other information, material or Intellectual Property supplied by or on behalf of the Customer, then Lonza shall not have any liability with regard to such Failed Drug Substance Batch or Failed Drug Product Batch.

7.9 Any cGMP Drug Substance Batch or any cGMP Drug Product Batch that is not required by this Agreement to meet Specifications or Specification (Drug Product) may not be rejected and Lonza shall not have any replacement or refund obligations in respect thereto, except if due to Lonza's gross negligence.

8 Price and Payment

Pricing

8.1 Subject to the provisions of this Agreement, Customer shall pay for all of the Services and the Batches (including Pilot Drug Substance Batches, Pilot Drug Product Batches, all cGMP Drug Substance Batches and all cGMP Drug Product Batches). Pricing for the Services and the Batches (including Pilot Drug Substance Batches, Pilot Drug Product Batches, all cGMP Drug Substance Batches and all cGMP Drug Product Batches) manufactured by Lonza are set out in, and based on the assumptions and information set out in, the applicable Project Plan. In the event of Changes based on Customer's request, Customer shall bear all additional costs.

8.2 Raw Materials, Resins and Handling Fees, External Laboratory and Handling Fee. In addition to Clause 8.1, Customer shall also pay for all Raw Materials, Resins, single use bags, consumables and the Handling Fee, and External Laboratory Charges and the Handling Fee.

8.3 Unless otherwise indicated in writing by Lonza, all Prices and charges are exclusive of value added tax (VAT) and of any other applicable taxes, levies, import duties and fees of whatever nature imposed by or under the authority of any government or public authority and all such charges applicable to the Services shall be paid by Customer, other than relevant income taxes of Lonza that shall be the responsibility of Lonza.

8.4 When sending payment to Lonza, the Customer shall quote the relevant invoice number in its remittance advice.

8.5 Payment Terms.

8.5.1 For Stages of Work of less than [***] (or equivalent in the applicable currency): Unless otherwise agreed in writing Lonza shall issue invoices to Customer for [***] percent ([***]%) of the Price upon completion of that Stage of Work.

8.5.2 For Stages of Work of [***] or more (or equivalent in the applicable currency): Unless otherwise agreed in writing Lonza shall issue all invoices to Customer for [***] percent ([***]%) of the Price for Product or Services upon commencement thereof and [***] percent ([***]%) upon Release of applicable Batches or completion of applicable Services, unless otherwise stated in the Project Plan.

8.5.3 Unless otherwise agreed in writing the Raw Materials (including media and feeds, but excluding Resins) and the applicable Handling Fee for each Batch shall be invoiced [***] percent ([***]%) upon the Commencement Date of the Batch, or the applicable Stage of Work, plus the Handling Fees. Resins and the Handling Fee in respect thereof, shall be invoiced on the placement of purchase orders by Lonza for such Resins. External Laboratory Charges and the Handling Fee shall be invoiced on completion of the applicable Stage of Work.

8.5.4 If the Certificate of Analysis requires the Customer to provide one or more elements of the Specification, but the Customer has not provided such information within the time agreed, then provided Lonza has completed those elements of the Certificate for Analysis for which it is responsible, Lonza can issue the applicable invoice at such time as set out in Clause 8.

8.5.5 All invoices are strictly net and payment must be made within [***] days of Customer's receipt of invoice. Payment shall be made without deduction, deferment, set-off, lien or counterclaim.

8.5.6 For Services performed in Switzerland, invoices may be issued in the name of Lonza AG.

8.6 If Customer fails to pay any undisputed invoice within the time set out in Clause 8.5.4 then Lonza shall have the option to change the payment terms such that [***] percent ([***]%) of the Price for any Stage of Work shall be payable on commencement and the price for Raw Materials and the Handling Fee shall also be payable [***] percent ([***]%) on commencement.

8.7 If in default of payment of any undisputed invoice on the due date, interest shall accrue on any amount overdue at the lesser of:

(i) the rate of [***] percent ([***]%) per month above the applicable currency below:

- Swiss Average Rate Overnight (SARON) (for invoices in CHF);
- the Secured Overnight Financing Rate (SOFR) (for invoices in USD);
- the Euro Interbank Offered Rate (EURIBOR) (for invoices in EUR); and
- the Sterling Overnight Index Average (SONIA) (for invoices in GBP);

or (ii) the maximum rate allowable by the governing law of this Agreement.

Interest shall accrue on a day to day basis until full payment. Lonza shall, at its sole discretion, and without prejudice to any other of its accrued rights, be entitled to suspend the provision of the Services and/or delivery of Product until all undisputed overdue amounts have been paid in full including interest for late payments and Customer shall be liable for any and all costs reasonably incurred by Lonza from any such delay to the Services.

8.8 Price adjustments.

8.8.1 Not more than once per calendar year and with effect from the first anniversary of the Effective Date, and then on each subsequent anniversary, Lonza may adjust the Prices as follows upon at least [***] days prior written notice to Customer (provided that in the event of any negative change in the applicable index there shall not be any negative change to the Prices):

(a) In respect of Services performed in the UK: the higher of: (i) the change from the previous calendar year of the index of labour costs per hour for private sector companies (ILCH) as published by the Office of National Statistics of the United Kingdom (or any successor index); or (ii) [***] percent ([***]%);

(b) In respect of Singapore: the higher of: (i) the change from the previous calendar year of the UBCIMI index (https://data.gov.sg) (or any successor index); or (ii) [***] percent ([***]%);

(c) In respect of Services performed in Switzerland: the higher of: (i) the change from the previous calendar year of the Swiss Producer Prices index (or any successor index); or (ii) [***] percent ([***]%);

(d) In respect of Services performed in USA: the higher of: (i) the change from the previous calendar year of the US Department of Labor's Bureau of Labor Statistics Other Biological Product Manufacturing, ethical PCU 325414 index (or any successor index); or (ii) [***] percent ([***]%).

The new Price reflecting such adjusted Price shall be effective for any Services and/or Batch for which the Commencement Date is on or after the date of Lonza's notice to Customer of the applicable Price adjustment.

8.8.2 In addition to the above, the Price may be changed by Lonza, upon reasonable prior written notice to Customer (providing reasonable detail in support thereof), to reflect: (i) an increase in variable costs (such as energy or Raw Materials) by more than [***] percent ([***]%) (based on the initial Price or any previously amended Price); (ii) material process adjustment or assumption changes; and/or (iii) any material change in an environmental, safety or regulatory standard that substantially impacts Lonza's cost and/or ability to perform the Services.

9. Capital Equipment

Any Capital Equipment required for the performance of the Services shall be acquired on terms to be reasonably agreed by the Parties prior to commencement of the relevant Services, which terms shall also specify ownership, risk of loss, and maintenance requirements of such Capital Equipment.

10. Intellectual Property

10.1 Neither Party nor any of their Affiliates will, as a result of this Agreement, acquire any right, title, or interest in any Background Intellectual Property of the other Party or any of its Affiliates.

10.2 Subject to Clause 10.3, Customer shall own all right, title, and interest in and to any and all Intellectual Property that Lonza and/or its Affiliates, the External Laboratories or other contractors or agents of Lonza develops, conceives, invents, first reduces to practice or makes, solely or jointly with Customer or others, in the course of the performance of the Services to the extent that it is both:

10.2.1 solely a direct derivative of or improvement to Customer Information and/or Customer Background Intellectual Property, or directly relies on or incorporates any Customer Information and/or Customer Background Intellectual Property; and

10.2.2 severable from and does not utilise, disclose or reveal any Lonza Background Intellectual Property, Lonza Information, and/or New Lonza Intellectual Property;

the "New Customer Intellectual Property"). For the avoidance of doubt, "New Customer Intellectual Property" shall include any material, processes or other items that solely embody, or that solely are claimed or covered by, any of the foregoing new Intellectual Property, but excluding any New Lonza Intellectual Property.

10.3 Notwithstanding Clause 10.2, Lonza shall own all right, title and interest in Intellectual Property that Lonza and/or its Affiliates, the External Laboratories or other contractors or agents of Lonza develops, conceives, invents, or first reduces to practice or makes, solely or jointly with Customer or others, in the course of the performance of the Services, that is either:

10.3.1 generally applicable to the development or manufacture of chemical or biological products or products components; or

10.3.2 an improvement to, or derivative of, any Lonza Background Intellectual Property, and/or Lonza Information;

(the "New Lonza Intellectual Property"). For the avoidance of doubt, "New Lonza Intellectual Property" shall include any material, processes or other items that embody, or that are claimed or covered by, any of the foregoing Intellectual Property.

10.4 Lonza hereby assigns to Customer all of its right, title and interest in any New Customer Intellectual Property. Lonza shall execute, and shall require its personnel as well as its Affiliates, External Laboratories or other contractors or agents and their personnel involved in the performance of the Services to execute any documents reasonably required to confirm Customer's ownership of the New Customer Intellectual Property, and any documents required to apply for, maintain and enforce any patent or other right in the New Customer Intellectual Property. To the extent that Customer has or obtains any rights, title or interest in New Lonza Intellectual Property, Customer hereby assigns to Lonza all of its right, title and interest in any New Lonza Intellectual Property. Customer shall execute, and shall require its personnel as well as its Affiliates, or contractors or agents and their personnel involved in the performance of the Services, to execute, any documents reasonably required to confirm Lonza's ownership of the New Lonza Intellectual Property, and any documents required to apply for, maintain and enforce any patent or other right in the New Lonza Intellectual Property.

10.5 Customer hereby grants Lonza and its Affiliates, sub-contractors and the External Laboratories the non-exclusive right to use the Customer Information, Customer Background Intellectual Property, Customer Materials, New Customer Intellectual Property, the Cell Line, and any and all other Intellectual Property, information or materials supplied by or on behalf of the Customer, during the Term solely for the purpose of fulfilling their obligations under this Agreement.

10.6 The transfer of the Manufacturing Process to either Customer and/or any Third Party manufacturer, for the manufacture of the Product (and no other products), shall be subject to Lonza's prior written consent (not to be unreasonably withheld, conditioned or delayed) and shall occur only pursuant to reasonable terms governing such technology transfer in a separate technology transfer agreement based on the Outline Terms for Technology Transfer Agreement set out in Appendix D, which may include a reasonable licensing fee applicable to such technology transfer. Customer shall reimburse Lonza for any reasonable costs (based on a full-time employee rate for such support) and expenses for any such transfer, as shall be set forth in such separate technology transfer agreement. If the Parties are unable to agree to such technology transfer terms, then the parties shall refer the matter to senior executives of both Parties in order to resolve any open issues and shall continue to negotiate and discuss in good faith. Thereafter, if the Parties are still unable to agree to such terms, Lonza shall be under no obligation to transfer the Manufacturing Process to Customer or any Third Party.

10.7 Prosecution of Patents.

10.7.1 Subject to the following subsection, Customer will have the sole right and discretion to file (or not file), prosecute and maintain patent applications and patents claiming the New Customer Intellectual Property, at Customer's expense. Lonza will cooperate with Customer, at Customer's expense, to file, prosecute, maintain, defend, and enforce patent applications and patents claiming any New Customer Intellectual Property.

10.7.2 Unless the Parties agree otherwise, at least [***] days prior to filing any application disclosing or claiming any New Customer Intellectual Property, Customer shall provide a draft thereof to Lonza, for Lonza's prior review and approval. Within [***] days of receipt of such an application ("Lonza Review Period"), Lonza shall notify Customer of any Lonza Background Intellectual Property, Lonza Information or any information that could be considered New Lonza Intellectual Property and, on Lonza's instruction, Customer shall either delete any information in such application that Lonza has reasonably identified within the Lonza Review Period as Lonza Background Intellectual Property, Lonza Information and/or delay the filing of the application until such time that it can be concurrently filed with a patent application from Lonza claiming such New Lonza Intellectual Property.

10.7.3 Lonza will have the sole right and discretion to file (or not file), prosecute and maintain patent applications and patents claiming the New Lonza Intellectual Property, at Lonza's expense. Customer will cooperate with Lonza, at Lonza's expense, to file, prosecute, maintain, defend, and enforce patent applications and patents claiming any New Lonza Intellectual Property. Unless the Parties agree otherwise, at least [***] days prior to filing any application disclosing or claiming any New Lonza Intellectual Property, Lonza shall provide a draft thereof to Customer, for Customer's prior review and approval. Within [***] days of receipt of such an application ("Customer Review Period"), Customer shall notify Lonza of any Customer Background Intellectual Property, Customer Information or any information that could be

considered New Customer Intellectual Property and, on Customer's instruction, Lonza shall either delete any information in such application that Customer has reasonably identified within the Customer Review Period as Customer Background Intellectual Property, Customer Information and/or delay the filing of the application until such time that it can be concurrently filed with a patent application from Customer claiming such New Customer Intellectual Property.

10.8 Services Data.

Notwithstanding the confidentiality provisions of Clause 13 (Confidentiality) as they may relate to the use of Services Data, the Parties agree that all Services Data may be collected, aggregated, hosted, mined or otherwise stored and maintained by Lonza and its Affiliates, contractors and External Laboratories. Both Lonza and its Affiliates, and Customer and its Affiliates, may use the Services Data, in any manner that is not inconsistent with the intellectual property-ownership terms set forth in this Clause 10, for further research, development, commercialization of, and securing rights to, development, manufacturing and testing systems, platforms, and service offerings, provided that said data shall be anonymized when used externally.

11. Warranties

11.1 Lonza warrants that:

11.1.1 the Services shall be performed in accordance with all Applicable Laws;

11.1.2 it or any of its Affiliates hold all necessary permits, approvals, consents and licenses to enable it to perform the Services at the Facility (subject always to Clause 11.2.4);

11.1.3 it has the necessary corporate authorisations to enter into and perform this Agreement;

11.1.4 in connection with its performance of the Services, Lonza shall take appropriate technical and organizational measures to ensure compliance with the applicable requirements of GDPR. Lonza shall act in compliance with GDPR as well as on Customer's request, destroy all personal data, unless applicable law prevents Lonza from such destruction. Lonza confirms that any personal data that Lonza shares with Customer is done in accordance with applicable GDPR requirements GDPR; and

11.1.5 in connection with its performance of the Services, Lonza shall comply with, and shall cause its Affiliates, subsidiaries, subcontractors, directors, officers, employees, agents or any other person acting on behalf of Lonza to comply with, all applicable Corruption Laws and International Trade Restrictions. Lonza's performance of the Services shall be in accordance with Applicable Laws, Corruption Laws and International Trade Restrictions and the laws of the countries in which the Services are performed.

11.2 Customer warrants that:

11.2.1 Customer has all the rights necessary to permit Lonza (and its relevant Affiliates any Subcontractors, and the External Laboratories) to perform the Services without infringing the Intellectual Property rights or other rights of any Third Party; and Customer warrants that the performance of the Services will not infringe, misappropriate or violate (as the case may be) any Intellectual Property rights or other rights of any Third Party;

11.2.2 Customer will promptly notify Lonza in writing if it receives or is notified of a formal written claim from a Third Party that Customer Information, Customer Background Intellectual Property, Customer Materials, New Customer Intellectual Property, the Cell Line, and/or any and all other information, materials and Intellectual Property supplied by or on behalf of the Customer, or that the supply to and/or use by Lonza (and/or its relevant Affiliates, any Subcontractors, and the External Laboratories) thereof for the provision of the Services, infringes any Intellectual Property rights or other rights of any Third Party;

11.2.3 all Raw Materials and Customer Materials actually supplied by Customer shall be provided with a certificate of analysis or other relevant documentation demonstrating that such Raw Materials and Customer Materials meet the following Lonza acceptance criteria: (i) are not contaminated, (ii) test negative for mycoplasma and bioburden (if applicable), (iii) have been manufactured in accordance with cGMP (if applicable), (iv) are free from all liens, charges, or encumbrances, and (v) meet other testing requirements and/or specifications as may be agreed in writing by the Parties. In addition, Customer has provided any environmental, health and safety information related to the Raw Materials and Customer Materials (including employee health and safety, of the handling, manufacture, distribution, use and disposal of the Raw Materials and Customer Materials), and will update, clarify, correct, supplement and amend such information as necessary;

11.2.4 Customer has all the rights necessary to provide and permit Lonza and its Affiliates, any Subcontractors, and the External Laboratories to use, for the purposes of this Agreement, the Customer Information, Customer Background Intellectual Property, Customer Materials, New Customer Intellectual Property, the Cell Line, and any and all other information, materials and Intellectual Property supplied by or on behalf of the Customer; and Customer warrants that the use of anything referred to in this Clause 11.2.4 will not infringe, misappropriate or violate the Intellectual Property rights or other rights of any Third Party;

11.2.5 Customer has the necessary corporate authorisations to enter into this Agreement and it has the full power and right to enter into this Agreement and that there are no outstanding agreements, assignments, licenses, encumbrances or rights of any kind, that would breach the provisions of this Agreement;

11.2.6 in connection with its receipt and usage of the Services and Products, Customer shall take appropriate technical and organizational measures to ensure compliance with the applicable requirements of GDPR. Customer shall act in compliance with GDPR as well as on Lonza's request, destroy all personal data, unless applicable law prevents Customer from such destruction. Customer confirms that any personal data that Customer shares with Lonza is done in accordance with applicable GDPR requirements;

11.2.7 in connection with its receipt and usage of the Services and Products, Customer shall comply with, and shall cause its Affiliates, subsidiaries, subcontractors, directors, officers, employees, agents or any other person acting on behalf of Customer to comply with, all applicable Corruption Laws and International Trade Restrictions. Customer's receipt and usage of the Services and Products shall be in accordance with Applicable Laws, Corruption Laws and International Trade Restrictions and the laws of the countries in which the Product is sold; and

11.2.8 Customer warrants that as at the time that the Quality Agreement is signed, Customer will have an appropriate Quality function to ensure Customer's ongoing compliance with cGMP.

11.3 Disclaimer: The warranties expressly set forth in this Agreement are in lieu of all other warranties, and all other warranties, both express and implied, are expressly disclaimed, including any warranty of merchantability or fitness for a particular purpose.

12. Indemnification and Liability

12.1 Indemnification by Lonza. Subject to Clauses 12.4 and 12.5, Lonza shall indemnify the Customer, its Affiliates, and the respective officers, employees and agents of Customer and/or its Affiliates ("Customer Indemnitees") from and against any loss, damage, costs, liability and/or expenses (including reasonable attorney fees) that Customer Indemnitees may suffer as a result of any Third Party claim arising directly out of:

12.1.1 any material breach of the warranties given by Lonza in Clause 11.1 above; and/or

12.1.2 any claim that the performance of the Services (excluding use by Lonza, Lonza's Affiliates, Lonza Indemnitees, Lonza contractors, and/or the External Laboratories of Customer Information, Customer Background Intellectual Property, Customer Materials, New Customer Intellectual Property, the Cell Line, and/or any and all information, materials and other Intellectual Property supplied by or on behalf of the Customer) infringe any Intellectual Property rights of a Third Party;

except, in each case (12.1.1 and/or 12.1.2), to the extent that such claims resulted from the negligence and/or breach of this Agreement and/or intentional misconduct by any Customer Indemnitees.

12.2 Indemnification by Customer. Subject to Clause 12.4, Customer shall indemnify Lonza, Lonza's Affiliates, and the respective officers, employees and agents of Lonza and/or its Affiliates ("Lonza Indemnitees") from and against any loss, damage, costs, liability and/or expenses (including reasonable attorney fees) that any Lonza Indemnitees may suffer as a result of any Third Party claim arising directly out of:

12.2.1 any material breach of the warranties given by Customer in Clause 11.2 above; and/or

12.2.2 any allegation that the performance of Services infringes any Intellectual Property rights of Third Parties; and/or

12.2.3 the manufacture, use, sale, processing, storage, packaging, labelling, marketing, promotion, or distribution of any Product (or any product that contains the Product), including but not limited to any claims of product liability; and/or

12.2.4 the supply to, and/or use by, Lonza, any of Lonza's Affiliates, Lonza Indemnitees, any Lonza contractors, any External Laboratory, and/or any Third Party of any Customer Information, Customer Background Intellectual Property, Customer Materials, New Customer Intellectual Property, the Cell Line, and/or any other information, materials or Intellectual Property provided by or on behalf of Customer (including any claim or allegation that such supply and/or use of any of the foregoing infringes any Intellectual Property rights or other rights of any Third Party);

except, in each case (12.2.1, 12.2.2, 12.2.3 and/or 12.2.4), to the extent that such claims resulted from the negligence and/or breach of this Agreement and/or intentional misconduct by any Lonza Indemnitees.

12.3 Indemnification Procedure. If the Party to be indemnified intends to claim indemnification under this Clause 12, it shall promptly notify the indemnifying Party

in writing of such claim. The indemnitor shall have the right to control the defence and/or settlement thereof; provided, however, that any indemnitee shall have the right to retain its own counsel at its own expense. The indemnitee, its employees and agents shall reasonably cooperate with the indemnitor in the investigation of any liability covered by this Clause 12. The failure to deliver prompt written notice to the indemnitor of any claim, to the extent that it is prejudicial to its ability to defend such claim, shall relieve the indemnitor of any obligation to the indemnitee under this Clause 12. The Party seeking indemnification shall not settle any claim in respect of which it will seek indemnification without the prior written consent of the indemnifying Party (not to be unreasonably withheld, conditioned or delayed).

12.4 Disclaimer of certain damages. In no event shall either Party and/or any of its Affiliates be liable (in each case whether in contract, tort, negligence, breach of statutory duty, under any indemnity, or otherwise howsoever arising) for any (i) (direct or indirect) loss of profits, loss of business, loss of revenues, loss of goodwill, loss of reputation, or (ii) for any incidental, indirect, special, punitive or consequential losses or damages, arising from or related to this Agreement; provided that this Clause 12.4 shall not preclude any claim by Lonza and/or any of its Affiliates for any unpaid invoices (including the profit element of its charges) and/or the Cancellation Fees and/or termination fees and provided that this Clause 12.4 shall not preclude any claim by Lonza and/or any of its Affiliates for the profit element of its charges; [***].

12.5 Limitation of liability. Subject always to Clause 12.6 [***], the aggregate liability of Lonza and its Affiliates under or in relation to this Agreement and the Project Plans (whether in contract, tort, negligence, breach of statutory duty, under indemnity, or otherwise howsoever arising) shall not exceed, in the aggregate, an amount equal to [***] under this Agreement by Customer to Lonza, [***]. For the avoidance of doubt this limitation of liability shall be an aggregate limitation of liability which is shared between Lonza and all of its Affiliates (including Lonza AG and Lonza Sales AG), and there shall not be a separate limit of liability for each separate Lonza entity.

12.6 Nothing in this Agreement shall operate so as to exclude or in any way limit any liability for fraud, or for death or personal injury, or for gross negligence or intentional misconduct, or for any liability that may not be excluded or limited as a matter of English law. Nothing in this Agreement shall exclude or limit Customer's liability to pay invoices and/or the Cancellation Fees, termination fees or agreed capital expenditure. For clarity, it is not the intention that this Clause 12.6 should apply to negligence which is not gross negligence and negligence which is not gross negligence shall be subject to Clauses 12.4 and (in the case of Lonza and its Affiliates) 12.5.

13. Confidentiality

13.1 A Party receiving Confidential Information (the "Receiving Party") agrees to strictly keep secret any and all Confidential Information received during the Term from, or disclosed on behalf of, the other Party (the "Disclosing Party"), as well as the terms of this Agreement, using at least the same level of measures as it uses to protect its own Confidential Information, but in any case at least commercially reasonable and customary efforts. Confidential Information shall include information disclosed in any form including but not limited to in writing, orally, graphically or in electronic or other form to, or observed or learned by, the Receiving Party or its Affiliates, or its or their Affiliate's, employees, agents, consultants, or representatives including any persons on plant (in each case such employees, agents, consultants, or representatives, or persons on plant, of Customer or any of its Affiliates), under or in relation to this Agreement, which the Receiving Party knows or reasonably should know is confidential or proprietary, as well as the terms of this Agreement.

13.2 Notwithstanding the foregoing, the Receiving Party may disclose to any courts and/or other authorities and/or any stock exchange upon which that Party's securities are then listed (except to any governmental patent office) Confidential Information of

the Disclosing Party which is or will be required pursuant to applicable governmental or administrative or public law, rule, regulation or order. In such case the Receiving Party will, to the extent legally permitted, inform the Disclosing Party promptly in writing, which may include by email (in the case of Context) to Lonza's then current program manager (unless an out of office response is received by Customer; in which case Customer shall contact Lonza to confirm an alternative), and reasonably cooperate with the Disclosing Party in seeking to minimise the extent of Confidential Information of the Disclosing Party which is required to be disclosed to the courts and/or other authorities and/or any stock exchange.

13.3 The obligation to maintain confidentiality under this Agreement does not apply to Confidential Information of the Disclosing Party, which:

13.3.1 at the time of disclosure was publicly available;

13.3.2 is or becomes publicly available other than as a result of a breach of this Agreement by the Receiving Party;

13.3.3 which the Receiving Party can establish by contemporaneous written records was rightfully in its possession at the time of disclosure by the Disclosing Party and had not been received from or on behalf of Disclosing Party;

13.3.4 which the Receiving Party can establish by contemporaneous written records is supplied to a Party by a Third Party which was not in breach of an obligation of confidentiality to Disclosing Party or any other party; or

13.3.5 which the Receiving Party can establish by contemporaneous written records is developed by the Receiving Party independently from and without use of the Confidential Information of the Disclosing Party.

13.4 The Receiving Party will use Confidential Information of the Disclosing Party only for the purposes of this Agreement and will not make any use of the Confidential Information for its own separate benefit or the benefit of any Third Party including with respect to research or product development or any reverse engineering or similar testing. The Receiving Party agrees to return or destroy promptly (and certify such destruction) on Disclosing Party's request all written or tangible Confidential Information of the Disclosing Party, except that one copy of such Confidential Information may be kept by the Receiving Party in its confidential files for record keeping purposes only.

13.5 Each Party will restrict the disclosure of the other Party's Confidential Information to its Affiliates, and such officers, employees, consultants and representatives of itself and its Affiliates who have been informed of the confidential nature of the Confidential Information and who have a need to know such Confidential Information for the purpose of this Agreement. Prior to disclosure to such persons, the Receiving Party shall bind itself and its Affiliates' officers, agents, employees, consultants and representatives to confidentiality and non-use obligations no less stringent than those set forth herein. The Receiving Party shall notify the Disclosing Party as promptly as practicable of any unauthorised use or disclosure of the Confidential Information of the Disclosing Party. Lonza may disclose the Customer's Confidential Information to Lonza's Affiliates, Subcontractors and the External Laboratories, in each case for the purposes of this Agreement.

13.6 The Receiving Party shall at all times be fully liable for any and all breaches of the confidentiality obligations in this Clause 13 by any of its Affiliates or the employees, officers, agents, consultants and representatives of itself or its Affiliates including any persons on plant.

13.7 Each Party hereto expressly agrees that any breach or threatened breach of the undertakings of confidentiality provided under this Clause 13 by a Party may cause

irreparable harm to the other Party and that money damages may not provide a sufficient remedy to the non-breaching Party for any breach or threatened breach. In the event of any breach and/or threatened breach, then, in addition to all other remedies available at law or in equity, the non-breaching Party shall be entitled to seek injunctive relief and any other relief deemed appropriate by the non-breaching Party.

14. Term and Termination

14.1 Term. This Agreement shall commence on the Effective Date and shall end on the date of completion of the Services unless terminated earlier as provided herein or extended by mutual written consent of the Parties (the "Term").

14.2 Termination. This Agreement or any Project Plan may be terminated as follows:

14.2.1 If it becomes apparent to either Lonza or the Customer at any stage in the provision of the Services that it will not be possible to complete the Services for a material scientific or material technical reasons, a [***] day period shall be allowed for good faith discussion and attempts to resolve such problems. If such problems are not resolved within such period, Lonza and the Customer shall each have the right to terminate the applicable Project Plan (or if there is only one Project Plan, this Agreement) forthwith by notice in writing;

14.2.2 by either Party, immediately, if the other Party commits a material breach of this Agreement or a Project Plan and fails to cure such breach to the reasonable satisfaction of the non-breaching Party within [***] days ([***] days for non-payment) following written notification of such breach from the non-breaching party to the breaching party; provided, however, that such [***] day period shall be extended as agreed by the Parties if the identified breach is incapable of cure within [***] days and if the breaching Party provides a plan and timeline to cure the breach, promptly commences efforts to cure the breach and diligently prosecutes such cure (it being understood that this extended period shall be unavailable for any breach regarding non-payment);

14.2.3 by either Party, immediately, if the other Party enters into administration, becomes insolvent, is dissolved or liquidated, makes a general assignment for the benefit of its creditors, or files or has filed against it, a petition in bankruptcy or has an administrator or receiver appointed for a substantial part of its assets; or

14.2.4 by either Party pursuant to Clause 15.

14.3 Consequences of Termination.

In the event of termination of this Agreement all Services and Batches which have been ordered, or to which the Customer is committed, in accordance with this Agreement (including those in the Project Plan to which the Parties are committed) shall be deemed to have been cancelled and Customer shall, within [***] days of such termination, pay Lonza for:

(a) all Services commenced up to the date of termination, including in respect of any Product in-process;

(b) all costs incurred through the date of termination, including all Raw Materials and Resins costs (and Handling Fees for Raw Materials and Resins) used or purchased or to which Lonza is irrevocably committed for use in connection with the Project Plan, and External Laboratory costs (and Handling Fees);

(c) all unused Raw Materials and Resins shall be paid for by Customer within [***] days of invoice and at Customer's option and cost will either be: (i) held by Lonza for future use for the production of Product; (ii) delivered to Customer; or (iii) disposed of by Lonza;

(d) all unreimbursed Capital Equipment and related decommissioning charges incurred pursuant to Clause 9; and

(e) Cancellation Fees in respect of all Batches and/or Services which have been ordered in accordance with this Agreement (including those in the Project Plan to which the Parties are committed) calculated in accordance with Clause 6.2 (other than in the event of termination by Customer pursuant to Clause 14.2.2 (material breach), or by either Party for an agreed scientific or technical reason pursuant to Clause 14.2.1 or by either Party pursuant to Clause 14.2.4 (Force Majeure), where in such instances no Cancellation Fees shall be payable). In the case of termination by Lonza for Customer's material breach, Cancellation Fees shall be calculated as of the date of written notice of termination.

Nothing in this Agreement shall require Customer to pay a Cancellation Fee more than once in respect for the same cancelled Stage of Work.

14.4 Survival. Neither the termination nor expiration of this Agreement shall affect the liability of a Party for breach of this Agreement. Notwithstanding anything contained in Clause 14, the rights and obligations of each Party which by their nature survive the termination or expiration of this Agreement shall survive the termination or expiration of this Agreement, including Clauses 5, 10-13 (inclusive) and 16 (to the extent relevant). Termination of this Agreement (including the consequences of termination set out in this Clause 14) shall not affect the accrued rights or liabilities of either Party and shall not preclude either Party from pursuing any remedies it may have hereunder, or at law or in equity, with respect to any breach of, or default under, this Agreement (subject always to Clauses 12.4 and 12.5). All confidentiality obligations set out in this Agreement shall survive termination or expiry of this Agreement.

15. Force Majeure

15.1 If either Party or any of its Affiliates is prevented or delayed in the performance of any of its obligations under the Agreement by Force Majeure (other than Customer's inability to make payments hereunder) and gives written notice thereof to the other Party specifying the matters constituting Force Majeure together with such evidence as such Party reasonably can give to the other Party and specifying the period for which it is estimated that such prevention or delay will continue, such Party shall be excused from the performance or the punctual performance of such obligations as the case may be from the date of such notice for so long as such cause of prevention or delay shall continue. Provided that, if such Force Majeure persists for a period of [***] months or more, either Party may terminate: (i) the affected Project Plan; or (ii) in the event that the Force Majeure event prevents the performance of the entire Agreement, this Agreement; in each case by delivering written notice to the other.

15.2 The Parties acknowledge that the COVID-19 virus is currently causing global disruption, and that there is a significant risk that Lonza's or Customer's performance under this Agreement may be affected by consequences of the COVID-19 virus, including but not limited to any measures taken by authorities, and/or the availability of human resources and raw materials, and that any such event shall be deemed a Force Majeure event.

15.3 "Force Majeure" shall be deemed to include any reason or cause beyond a Party's reasonable control affecting the performance by such Party of its obligations under the Agreement, including, but not limited to, any cause arising from or attributable to acts of God, epidemic, pandemic, strike, lockouts, labour troubles, restrictive governmental orders or decrees, riots, insurrection, war, terrorists acts, or as regards Lonza the inability of Lonza to obtain any required raw material, energy source, equipment, labour or transportation, at prices and on terms deemed by Lonza to be reasonably practicable, from Lonza's usual sources of supply or, in the case of Lonza, the detection of a viral, bacterial or mycoplasmal contamination that causes a shutdown of the Facility or any part thereof.

15.4 With regard to Lonza, any such event of Force Majeure affecting services or Production at its Affiliates or suppliers shall be regarded as an event of Force Majeure.

16. Miscellaneous

16.1 Independent Contractors. Each of the Parties is an independent contractor and nothing herein contained shall be deemed to constitute the relationship of partners, joint venturers, nor of principal and agent between the Parties (save as set out in Clause 7.2). Neither Party shall at any time enter into, incur, or hold itself out to Third Parties as having authority to enter into or incur, on behalf of the other Party, any commitment, expense, or liability whatsoever.

16.2 No Presumption Against Drafter. Each Party and its legal counsel have reviewed and revised this Agreement. The rule of construction that requires that ambiguities in this Agreement (including any Appendix hereto) be construed against the drafter shall be waived by both Parties in the interpretation of this Agreement.

16.3 Waiver. The failure of any Party at any time or times to require performance of any provision of this Agreement (including any Appendix hereto) will in no manner affect its rights at a later time to enforce the same. No waiver by any Party of any term, provision or condition contained in this Agreement (including any Appendix hereto), whether by conduct or otherwise, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition or of any other term, provision or condition of this Agreement (including any Appendix hereto).

16.4 Severability. If any provision hereof is or becomes at any time illegal, invalid or unenforceable in any respect, neither the legality, validity nor enforceability of the remaining provisions hereof shall in any way be affected or impaired thereby. The Parties hereto undertake to substitute any illegal, invalid or unenforceable provision by a provision which is as far as possible commercially equivalent considering the legal interests and the purpose.

16.5 Amendments. Modifications and/or amendments of this Agreement must be in writing and signed by the Parties. The Parties may amend this Agreement without the consent of the Affiliates of either Party.

16.6 Delegation / Assignment. Lonza shall be entitled to instruct one or more of its Affiliates to perform any of Lonza's obligations contained in this Agreement, but Lonza shall remain fully responsible in respect of those obligations (subject to clause 2.1). Subject thereto, neither Party may assign its interest under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed, provided, however that:

(1) (a) Lonza may, without the consent of the Customer, assign this Agreement to: (i) any Affiliate of Lonza; or (ii) any third party in connection with the sale or transfer (by whatever method) of all or substantially all of the assets of the business related to the Facility or providing the Services; and

(b) Lonza shall be entitled to sell, assign and/or transfer its trade receivables resulting from this Agreement without the consent of the Customer; and

(2) Customer may assign this Agreement without the consent of Lonza, to: [***].

For the purposes of this Clause 16.6, the terms “assign” and “assignment” shall include: (i) the sale of fifty percent (50%) or more of the outstanding stock of such Party to an Affiliate of such Party or an unrelated entity or natural person; (ii) the sale or transfer or other assignment of all or substantially all of the assets of the Party or the line of business or Product to which this Agreement relates; and (iii) a merger, consolidation, acquisition or other form of business combination. Any purported assignment without a required consent shall be void. No assignment shall relieve any Party of responsibility for the performance of any obligation or liability that accrued prior to the effective date of such assignment. Subject to the foregoing, this Agreement shall be binding on the successors and permitted assignees of each Party.

16.7 Notice. All notices (including any notice of cancellation or termination given in accordance with the terms of this Agreement) must be written and sent to the address of the Party first set forth above (or such other address as a Party may provide notice of to the other Party). All notices must be given (a) by personal delivery, with receipt acknowledged, or (b) by prepaid certified or registered mail, return receipt requested, or (c) by prepaid recognised next business day delivery service. Notices will be effective upon receipt or at a later date stated in the notice.

16.8 Governing Law/Jurisdiction. This Agreement is governed in all respects by the laws of the State of New York. USA. The Parties agree to submit to the jurisdiction of the courts located within or jurisdiction over the State of New York, USA.

16.9 Third Parties. The Parties to this Agreement do not intend that any term hereof should be enforceable by any person who is not a party to this Agreement, save that Affiliates of Lonza may rely on and enforce the indemnities granted to them and limitations and exclusions of liability contained herein and Affiliates of Lonza which have executed a Statement of Work or Project Plan under this Agreement shall be entitled to enforce this Agreement with respect to such Project Plan or Statement of Work in its own name as an intended third party beneficiary. This Agreement may be amended without the consent of any Affiliates of Lonza.

16.10 Announcements / Press Releases. Neither Party shall make any press release or announcement regarding the subject matter of this Agreement without the prior written consent of the other, except that either Party may make an applicable filing concerning the existence or terms of this Agreement, and/or the relationship between the Parties in accordance with Section 13.2.

16.11 Entire Agreement. This Agreement contains the entire agreement between the Parties as to the subject matter hereof and supersedes all prior and contemporaneous agreements with respect to the subject matter hereof. Nothing in this Agreement (or any Project Plan entered into pursuant to this Agreement) shall supersede, amend or otherwise modify any terms or conditions or other provisions of any other unrelated agreement between the Parties.

16.12 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same document. Each party acknowledges that an original signature or a copy thereof transmitted by facsimile or by .pdf shall constitute an original signature for the purposes of this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, each of the Parties hereto has caused this Agreement to be executed by its duly authorised representative effective as of the date written above.

LONZA SALES AG

By: /s/ Albert Pereda
Name Albert Pereda
Title Associate General Counsel

By: /s/ Marc Augustin
Name Marc Augustin
Title VP Finance Biologics

LONZA AG

By: /s/ Albert Pereda
Name Albert Pereda
Title Associate General Counsel

By: /s/ Marc Augustin
Name Marc Augustin
Title VP Finance Biologics

CONTEXT THERAPEUTICS INC.

By: /s/ Martin Lehr
Name Martin Lehr
Title CEO

APPENDIX A
Product and Project Plan

[***]

APPENDIX B
Pricing

[***]

APPENDIX C
Quality Agreement

[***]

APPENDIX D

Outline Terms For Technology Transfer Agreement

1. License to Lonza Intellectual Property

Non-exclusive license, including the right to grant sublicense to an identified third party contract manufacturer, under the Lonza Confidential Information and Lonza Background Intellectual Property, to the extent necessary to manufacture, have manufactured and to supply the Product, but no other product, using the Manufacturing Process.

2. [***]

3. [***]

4. [***]

5. [***]

6. Price and payment

£750,000 one-time fee, which shall be reduced [***].

[***].

Lonza

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

LICENCE AGREEMENT

between

LONZA SALES AG

and

CONTEXT THERAPEUTICS INC.

INDEX

APPENDIX

THIS AGREEMENT is made the 7th day of November 2022
("**Effective Date**")

BETWEEN

LONZA SALES AG incorporated and registered in Switzerland whose registered office is at Muenchensteinerstrasse 38, CH-4002, Basel, Switzerland (hereinafter referred to as "**Lonza**"), and

CONTEXT THERAPEUTICS INC., incorporated and registered in USA whose registered office is at 2001 Market Street, Suite 3915, Unit 15, Philadelphia, PA 19103 USA
(hereinafter referred to as "**Licensee**")

The Licensee and Lonza shall jointly be referred to as the "**Parties**" and individually as the "**Party**".

WHEREAS

A Lonza is the proprietor of the System and the CDACF System and has the right to grant certain Intellectual Property Rights in relation thereto (all as defined below).

B. Lonza and Licensee intend to enter in a Manufacturing Services Agreement on or about the Effective Date, pursuant to which Lonza shall use and/or may use the System and CDACF System to construct the Transfected Cell Line and manufacture Product on behalf of Licensee (such terms as defined below).

C. The Licensee now wishes to take a licence under Intellectual Property Rights of which Lonza is the proprietor in order to continue using the System and CDACF System (together with the Transfected Cell Line) to develop, and commercially exploit the Product (as defined below) on the terms set out in this Agreement.

NOW THEREFORE the Parties hereby agree as follows:

1. Definitions and Interpretation

1.1 In this Agreement the following words and phrases shall have the following meanings:

"Affiliate" means any company, corporation, limited liability company, partnership or other entity which directly or indirectly controls, is controlled by or is under common control, directly or indirectly, with the relevant Party to this Agreement. "Control" means the ownership of more than fifty percent (50%) of the issued share capital of the entity in question or the legal power to direct or cause the direction of the general management and policies of the entity in question. Such entity shall be deemed an Affiliate only so long as it satisfies the foregoing definition.

"**Approved Territory**" means the [***].

"**Biosimilar Product**" means a product sold by a Third Party in a Sales Country (as defined in Clause 5.2) that:

(a) has received all necessary approvals by the applicable regulatory authorities in such Sales Country to market and sell such product as a pharmaceutical product;

(b) such Third Party has not obtained the rights to market or sell such product as a licensee, sublicensee or distributor of Licensee (or any of its Affiliates, licensees or sublicensees) with respect to such product; and

(c) is approved as: (i) a "biosimilar" (in the United States) of the Product, (ii) a "similar biological medicinal product" (in the EU) with respect to

which the Product is the "reference medicinal product" or (iii) if not in the US or EU, the equivalent of a "biosimilar" or "similar biological medicinal product" of the Product; in each case for use in such Sales Country pursuant to an expedited regulatory approval process governing approval of generic biologics based on the then-current standards for regulatory approval in such country and where such regulatory approval was based in significant part upon clinical data generated on the Product.

"CDACF Base Powders" means the applicable version of the powders set out in Appendix 2.

"CDACF Feeds" means the applicable version of the concentrated nutrient solutions used in order to maintain the growth and productivity of mammalian cells, as more fully set out in Appendix 3.

"CDACF Know-How" means any Know-How specifically relating to the applicable version of the CDACF Base Powders, CDACF Feeds, CDACF Media or the CDACF Supplements used either in combination or individually, as set out in Appendix 4.

"CDACF Media" means the applicable version of the solutions of nutrients used in mammalian cell culture, as more fully set out in Appendix 3.

"CDACF Supplements" means the applicable version of the supplement solutions, as more fully set out in Appendix 3.

"CDACF System" means the CDACF Base Powders, CDACF Feeds, CDACF Media, CDACF Know-How and the CDACF Supplements used either in combination or individually.

"Cell Line" means Lonza's CHOK1SV GS-KO®[1] cell line.

"Confidential Information" means any Know-How and confidential information (in any format and on any media) disclosed by one Party to the other in connection with this Agreement including for the avoidance of doubt the terms of this Agreement itself. In the case of Lonza, Confidential Information shall mean all information relating to the System and/or CDACF System and any other materials, specifications or information which is provided and/or disclosed by Lonza, its Affiliates and their respective officers, employees, agents and advisors to the Licensee and its officers, employees, agents and advisors, whether directly or indirectly, including, without limitation, all agreements, research databases, trade secrets, Intellectual Property Rights, business and/or commercial and/or financial data, specifications, technical designs, documents and drawings which are related to the System, the CDACF System and/or Lonza's business.

"Effective Date" means the date first above written.

"First Commercial Sale" means the date of the first sale or other disposal of Product to a Third Party for consideration by or on behalf of Licensee in that particular country following regulatory approval in such country.

"**GS piggyBac®**" means Lonza's gene delivery system known as GS piggyBac® for use in the GS piggyBac® Field consisting of the GS piggyBac® Materials and the GS piggyBac® Know-How, whether used individually or in combination with each other. For the avoidance of doubt, any gene or genes proprietary to Licensee inserted into GS piggyBac® do not form part of GS piggyBac®.

"**GS piggyBac® Field**" means the use of Cell Line and the production and use of Vectors and/or the GS piggyBac® Materials to produce biological molecules for all

[1] *All trade marks (®) are registered in CH, EU or USA*

purposes directly related to the production of human therapeutic products only (not for animal therapeutic products).

"**GS piggyBac® Know-How**" means Know-How relating directly or indirectly to GS piggyBac® known to Lonza, or its Affiliates, from time to time of which Lonza, or its Affiliates, is the proprietor or in which Lonza, or its Affiliates, has certain rights including for use in the GS piggyBac® Field and which at all times vests in Lonza.

"**GS piggyBac® Materials**" means those materials referred to in Appendix 6.

"Initiation" means, with respect to any clinical trial, the first date that a human subject is dosed in such clinical trial.

"Intellectual Property Rights" means all rights, title and interests, vested and/or arising out of any industrial or intellectual property, whether protected at common law or under statute, which includes (without limitation) any rights and interests in patents, copyrights, designs, trademarks, service marks, trade-names, technology, business names, logos, commercial symbols, processes, developments, licenses, trade secrets, goodwill, drawings, computer software, formulae, technical information, research data, procedures, Confidential Information and any other knowledge of any nature whatsoever throughout the world whether in existence today or which will come into existence in the future, and including all applications for patents, copyrights, trademarks, trade names, rights to apply and any amendments/modifications or renewals thereto; and all other intellectual property rights.

"Know-How" means any technical and other information, whether patented or unpatented, including, but without prejudice to the generality of the foregoing, ideas, concepts, trade secrets, know-how, inventions, discoveries, data, formulae, specifications, processes, procedures for experiments and tests and other protocols, results of experimentation and testing, fermentation and purification techniques and assay protocols.

"Licensed Know-How" means the System Know-How, GS piggyBac® Know-How and CDACF Know-How.

"Net Sales" means all revenues recorded by or on behalf of Licensee or its Sublicensees for Product sold in the Territory (including without limitation where such sales are made by way of an alternative fee arrangement or commission arrangement when and to the extent that such selling entity recognises the applicable revenue under GAAP). The permitted deductions booked on an accrual basis by Licensee and its Sublicensees under their respective accounting standards to calculate the recorded net sales from gross sales are as follows:

(a) [***];

(b) [***]; and

(c) [***].

Such permitted deductions shall not include, without limitation, [***].

Subject to the qualification stated below, [***].

Notwithstanding anything contained in this Agreement to the contrary, [***] shall not be included in this provision.

ıe Product is sold as a combined product that consists of Product together with another therapeutically active ingredient or product (a **"Combination"**), the Net Sales will be calculated by multiplying the Net Sales of the Combination (as defined using the Net Sales definition above) by the fraction, A/(A+B) where A is the weighted (by sales volume) average sale price of the Product in the relevant country, and B is the weighted average sale price (by sales volume) in that country of the product(s)

containing the other component(s) in finished form. Regarding prices comprised in the weighted average price when sold separately referred to above, if these are available for different dosages from the dosages of Product and other components that are included in the Combination, then the Parties shall mutually agree on the appropriate proportional adjustment to such prices in calculating the royalty-bearing Net Sales of the Combination. If the weighted average sale price cannot be determined for the Product or other component(s), the calculation of Net Sales for a Combination will be mutually agreed upon by the Parties based on the relative value contributed by each component, such agreement to be negotiated in good faith without unreasonable delay. If agreement on this basis cannot be reached, then the Parties will refer to the relative pricing of dosages as observed for biosimilar products in the same country. For the avoidance of doubt, in no event will a bioconjugate be deemed to be a Combination for the purposes of this Agreement.

"Patent Rights (Lonza)" means the patents and applications, short particulars of which are set out in Appendix 1A, and all patents and applications thereof of any kind throughout the world whether national or regional including but without prejudice to the generality of the foregoing, author certificates, inventor certificates, improvement patents, utility certificates and models and certificates of addition, and including any divisions, renewals, continuations, continuations in part, reissues, patent disclosures, improvements and extensions of reissue thereof.

"Patent Rights (Third Party)" means the patents and applications, short particulars of which are set out in Appendix 1B, and to the extent granted to Lonza by the owners of the Patent Rights (Third Party), all patents and applications thereof of any kind throughout the world whether national or regional including but without prejudice to the generality of the foregoing, author certificates, inventor certificates, improvement patents, utility certificates and models and certificates of addition, and including any divisions, renewals, continuations, continuations in part, reissues, patent disclosures, improvements and extensions of reissue thereof.

"Pre-Approved Affiliates" shall mean those entities set out in Appendix 7.

"Product" means Licensee's Claudin 6 x CD3 ("CLDN6xCD3") bispecific antibody in which Licensee has Proprietary Rights and which (or a component of which) is obtained by the expression of any one gene or of any combination of genes by use of the System and/or CDACF System, or any formulation containing the same.

"Proprietary Rights" means sole or co-ownership, or an exclusive or sole licence, or those rights obtained by Licensee or its Affiliate pursuant to that certain Research Collaboration and License Agreement, as may be amended, with Integral Molecular, Inc. entered into on 6 April 2021.

"Royalty Term" shall have the meaning ascribed to it in Clause 5.3.

"Strategic Partner" means a person or entity after the Effective Date: (i) [***]; and (ii) [***]. In no event may any entity whose role in the relationship is [***].

"Sublicensee" means any Strategic Partner or other Third Party to which Licensee grants a sublicence of the rights granted to Licensee pursuant to this Agreement.

"System" means Lonza's [***] gene expression system known as GS Xceed® consisting of the System Materials, the System Know-How and GS piggyBac® (whether used individually or in combination with each other) and including any part of such system that is embodied within or otherwise used to create the Transfected Cell Line(s). For the avoidance of doubt, any gene in which Licensee has Proprietary Rights inserted into the System for the purposes of producing Product does not form part of the System.

"System Know-How" means Know-How relating directly or indirectly to the System known to Lonza from time to time, of which Lonza is the proprietor (including, without limitation: (i) manuals of operating procedures for the System; (ii) regulatory

information supplied in connection with the System; (iii) vector nucleotide sequences; (iv) Know-How concerning the composition of the System; and (v) any such Know-How that is otherwise embodied within one or more component(s) of the System).

"System Materials" means the Cell Line and Vectors.

"Territory" means worldwide.

"Third Party" means any individual or entity other than Lonza and Licensee.

"Transfected Cell Line(s)" means the Cell Line transfected by or on behalf of Licensee and which expresses Product.

"Valid Claim" means a claim within the Patent Rights (Lonza) or the Patent Rights (Third Party) (including any re-issued and unexpired claims) which, but for the licence and other rights granted pursuant to Clauses 4.1 to 4.4 hereof, would be infringed by the manufacture, use, sale, offer for sale, exportation or importation of Product by Licensee or its Sublicensees and which:

(a) has not been finally cancelled, withdrawn, abandoned or rejected by any administrative agency or other body of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal; and

(b) has not been finally revoked, held invalid or declared unpatentable or unenforceable in a decision of a court or other body of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal.

"Vectors" means Lonza's [***] vectors set out in Appendix 5.

1.2 The headings of this Agreement are inserted only for convenience and shall not affect the construction hereof.

1.3 Where appropriate words denoting a singular number only shall include the plural and vice versa.

1.4 References to the recitals, clauses and appendices shall be deemed to be a reference to the recitals, clauses and appendices to this Agreement and shall form an integral part of this Agreement.

1.5 References to any statute or statutory provision include a reference to the statute or statutory provision as from time to time amended, extended or re-enacted.

1.6 Reference in this Agreement to Lonza shall, unless repugnant to the subject or context thereof, include its Affiliates, successors and assigns.

2. Supply of System Know-How, GS piggyBac® Know-How and CDACF System

2.1 Unless previously supplied by Lonza under a separate agreement, Lonza shall, if requested by Licensee in writing, supply further System Know-How as required by Licensee solely for regulatory purposes (and which shall only be supplied directly to the regulatory agency by Lonza). Any such System Know-How provided hereunder (together with all other applicable components of the System previously received by Licensee) shall be used strictly in accordance with the terms of this Agreement.

2.2 In relation to the CDACF System, Lonza shall following signature of this Agreement: (a) provide Licensee with details of how to purchase the CDACF Base Powders and CDACF Supplements to enable Licensee to make CDACF Feeds and CDACF Media; and (b) if requested in writing by Licensee and required for use under this Agreement, supply Licensee with the CDACF Know-How.

2.3 Should any transportation of the System and/or CDACF System be arranged by Lonza on behalf of Licensee such transportation shall be made at the sole risk of the

Licensee. The Licensee shall indemnify Lonza against all losses, expenses, demands, claims, actions, judgments, assessments, damages, liabilities, fines, penalties, costs and fees incurred by Lonza by reason of such transportation, other than such losses directly attributable to Lonza's negligence or wilful misconduct.

3. Ownership of Property and Intellectual Property

3.1 Save for any Intellectual Property Rights licensed to Lonza, it is hereby acknowledged and agreed that as between the Parties any and all property and Intellectual Property Rights in the System and the CDACF System is vested in Lonza. Similarly it is hereby acknowledged as between the Parties any and all Intellectual Property Rights in the Product and any gene proprietary to Licensee (or any of its licensors or sublicensees) inserted into the System, or used with the System and/or CDACF System, for the purpose of producing Product is vested in Licensee (or its applicable licensors and sublicensees) to the extent that this is severable from and does not utilise, disclose, infringe or reveal any Intellectual Property Rights of Lonza.

4. Licences

Commercial Activities Licence

4.1 Lonza hereby grants to Licensee on the Effective Date:

4.1.1 a worldwide non-exclusive licence under the System, CDACF System, and the Patent Rights (Lonza) (with the right to sublicence, subject to Clause 4.2 below); and

4.1.2 a worldwide non-exclusive sublicence under the Patent Rights (Third Party) (with the right to sublicense, subject to Clause 4.2 below),

in each case Clause 4.1.1 and Clause 4.1.2 to [***], market, sell, offer for sale, distribute, import and export Product in the Territory ("**Commercial Activities**").

4.2 Subject to the provisions of this Clause 4.2 and the terms and conditions of this Agreement, Licensee shall be entitled to grant a sublicence to the rights (excluding the right to grant additional tiers of sublicences) granted by Clause 4.1 (each a "**Commercial Activities Sublicence**") to any one or more Third Parties for the purposes of any such Third Party undertaking Commercial Activities for or on behalf of Licensee (each a "**Commercial Activities Sublicensee**") provided always:

4.2.1 Licensee shall ensure such Commercial Activities Sublicensee's use of the Product is undertaken solely for undertaking Commercial Activities for or on behalf of Licensee;

4.2.2 The Commercial Activities Sublicensee shall not, by virtue of this Agreement, be granted any right or licence, either express or implied, to the System, CDACF System, Patent Rights (Lonza) and the Patent Rights (Third Party) other than for undertaking Commercial Activities for or on behalf of Licensee. Licensee agrees to ensure that such Commercial Activities Sublicensee shall not assign, transfer, further sublicense or otherwise make over the benefit or the burden of the rights granted to it pursuant to the Commercial Activities Sublicence; and

4.2.3 Licensee shall notify Lonza in writing within a period of [***] days of granting a Commercial Activities Sublicence under this Agreement.

Manufacturing Activities Licence:

4.3 Lonza hereby grants to Licensee on the Effective Date:

4.3.1 a non-exclusive licence under the System, CDACF System, and the Patent Rights (Lonza) (with the right to sublicence, subject to Clause 4.4 below); and

4.3.2 a non-exclusive sublicence under the Patent Rights (Third Party) (with the right to sublicense, subject to Clause 4.4 below),

in each case 4.3.1 and 4.3.2 to use, develop and manufacture Product ("**Manufacturing Activities**") at Licensee's premises located at 2001 Market Street, Suite 3915, Unit 15, Philadelphia, PA 19103 USA, or such other premises approved in writing by Lonza under the terms of this Agreement, such approval not to be unreasonably withheld, conditioned or delayed. It is agreed between the Parties that Lonza shall be considered to be reasonably withholding its consent if it holds commercial concerns as to protection of its Intellectual Property Rights and confidentiality should Manufacturing Activities be carried out at Licensee's proposed premises.

4.4 Subject to the provisions of this Clause 4.4 and the terms and conditions of this Agreement, Licensee shall be entitled to grant a sublicence to the rights (excluding the right to further sublicense) granted by Clause 4.3 (each a "**Manufacturing Sublicence**") to any one or more Third Parties for the purposes of any such Third Party undertaking Manufacturing Activities at a facility owned or controlled by such Third Party(ies) for or on behalf of Licensee (each a "**Manufacturing Sublicensee**") provided always:

4.4.1 Licensee shall ensure such Manufacturing Sublicensee's use of the System, the CDACF System and Lonza's Intellectual Property Rights (subject always to Clause 4.6) is undertaken solely for undertaking Manufacturing Activities for or on behalf of Licensee;

4.4.2 The Manufacturing Sublicensee shall not, by virtue of this Agreement, be granted any right or licence, either express or implied, under any patent or proprietary right vested in Lonza or otherwise, to use the System, the CDACF System, Lonza's Intellectual Property Rights or the Product other than for undertaking Manufacturing Activities for or on behalf of Licensee. Licensee agrees to ensure that such Manufacturing Sublicensee shall not assign, transfer, further sublicense or otherwise make over the benefit or the burden of the rights granted to it pursuant to this Agreement;

4.4.3 Prior to the grant of any Manufacturing Sublicence pursuant to this Clause 4, subject to Clause 4.4.4 below, Licensee shall obtain the written consent of Lonza (such consent not to be unreasonably withheld, conditioned or delayed) to the grant of such sublicence. It is agreed between the Parties that Lonza shall be considered to be reasonably withholding its consent if it holds commercial concerns as to protection of its Intellectual Property Rights and confidentiality should Lonza's Intellectual Property Rights be sub-licensed to the proposed Manufacturing Sublicensee. The Licensee shall notify Lonza in writing within a period of [***] days of granting each Manufacturing Sublicence under this Agreement;

4.4.4 Notwithstanding Clause 4.4.3, Lonza hereby grants its consent to the grant of a Manufacturing Sublicence by Licensee to [***]. For the avoidance of doubt, such consent shall extend only to the location of the [***]. In the event that [***] intends to carry out Manufacturing Activities in any other location such location shall be subject to the prior written consent of Lonza in accordance with Clause 4.4.3; and

4.4.5 Within [***] business days following termination of this Agreement or termination or expiry of Licensee's arrangements with any such Manufacturing Sublicensee (whichever occurs earlier), Licensee shall confirm in writing to Lonza that Transfected Cell Lines and Licensed Know-How (including materials provided to Manufacturing Sublicensee relating directly or

indirectly to the System or the CDACF System) are destroyed and/or returned to Licensee.

General Licence Restrictions (Commercial Activities and Manufacturing Activities)

4.5 Any Manufacturing Sublicence or Commercial Activities Sublicence granted by Licensee shall be granted expressly subject to the terms of this Agreement, and it shall be Licensee's responsibility to ensure the strict adherence by each Manufacturing Sublicensee and Commercial Activities Sublicensee hereunder to the terms and conditions of this Agreement. Licensee shall be responsible and liable for the acts or omissions of each Manufacturing Sublicensee and Commercial Activities Sublicensee herein and Licensee shall indemnify Lonza against all costs, expenses, claims, loss or damage incurred or suffered by Lonza, or for which Lonza may become liable arising out of any act or omission of any Sublicensee, including any product liability claim relating to Product manufactured, supplied or put into use by the Sublicensee, except in all instances if directly related to the gross negligence or wilful misconduct of Lonza.

4.6 Notwithstanding any other provision, Licensee shall not transfer the Cell Lines and/or Vectors and/or GS piggyBac® Materials to any Third Party without Lonza's prior and express written consent (such consent not to be unreasonably withheld, conditioned or delayed), provided, however, that Licensee is allowed to transfer the Transfected Cell Lines to a Manufacturing Sublicensee for the purposes of and subject to Clause 4.4. It is agreed between the Parties that Lonza shall be considered to be reasonably withholding its consent if it holds commercial concerns as to protection of its Intellectual Property Rights and confidentiality should Lonza's Intellectual Property Rights be transferred to the proposed recipient of such materials. Licensee shall not transfer any Licensed Know-How without prior written approval by Lonza, which shall only be granted to the extent strictly required for Manufacturing Activities.

4.7 Licensee hereby undertakes that it will neither reverse engineer nor make any modifications, adaptations or improvements to the System and/or the CDACF System and/or Transfected Cell Lines (including for the avoidance of doubt but not by way of limitation, inserting alternate cell lines and/or vectors) without Lonza's prior written consent, except and only to the extent that such activity is expressly permitted by applicable law notwithstanding this limitation.

4.8 Licensee shall use the System only in accordance with the licences granted under Clause 4, and shall not use, cause the use of or permit to be used the System for any purpose not directly authorised by this Agreement.

4.9 The CDACF System may only be used in conjunction with the System and may not be used in conjunction with any other gene expression system or for any other purpose whatsoever.

4.10 If, on a country-by-country basis, any granted patents that form part of the Patent Rights (Lonza) or Patent Rights (Third Party) (including any re-issued patents and unexpired patents), subsequently expire or no longer contain a Valid Claim such Patent Rights (Lonza) or Patent Rights (Third Party) shall automatically fall outside the scope of this Agreement for that particular country and the provisions of Clauses 4.1 to 4.9 shall only apply in that particular country, with respect to granted patents, to those granted patents which contain a Valid Claim and form part of the Patent Rights (Lonza) or Patent Rights (Third Party) for as long as those granted patents remain in force.

4.11 Notwithstanding Clause 4.10, on a country-by-country basis, where no Valid Claim remains in force, the provisions of Clauses 4.1 to 4.9 shall continue to apply with respect to: (i) [***]; and (ii) [***].

4.12 No licence is granted save as expressly provided herein and no licence in addition thereto shall be deemed to have arisen or be implied by way of estoppel or otherwise.

Additional Licensee Obligations

4.13 Licensee shall notify Lonza within [***] days of when Product changes its phase of clinical trial and/or when it is first offered for commercial sale.

4.14 Licensee shall obtain at its own expense all licences, permits and consents necessary for the provision of Product in the Territory.

4.15 Licensee acknowledges and agrees that the exercise of the licence granted to the Licensee under this Agreement is subject to all applicable laws, enactments, regulations and other similar instruments in the Territory, and the Licensee understands and agrees that it shall at all times be solely liable and responsible for such due observance and performance.

4.16 Licensee represents and warrants it has all the requisite authority and rights in Product to enter into this Agreement and exercise the rights being granted to it under this Agreement, other than any rights as may be required from Lonza.

5. Payments

5.1 In consideration of the licences granted to Licensee pursuant to Clauses 4.1 and 4.3 above, and in consideration for the right to sublicence the rights granted by Clauses 4.1 and 4.3, pursuant to Clauses 4.2 and 4.4 respectively, Licensee shall pay Lonza as follows, subject to the adjustment as set forth in Clause 5.2 and Clause 5.5 (as applicable):

5.1.1 in respect of Product manufactured by Lonza, a royalty of [***] percent ([***]%) of Net Sales;

5.1.2 where [***] manufactures Product (whether for clinical or commercial purposes):

5.1.2.1 a payment of [***] ([***]) due annually during the course of this Agreement, and being first payable upon [***] and thereafter on each anniversary of such date; and

5.1.2.2 a royalty of [***] percent ([***]%) of Net Sales of Product;

5.1.3 where any person or entity other than [***] manufactures Product (whether for clinical or commercial purposes) ("[***]"):

5.1.3.1 a payment of [***] ([***]) [***] due annually during the course of such [***] (irrespective as to the years of manufacture), and being first payable on the commencement date of the relevant [***]; and

5.1.3.2 a royalty of [***] percent ([***]%) of Net Sales of Product.

5.2 If, on a country-by-country basis, neither (i) the use, sale, offer for sale or import of the Product in a particular country ("**Sales Country**") nor (ii) the manufacture and/or export for sale of the Product in the country of its manufacture (whether in the Sales Country or otherwise) ("**Manufacture Country**") are covered by a Valid Claim (either because no patent or application was ever filed for any such country or the patent or application is no longer of effect) then in respect of sales in that Sales Country:

5.2.1 the royalties referred to in Clauses 5.1.1 and 5.1.2.2 shall be at the rate of [***] percent ([***]%) and [***] percent ([***]%) respectively of the Net Sales in that Sales Country; and

5.2.2 the royalties referred to in Clause 5.1.3.2 shall be at the rate of [***] percent ([***]%) of the Net Sales in that Sales Country.

5.3 Any royalty payments due under this Clause 5 shall be required in each country of the world on a country-by-country basis until the later of:

5.3.1 expiry of the last Valid Claim in that particular Sales Country;

5.3.2 expiry of the last Valid Claim in the Manufacture Country; and

5.3.3 ten (10) years from the First Commercial Sale of the Product in that particular Sales Country,

(the "**Royalty Term**"). For the avoidance of doubt, (i) upon expiration of a Royalty Term in any individual country, all other terms and conditions of this Agreement shall remain in full force and effect, and (ii) there should be no payments due hereunder pursuant to Clauses 5.1.2.2 or 5.1.3.2.

5.4 The Royalty Term for a particular country shall end earlier than as set out in Clause 5.3 in the event that, and on the date upon such receipt by Licensee, Licensee receives either: (i) [***]; (ii) [***]; or (iii) [***].

5.5 [***]

5.5.1 In the event that, on a country-by-country basis: (i) [***]; (ii) [***]; and (iii) [***]:

Product manufactured by Lonza (Clause 5.1.1)	***Product manufactured by*** [***] ***(Clause 5.1.2.2)***	***Product manufactured by*** [***] ***(Clause 5.1.3.2)***
[***]%	[***]%	[***]% [***]

5.5.2 In the event that, following the expiry of a Royalty Term in a country in the Approved Territory, a [***].

5.5.3 The [***] set out in Clauses 5.5.1 and 5.5.2 above shall be conditional on Licensee giving written notice to Lonza regarding [***].

5.6 The provisions of this Clause 5 shall remain in effect notwithstanding termination of this Agreement until the settlement of all subsisting claims by Lonza.

6. Royalty Procedures

6.1 Licensee shall, and shall ensure that its Sublicensees shall, keep true and accurate records and books of account (including but not limited to easily accessible electronic database records) containing all data necessary for the calculation of royalties payable to Lonza and in accordance with accounting best practice.

6.2 Licensee shall prepare a statement in respect of each calendar quarter which shall show for the immediately preceding quarter details of the sales of Product on a country-by-country basis, including a full list of all of the permitted deductions which have been applied by Licensee when calculating the Net Sales from the gross sales, and the royalty due and payable to Lonza thereon. Such statement shall be submitted to Lonza within [***] days after the end of the calendar quarter to which it relates, together with a remittance for the royalties due to Lonza to which Lonza shall issue a receipted invoice in return.

6.3 The records and books of account referred to in Clause 6.1 shall, upon reasonable notice having been given by Lonza (which in no event shall be less than [***] days prior notice), be open at all reasonable times during regular business hours for

inspection by independent auditors selected by Lonza and reasonably acceptable to Licensee. The audit shall take place where the Licensee maintains such records and books of account. In the event that a visit to a separate location is required for the purpose of conducting the audit, Licensee will reimburse Lonza for any additional costs reasonably incurred by the auditors as a result. The auditors shall be entitled to take copies as reasonably necessary in order for the auditor to carry out its audit effectively of Licensee's records and books of account. Such independent auditors shall agree to maintain the confidentiality of the information and materials disclosed during the audit. Any such audit shall be conducted in a manner that does not interfere unreasonably with the operations of Licensee's business. Lonza may perform an audit no more than [***]. Each audit shall begin upon the date specified by Lonza and shall be completed as soon as reasonably practicable. Lonza shall pay the costs of the independent auditors conducting such audit, unless the results of the audit reveal an underpayment of [***] percent ([***]%) or more by Licensee, in which case Licensee shall pay the reasonable costs of the independent auditors. If an audit concludes that an underpayment has occurred during the audited period, such underpayment shall be remitted by the Licensee to Lonza within [***] days after the date such auditor's written report identifying the underpayment is delivered to the Licensee. If an audit concludes that an overpayment has occurred during the audited period, such overpayment shall be carried forward and offset against future amounts payable by Licensee to Lonza, or otherwise promptly refunded to Licensee if no additional payments are due at the time such audit is concluded or otherwise anticipated to become due to cover such amount. Receipt or acceptance by Lonza of royalty statements or payments due from Licensee pursuant to this Agreement shall not preclude Lonza from later questioning the accuracy or completeness of such statements. The Licensee shall procure that its Sublicensees shall grant rights directly to Lonza corresponding to those granted by the Licensee under this Clause 6.3.

6.4 All sums due under this Agreement:

6.4.1 shall be paid in [***] to Lonza;

6.4.2 are exclusive of any value added tax or of any other applicable taxes, levies, imposts, duties and fees of whatever nature imposed by or under the authority of any government or public authority, which shall be paid by Licensee (other than taxes on Lonza's income); and

6.4.3 shall be paid free and clear and without deduction for any present and future taxes imposed by any taxing authority. If Licensee is required by law to deduct or withhold taxes from sums due to Lonza under this Agreement, Licensee shall pay to Lonza such additional amounts as are necessary to ensure receipt by Lonza of the full amount which Lonza would have received but for the deduction or withholding, other than for payments related to Lonza's income. If such additional amounts can be reduced or eliminated under local or treaty law, Lonza shall cooperate with Licensee in obtaining such deduction or exemption, it being understood that the primary responsibility for completion and timely filing of any applicable forms in this respect resides with Licensee and any withholding tax that could not be reduced or eliminated is to be born and paid by Licensee.

6.5 To the extent that Licensee reports Net Sales otherwise than in United States Dollars then royalty payments due to Lonza shall be first calculated in the local currency in which Net Sales are reported and then shall be converted to a United States Dollars value at the rate of exchange first published in the Financial Times (London) on the first business day after the relevant quarterly reporting period.

6.6 Where Lonza does not receive payment of any sum by the due date, interest shall accrue thereafter on the sum due and owing to Lonza at the rate of [***] percent ([***]%) per annum over the base rate from time to time of National Westminster

Bank plc, interest to accrue on a day-to-day basis without prejudice to Lonza's right to receive payment on the due date.

7. Liability and Warranties

7.1 Lonza warrants that the patents included in the Patent Rights (Lonza) and Patent Rights (Third Party) are the only patents that must be licensed or sub-licensed from Lonza and/or its Affiliates in order to operate the System in accordance with the terms of this Agreement.

7.2 Subject to Clause 7.1, Lonza gives no representation or warranty that the Patent Rights (Lonza) or Patent Rights (Third Party) which are patent applications will be granted or if granted will be valid nor that the exercise of the rights granted to Licensee hereunder will not infringe other patent rights or intellectual property rights vested in Lonza or any Third Party.

7.3 The Licensee hereby acknowledges: (i) this is a licence to the Licensed Know-How, Patent Rights (Lonza) and the Patent Rights (Third Party) and not to any other Lonza Intellectual Property Rights; and (ii) that in order to exploit the rights granted herein the Licensee may require licences under Lonza Intellectual Property Rights (other than those herein licensed) or under Third Party patent rights (including those vested in Affiliates of Lonza) that may be infringed by the use by the Licensee of the rights licensed herein. It is hereby agreed that it shall be the Licensee's responsibility to satisfy itself as to the need for such licences and if necessary to obtain such licences; provided that where any such Intellectual Property Rights vested in Lonza or its Affiliates would prevent the Licensee and its Sublicensees from operating the System as permitted by the terms of this Agreement, then such patent rights shall be automatically included within the Intellectual Property Rights licensed to Licensee hereunder.

7.4 Each Party ("**Indemnifying Party**") shall indemnify and hold harmless the other Party and its Affiliates, and their respective officers, employees and agents (each an "**Indemnified Party**") at all times in respect of any and all losses, damages, costs and expenses (collectively "**Losses**") suffered or incurred as a result of any contractual, tortious or other claims or proceedings by Third Parties (collectively "**Third Party Claims**") against Indemnified Party arising out of the Indemnifying Party's breach of this Agreement, including breach of representations or warranties, violation of applicable law, negligence or wilful misconduct; provided that with respect to any Third Party Claim for which each Party is entitled hereunder to seek indemnification from the other Party, each Party as the Indemnifying Party shall indemnify the other Party for its Losses only to the extent of the Indemnifying Party's relative responsibility for the facts underlying the Third Party Claim.

7.5 With respect to product liability claims or proceedings, the following shall apply: (a) except to the extent provided in (b) below, Licensee shall indemnify and hold harmless Lonza, its Affiliates and their respective officers, employees and agents at all times in respect of any and all losses, damages, costs and expenses suffered or incurred as a result of any tortious claims or proceedings of death or bodily injury relating to the Product, and (b) Lonza shall indemnify and hold harmless Licensee, its Affiliates and their respective officers, employees and agents at all times in respect of any and all losses, damages, costs and expenses suffered or incurred as a result of any tortious claims or proceedings of death or bodily injury relating to the Product to the extent such claims or proceedings result directly from defects in the Cell Lines, Vectors or GS piggyBac® Materials.

7.6 Any condition or warranty other than those relating to title which might otherwise be implied or incorporated within this Agreement by reason of statute or common law or otherwise is hereby expressly excluded.

7.7 EXCEPT FOR EITHER PARTY'S BREACH OF CLAUSE 8 HEREOF SUBJECT TO CLAUSE 7.8, IN NO EVENT SHALL EITHER PARTY AND/OR THEIR RESPECTIVE AFFILIATES BE LIABLE TO THE OTHER PARTY, THEIR AFFILIATES AND THEIR

RESPECTIVE OFFICERS, EMPLOYEES AND AGENTS WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT WHETHER IN CONTRACT IN TORT IN NEGLIGENCE OR FOR BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY LOSS OF PROFITS, OR FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES.

7.8 Nothing in this Agreement shall exclude or limit the liability of either Party for fraud or for death or personal injury caused by its negligence or for wilful or deliberate breach of this Agreement or for any other liability that may not be limited or excluded as a matter of law.

8. Confidentiality

8.1 Licensee expressly acknowledges that Confidential Information disclosed by Lonza pursuant to this Agreement is supplied in circumstances imparting an obligation of confidence and Licensee shall keep such Confidential Information secure, secret and confidential and undertakes to respect Lonza's proprietary rights therein and to use the same for the sole purpose of this Agreement and not during the period of this Agreement or at any time for any reason whatsoever to disclose, cause or permit to be disclosed such Confidential Information to any Third Party other than its Sublicensee hereunder for use in accordance with and subject to the terms of this Agreement. Licensee shall procure that only its employees and employees of its Sublicensee hereunder shall have access to Confidential Information and then only on a need-to-know basis and that all such employees shall be informed of their secret and confidential nature and shall be subject to the same obligations as Licensee and its Sublicensee hereunder pursuant to this Clause 8.1.

8.2 Lonza expressly acknowledges and undertakes that any Confidential Information disclosed by the Licensee to Lonza pursuant to this Agreement is disclosed in circumstances imparting an obligation of confidence and Lonza shall keep such Licensee's Confidential Information secure, secret and confidential and undertakes to respect Licensee's proprietary rights therein and to use the same for the sole purpose of this Agreement and not during the period of this Agreement or at any time for any reason whatsoever to disclose and/or cause and/or permit to be disclosed such Licensee's Confidential Information to any Third Party.

8.3 Each Party will restrict the disclosure of the terms of this Agreement to such officers, employees, professional advisers, finance-providers, and consultants of itself and its Affiliates (**"Representatives"**) who have been informed of the confidential nature of the same and who have a need to know such terms. Prior to disclosure to such persons, the Party in receipt of the Confidential Information shall bind its and its Affiliates' Representatives to confidentiality and non-use obligations no less stringent than those set forth herein. The receiving Party shall notify the disclosing Party as promptly as practicable of any unauthorized use or disclosure. To the extent that either Party wishes to disclose any other Confidential Information to any of its Representatives, save as expressly permitted by this Clause 8, this shall be subject to obtaining the prior written consent of the other Party.

8.4 The obligations of confidence referred to in this Clause 8 shall not extend to any information which the receiving Party demonstrates:

8.4.1 is or shall become generally available to the public otherwise than by reason of a breach by the recipient Party of such information of the provisions of this Clause 8;

8.4.2 is known to the recipient Party of such information and is at its free disposal prior to its receipt from the other;

8.4.3 is subsequently disclosed to the recipient Party without obligations of confidence by a Third Party owing no such obligation of confidentiality to the disclosing Party; or

8.4.4 can be demonstrated by competent written evidence as having been independently developed by the recipient of the information in question without access to or use or knowledge of the information of the disclosing Party.

8.5 Notwithstanding the foregoing it is acknowledged between the Parties that Lonza or Licensee may be required to disclose Confidential Information and/or this Agreement to a government agency for the purpose of any statutory, regulatory or similar legislative requirement applicable to Licensee and/or the production of Product, or to a court of law or to meet the requirements of any Stock Exchange to which a Party may be subject. In such circumstances the disclosing Party will inform the other Party prior to disclosure being made as to the nature of the required disclosure, shall only make the disclosure to the extent legally required and shall seek to impose obligations of secrecy and/or confidential treatment wherever possible. Notwithstanding such disclosure such Confidential Information shall otherwise remain subject to this Clause 8.

8.6 Each Party expressly agrees that any breach or threatened breach of the undertakings of confidentiality provided hereunder by a Party may cause irreparable harm to the other Party ("**Non-Breaching Party**") and that money damages may not provide a sufficient remedy to the Non-Breaching Party for any breach or threatened breach. In the event of any breach and/or threatened breach, then in addition to all other remedies available at law or in equity, the Non-Breaching Party shall be entitled to seek injunctive relief and any other relief deemed appropriate by the Non-Breaching Party.

9. Intellectual Property Enforcement

9.1 Lonza hereby undertakes and agrees that at its own discretion and expense it will:

9.1.1 prosecute or procure prosecution of such of the Patent Rights (Lonza) which are patent applications diligently so as to secure the best commercial advantage obtainable, as determined by Lonza in its commercially reasonable discretion, and will pursue, as determined by Lonza in its commercially reasonable discretion, all necessary actions against any Third Party that Lonza reasonably believes is infringing, misappropriating or violating any Lonza Intellectual Property Rights; and

9.1.2 pay or procure payment of all renewal fees in respect of the Patent Rights (Lonza) for the full term thereof and in particular will procure such renewal of the registrations thereof as may be necessary from time to time so far as it is reasonable to do so with particular reference to Lonza's commercial considerations.

9.2 Licensee shall promptly notify Lonza in writing of any infringement or improper or unlawful use of or of any challenge to the validity of the Patent Rights (Lonza) and/or Licensed Know-How. Lonza undertakes and agrees to take all such steps and proceedings and to do all other acts and things as may in Lonza's sole discretion be necessary to restrain any such infringement or improper or unlawful use or to defend such challenge to validity and Licensee shall permit Lonza to have the sole conduct of any such steps and proceedings including the right to settle them whether or not Licensee is a party to them. Licensee shall have the right at its own cost and for its own benefit to initiate, prosecute and control the enforcement of the Patent Rights (Lonza) against infringement by a Third Party in the Territory if all of the following conditions are fulfilled (a) the product manufactured through the infringing activity is a competing product to the Product, (b) Lonza has not granted rights to Third Parties which prevent Lonza from granting such a right to enforce to Licensee, and (c) Lonza does not take steps to enforce its rights within [***] days of being requested to do so by Licensee.

10. Term and Termination

10.1 This Agreement shall commence on the Effective Date and shall continue in full force and effect in each country of the world unless terminated earlier in accordance with the provisions of this Clause 10 or Clause 13.

10.2 Licensee may terminate this Agreement by giving [***] days' notice in writing to Lonza.

10.3 Either Lonza or Licensee may terminate this Agreement forthwith by notice in writing to the other upon the occurrence of any of the following events:

10.3.1 if the other commits a material breach of this Agreement which is irremediable or (in the case of a breach capable of remedy) shall not have been remedied within [***] days of the receipt by the other of a notice identifying the breach and requiring its remedy; or

10.3.2 if the other is unable to pay its debts or enters into compulsory or voluntary liquidation (other than for the purpose of effecting a reconstruction or amalgamation in such manner that the company resulting from such reconstruction or amalgamation if a different legal entity shall agree to be bound by and assume the obligations of the relevant Party under this Agreement) or compounds with or convenes a meeting of its creditors or has a receiver or administrator appointed over all or any part of its assets or takes or suffers any similar action in consequence of a debt, or ceases for any reason to carry on business.

10.4 Without prejudice to any rights that have accrued under this Agreement or any of its rights or remedies, Lonza may terminate this Agreement immediately by giving written notice to Licensee if:

10.4.1 the Licensee contests the secret or substantial nature of the Licensed Know-How.

10.4.2 there is a change of control of Licensee (within the meaning of section 1124 of the Corporation Tax Act 2010) in circumstances where:

(a) [***]; or

(b) [***]; or

(c) [***].

10.5 If this Agreement is terminated for any reason any and all licences and sublicences granted hereunder shall terminate with effect from the date of termination and Licensee shall destroy (or otherwise procure the destruction of) all System Materials, Transfected Cell Lines, GS piggyBac® Materials and Product and all Confidential Information which is provided by Lonza (including all Know-How, all System Know-How, all GS piggyBac® Know-How and all CDACF System Know-How) forthwith and shall certify such destruction immediately thereafter in writing to Lonza; provided, however, that the Licensee and its Sublicensees shall have the right to sell or otherwise dispose of all Product then on hand, subject to the payment of royalties and the other terms of this Agreement.

10.6 Termination for whatever reason of this Agreement shall not affect the accrued rights of the Parties arising in any way out of this Agreement as at the date of termination. The right to recover damages against the other and all provisions which are expressed to survive this Agreement shall remain in full force and effect.

10.7 The terms of Clauses 3, 4.5 to 4.9 (subject always to the consequences of termination in Clause 10.5), 5, 6, 7, 8, 10, 11, 12, 14, 15 and 16 shall survive termination of this Agreement for whatever reason.

11. Assignment

11.1 Subject to Licensee's rights to sublicence in accordance with Clause 4 and subject to Clause 11.2 below, neither Party shall be entitled to assign, transfer, charge or in any way make over the benefit and/or the burden of this Agreement without the prior written consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed).

11.2 Lonza shall be entitled without the prior written consent of Licensee to assign, transfer, charge, sub-contract, deal with or in any other manner make over the benefit and/or burden of this Agreement: (i) to an Affiliate; (ii) to any joint venture company of which Lonza is the beneficial owner of at least fifty percent (50%) of the issued share capital thereof; (iii) to any company with which Lonza may merge; or (iv) to any company to which Lonza may transfer its assets and undertaking.

11.3 Licensee shall be entitled to assign, transfer, deal with or in any other manner make over the benefit and/or burden of this Agreement without the prior written consent of Lonza but on giving written notice: [***].

11.4 This Agreement shall be binding upon the successors and assigns of the Parties and the name of a Party appearing herein shall be deemed to include the names of its successors and assigns provided always that nothing herein shall permit any assignment by either Party except as expressly provided herein.

12. Governing Law and Dispute Resolution

12.1 This Agreement shall be governed by and construed in accordance with the laws of England and Wales.

12.2 Any dispute arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination, shall be referred to and finally resolved by arbitration under the London Court of International Arbitration (LCIA) Rules, which Rules are deemed to be incorporated by reference into this Clause, by a panel of three (3) arbitrators appointed in accordance with the said Rules. The seat, or legal place of arbitration shall be London, England and the arbitration shall be conducted in the English language. The arbitrator's award shall be final and binding.

13. Force Majeure

13.1 Neither Party shall be in breach of this Agreement if there is any total or partial failure of performance by it of its duties and obligations under this Agreement occasioned by any act of God, fire, act of government or state, war, civil commotion, insurrection, embargo, prevention from or hindrance in obtaining any raw materials, energy or other supplies, labour disputes of whatever nature and any other reason beyond the reasonable control of that Party. If that Party is unable to perform its duties and obligations under this Agreement as a direct result of the effect of one of the reasons set out in this Clause 13 such Party shall give written notice to the other of such inability stating the reason in question. The operation of this Agreement shall be suspended during the period (and only during the period) in which the reason continues. Forthwith upon the reason ceasing to exist the Party relying upon it shall give written notice to the other of this fact. If the reason continues for a period of more than [***] days and substantially affects the commercial basis of this Agreement the Party not claiming under this Clause 13 shall have the right to terminate this Agreement by giving [***] days written notice of such termination to the other Party.

14. Illegality

14.1 If any provision or term of this Agreement or any part thereof shall become or be declared illegal, invalid or unenforceable for any reason whatsoever including but without limitation by reason of the provisions of any legislation or other provisions

having the force of law or by reason of any decision of any Court or other body or authority having jurisdiction over the Parties or this Agreement (including the EC Commission or the European Court of Justice, to the extent applicable):

14.1.1 such provision shall, so far as it is illegal, invalid or unenforceable, be given no effect by the Parties and shall be deemed not to be included in this Agreement;

14.1.2 the other provisions of this Agreement shall be binding on the Parties as if such provision was not included therein; and

14.1.3 the Parties agree to negotiate in good faith to amend such provision to the extent possible for incorporation herein in such reasonable manner as most closely achieves the intention of the Parties without rendering such provision invalid or unenforceable.

15. Miscellaneous

15.1 This Agreement embodies and sets forth the entire agreement and understanding of the Parties and supersedes all prior oral and written agreements, representations, misrepresentations (where innocently or negligently made), understandings or arrangements relating to the subject matter of this Agreement ("**Understandings**"). Neither Party shall be entitled to rely on any Understandings which are not expressly set forth in this Agreement.

15.2 This Agreement shall not be amended, modified, varied or supplemented except in writing signed by duly authorised representatives of the Parties.

15.3 No failure or delay on the part of either Party to exercise any right or remedy under this Agreement shall be construed or operated as a waiver thereof nor shall any single or partial exercise of any right or remedy under this Agreement preclude the exercise of any other right or remedy or preclude the further exercise of such right or remedy as the case may be. The rights and remedies provided in this Agreement are cumulative and are not exclusive of any rights or remedies provided by law.

15.4 Except as required by law, the text of any press release or other communication to be published by or in the media whether of a scientific nature or otherwise and concerning the terms of this Agreement (or Lonza's System and/or CDACF System) shall require the prior written approval of both Parties. [***].

15.5 It is agreed and declared that the relationship between the Parties is on a principal-to-principal basis. Nothing contained in this Agreement shall constitute either Party as the legal representative and/or agent of the other Party, nor shall either Party have the right and/or authority to assume, create and/or incur any liability and/or obligation, express and/or implied in the name of or on behalf of the other Party.

15.6 Each of the Parties shall be responsible for its respective legal and other costs incurred in relation to the preparation of this Agreement.

15.7 The Parties do not intend that any term hereof should be enforceable by virtue of the Contracts (Rights of Third Parties) Act 1999, or by any other statute or common-law principle, by any person who is not a party to this Agreement.

15.8 This Agreement may be executed in two (2) counterparts and by each Party on a separate counterpart, each of which when executed and delivered shall constitute an original, but both counterparts shall together constitute but one and the same instrument. Delivery of an executed counterpart of a signature page of this Agreement by electronic imaging means (e.g., "pdf" or "tif") shall be effective as delivery of a manually executed counterpart of this Agreement.

16. Notice

16.1 Any notice or other document to be given under this Agreement shall be in writing and shall be deemed to have been duly given if sent by registered post or by a reputable overnight courier or by email to a Party or delivered in person to a Party at the address set out below for such Party or such other address as the Party may from time to time designate by written notice to the other:

Address of Lonza
Lonza Sales AG, Muenchensteinerstrasse 38 CH-4002, Basel, Switzerland

With a copy to: Lonza Biologics Plc
228 Bath Road, Slough, Berkshire SL1 4DX, UK
E-mail: [***]
For the attention of the Head of Legal Services

Address of Licensee
Context Therapeutics Inc., 2001 Market Street, Suite 3915, Unit 15, Philadelphia, PA 19103 USA Attn: [***], SVP, Operations

With a copy to: Context Therapeutics Inc.
2001 Market Street, Suite 3915, Unit 15
Philadelphia, PA 19103 USA
Email: [***]
For the attention of the Chief Legal Officer

16.2 All such notices and documents shall be in the English language. Any such notice or other document shall be deemed to have been received by the addressee [***] days following the date of dispatch of the notice or other document by post or, where the notice or other document is delivered by hand, at the time of such delivery or if by email simultaneously with the transmission. To prove the giving of a notice or other document it shall be sufficient to show that it was dispatched.

[Signature Page Follows]

AS WITNESS the hands of the duly authorised representatives of the Parties hereto

Signed for and on behalf of /s/ Marc Augustin
LONZA SALES AG
Head Finance Biologics..... TITLE

Signed for and on behalf of /s/ Albert Pereda
LONZA SALES AG
Associate General Counsel..... TITLE

Signed for and on behalf of /s/ Martin Lehr
CONTEXT THERAPEUTICS INC.
CEO..... TITLE

Lonza

APPENDIX 1A

PATENT RIGHTS (LONZA)

[***]

APPENDIX 1B

PATENT RIGHTS (THIRD PARTY)

[***]

APPENDIX 2

CDACF BASE POWDERS

[***]

APPENDIX 3

CDACF SUPPLEMENTS, MEDIA AND FEEDS

[***]

APPENDIX 4

CDACF KNOW-HOW

[***]

APPENDIX 5

VECTORS

[***]

APPENDIX 6

GS piggyBac® Materials

[***]

APPENDIX 7

Pre-Approved Affiliates

[***]

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: November 9, 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: November 9, 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 September 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: November 9, 2022	Martin Lehr Chief Executive Officer (Principal Executive Officer)
	/s/ Jennifer Minai-Azary
Date: November 9, 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."