

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2024

OR

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: 001-41855

Lexeo Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

345 Park Avenue South, Floor 6
New York, NY

(Address of principal executive offices)

85-4012572

(I.R.S. Employer
Identification No.)

10010

(Zip Code)

(212) 547-9879

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock (\$0.0001 par value)	LXEO	The Nasdaq Global Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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

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

The registrant had 33,061,004 shares of common stock outstanding as of August 8, 2024.

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Special Note Regarding Forward Looking Statements

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial position, business strategy, development plans, planned preclinical studies and clinical trials, future results of clinical trials, expected research and development costs, regulatory strategy, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “estimate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions intended to identify statements about the future. Forward-looking statements contained in this Quarterly Report include, without limitation, statements about:

- the timing, progress and results of our preclinical studies and clinical trials of our product candidates, 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 of our planned investigational new drug, or IND, submissions, initiation of planned clinical trials and timing of expected clinical results for LX2006, LX1001, LX2020, if applicable, and our other future product candidates;
- the timing of any submission of filings for regulatory approval of and our ability to obtain and maintain regulatory approvals for LX2006, LX1001, LX2020 and any other product candidates;
- the impact of public health crises (such as COVID-19) and other adverse global economic conditions on our operations and the potential disruption in the operations and business of third-party manufacturers, contract research organizations, or CROs, other service providers, and collaborators with whom we conduct business;
- our ability to identify patients with the diseases treated by our product candidates, and to enroll patients in trials;
- our expectations regarding the size of the patient populations, market acceptance and opportunity for and clinical utility of our product candidates, if approved for commercial use;
- our manufacturing capabilities and strategy, including the scalability and commercial viability of our manufacturing methods and processes;
- our reliance on third party manufacturing partners to comply with significant regulations with respect to manufacturing our products;
- our expectations regarding the scope of any approved indication for LX2006, LX1001, LX2020 or any other product candidate;
- our ability to successfully commercialize our product candidates, if approved;
- our ability to leverage our platform to identify and develop future product candidates;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our need for or ability to obtain additional funding before we can expect to generate any revenue from product sales;
- our ability to establish or maintain collaborations or strategic relationships and any expected benefits related thereto;
- our ability to identify, recruit and retain key personnel;
- our reliance upon intellectual property licensed from third parties and our ability to obtain such licenses on commercially reasonable terms or at all;
- our ability to protect and enforce our intellectual property position for our product candidates, and the scope of such protection;

- our financial performance;
- our competitive position and the development of and projections relating to our competitors or our industry;
- our estimates regarding future revenue, expenses and needs for additional financing;
- the impact of laws and regulations; and
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or JOBS Act.

We caution you that the foregoing list does not contain all of the forward-looking statements made in this Quarterly Report. We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of risks, uncertainties and assumptions described in the section titled “Item 1A. Risk Factors” and elsewhere in this Quarterly Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report, the events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

PART I-FINANCIAL INFORMATION

Item 1. Financial Statements.

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Lexeo Therapeutics, Inc.

Condensed Balance Sheets

(Unaudited, in thousands, except share and per share amounts)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 174,981	\$ 121,466
Prepaid expenses and other current assets	2,168	2,828
Total current assets	177,149	124,294
Restricted cash	3,252	3,252
Property and equipment, net	1,205	1,056
Lease right-of-use assets - finance, net	1,620	1,763
Lease right-of-use assets - operating	8,781	9,442
Total assets	\$ 192,007	\$ 139,807
Liabilities and Stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,765	\$ 3,794
Accrued expenses and other current liabilities	10,442	10,840
Current portion of lease liabilities - finance	572	518
Current portion of lease liabilities - operating	2,098	2,087
Total current liabilities	18,877	17,239
Non-current liabilities		
Non-current portion of lease liabilities - finance	1,043	1,247
Non-current portion of lease liabilities - operating	7,139	7,786
Total liabilities	27,059	26,272
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, \$0.0001 par value, 500,000,000 shares authorized as of June 30, 2024; 33,054,253 shares issued and 33,039,911 shares outstanding as of June 30, 2024; 500,000,000 shares authorized as of December 31, 2023; 26,668,485 shares issued and 26,646,378 shares outstanding as of December 31, 2023	3	3
Treasury stock, at cost, 2,991 common shares at June 30, 2024 and 0 common shares at December 31, 2023	(13)	-
Additional paid-in capital	389,718	295,372
Accumulated deficit	(224,760)	(181,840)
Total stockholders' equity	164,948	113,535
Total liabilities and stockholders' equity	\$ 192,007	\$ 139,807

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

Lexeo Therapeutics, Inc.

Condensed Statements of Operations and Comprehensive Loss

(Unaudited, in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses				
Research and development	\$ 16,560	\$ 11,236	\$ 32,302	\$ 27,674
General and administrative	6,990	2,739	14,539	5,592
Total operating expenses	23,550	13,975	46,841	33,266
Operating loss	(23,550)	(13,975)	(46,841)	(33,266)
Other income and expense				
Other income (expense), net	(1)	(3)	(6)	(7)
Interest expense	(35)	(53)	(72)	(103)
Interest income	2,348	590	3,999	1,277
Total other income and expense	2,312	534	3,921	1,167
Loss from operations before income taxes	(21,238)	(13,441)	(42,920)	(32,099)
Income taxes	-	-	-	-
Net loss and comprehensive loss	\$ (21,238)	\$ (13,441)	\$ (42,920)	\$ (32,099)
Net loss per common share, basic and diluted	\$ (0.64)	\$ (8.30)	\$ (1.41)	\$ (19.87)
Weighted average number of shares outstanding used in computation of net loss per common share, basic and diluted	33,001,946	1,619,547	30,490,892	1,615,194

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

Lexeo Therapeutics, Inc.

Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(Unaudited, in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Treasury Stock	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances at December 31, 2023	-	\$ -	26,646,378	\$ 3	\$ -	\$ 295,372	\$ (181,840)	\$ 113,535
Exercise of stock options	-	-	942	-	-	10	-	10
Amounts reclassified from deposit liabilities upon the vesting of early-exercised stock options previously subject to repurchase, net of proceeds received from early exercise of unvested stock options subject to repurchase and recorded as deposit liabilities	-	-	1,916	-	-	3	-	3
Issuance of common stock upon private placement offering, net of commissions and offering costs of \$6,246	-	-	6,278,905	-	-	88,753	-	88,753
Stock-based compensation expense	-	-	-	-	-	2,331	-	2,331
Net loss	-	-	-	-	-	-	(21,682)	(21,682)
Balances at March 31, 2024	-	\$ -	32,928,141	\$ 3	\$ -	\$ 386,469	\$ (203,522)	\$ 182,950
Exercise of stock options	-	-	108,912	-	-	419	-	419
Amounts reclassified from deposit liabilities upon the vesting of early-exercised stock options previously subject to repurchase	-	-	5,849	-	-	26	-	26
Additional offering costs incurred related to issuance of common stock upon private placement offering	-	-	-	-	-	(42)	-	(42)
Treasury stock repurchase	-	-	(2,991)	-	(13)	-	-	(13)
Stock-based compensation expense	-	-	-	-	-	2,846	-	2,846
Net loss	-	-	-	-	-	-	(21,238)	(21,238)
Balances at June 30, 2024	-	\$ -	33,039,911	\$ 3	\$ (13)	\$ 389,718	\$ (224,760)	\$ 164,948
	Convertible Preferred Stock		Common Stock		Treasury Stock	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances at December 31, 2022	143,653.5	\$ 45	1,607,185	\$ -	\$ -	\$ 2,492	\$ (115,446)	\$ (112,954)
Exercise of stock options	-	-	1,494	-	-	12	-	12
Amounts reclassified from deposit liabilities upon the vesting of early-exercised stock options previously subject to repurchase, net of proceeds received from early exercise of unvested stock options subject to repurchase and recorded as deposit liabilities	-	-	5,325	-	-	21	-	21
Stock-based compensation expense	-	-	-	-	-	397	-	397
Net loss	-	-	-	-	-	-	(18,658)	(18,658)
Balances at March 31, 2023	143,653.5	\$ 45	1,614,004	\$ -	\$ -	\$ 2,922	\$ (134,104)	\$ (131,182)
Exercise of stock options	-	-	2,342	-	-	9	-	9
Amounts reclassified from deposit liabilities upon the vesting of early-exercised stock options previously subject to repurchase	-	-	5,708	-	-	26	-	26
Stock-based compensation expense	-	-	-	-	-	969	-	969
Net loss	-	-	-	-	-	-	(13,441)	(13,441)
Balances at June 30, 2023	143,653.5	\$ 45	1,622,054	\$ -	\$ -	\$ 3,926	\$ (147,545)	\$ (143,619)

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

Lexeo Therapeutics, Inc.

Condensed Statements of Cash Flows

(Unaudited, in thousands)

	Six Months Ended June 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (42,920)	\$ (32,099)
Adjustments to reconcile net loss to net cash used in operating activities:		
Reduction in the carrying amount of ROU assets, operating	661	629
Reduction in the carrying amount of ROU assets, finance	165	148
Stock based compensation expense	5,177	1,366
Depreciation and amortization expense	146	116
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	660	336
Accounts payable	1,698	(864)
Accrued expenses and other current liabilities	19	(587)
Lease liabilities, operating	(636)	(611)
Lease liabilities, finance	11	-
Net cash used in operating activities	(35,019)	(31,566)
Cash flows from investing activities:		
Purchase of internal use software	(13)	-
Purchase of property and equipment	(398)	(39)
Net cash used in investing activities	(411)	(39)
Cash flows from financing activities:		
Proceeds from exercise of stock options	429	21
Payments on finance leases	(183)	(213)
Treasury stock repurchase	(13)	-
Proceeds from issuance of common stock upon private placement offering, net of commissions and offering costs	88,712	-
Net cash provided by (used in) financing activities	88,945	(192)
Net change in cash, cash equivalents and restricted cash	53,515	(31,797)
Cash, cash equivalents and restricted cash at beginning of period	124,718	80,588
Cash, cash equivalents and restricted cash at end of period	\$ 178,233	\$ 48,791
Supplemental disclosure of non-cash activities		
Offering costs included in accounts payable and accrued expenses	\$ 389	\$ 796
Issuance costs related to convertible debt included in accounts payable and accrued expenses	\$ 24	\$ -
(Property and equipment purchased in the prior period and paid in the current period), net of property and equipment purchased in the current period included in accounts payable and accrued expenses	\$ (116)	\$ 54
Finance lease right-of use assets and finance lease liabilities recognized	\$ 22	\$ -
Amounts reclassified from deposit liabilities upon the vesting of early-exercised stock options previously subject to repurchase, net of proceeds received from early exercise of unvested stock options subject to repurchase and recorded as deposit liabilities	\$ 28	\$ 47

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

Lexeo Therapeutics, Inc.

Notes to Condensed Financial Statements

(Unaudited, table amounts in thousands, except share and per share amounts)

1. Description of Business and Basis of Presentation

Description of Business—Lexeo Therapeutics, Inc. (the “Company”) is a clinical stage genetic medicine company with a focus on hereditary and acquired diseases of high unmet need. The Company’s investigational therapies have the potential to offer gene therapy-based treatments to address many diseases that have eluded today’s existing drug delivery platforms. The Company utilizes adeno-associated viruses (“AAV”) that have been engineered to transfer genes to patients. The Company’s therapeutic investigational treatments include gene therapies primarily in the early clinical and late pre-clinical stages of research and development.

The Company is located in New York, NY and was first formed on February 17, 2017, as an LLC under the laws of the State of Delaware under the legal name Lexeo Therapeutics, LLC. The Company filed and executed a certificate of conversion to corporation on November 20, 2020, to convert the LLC to Lexeo Therapeutics, Inc, a Delaware corporation. All of the Company’s tangible assets are held in the United States (“U.S.”).

Basis of Presentation and Principles of Consolidation—The Company’s fiscal year ends on December 31, and its fiscal quarters end on March 31, June 30, and September 30.

These unaudited condensed financial statements and accompanying notes reflect the operations of the Company that have been prepared in conformity with generally accepted accounting principles in the United States of America (“GAAP”) for interim financial information. Accordingly, they do not include all of the information and disclosures required by GAAP for complete financial statements. These unaudited condensed financial statements and accompanying notes should be read in conjunction with the Company’s audited consolidated financial statements and notes thereto for the year ended December 31, 2023 (the “Annual Financial Statements”) included in the Company’s Annual Report on Form 10-K, filed with the United States Securities and Exchange Commission on March 11, 2024. The unaudited condensed balance sheet at December 31, 2023 has been derived from the audited consolidated financial statements at that date. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary to present fairly the financial position of the Company and its results of operations and cash flows for the periods presented have been included. Operating results for the three and six months ended June 30, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024, for any other interim period, or for any other future year.

Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) of the Financial Accounting Standards Board (“FASB”). The Company has no unconsolidated subsidiaries. Certain prior period balances have been reclassified to conform to the current period presentation.

A 10.594230-for-1 reverse share split of the Company’s series A convertible preferred stock, series B convertible preferred stock, common stock, and options to purchase common stock under the Company’s 2021 Equity Incentive Plan (as defined in Note 8), as well as corresponding adjustments in the respective conversion prices of the series A convertible preferred stock and series B convertible preferred stock, was effected on October 13, 2023 as approved by the Company’s board of directors (the “Board of Directors”) and its shareholders (the “Stock Split”). The Stock Split reduced the number of shares of the Company’s authorized, issued and outstanding common stock, as well as the numbers of shares reserved and available for future issuance and underlying outstanding options to purchase common stock under its 2021 Equity Incentive Plan, on a 10.594230-for-1 basis. As such, all references to series A convertible preferred stock and series B convertible preferred stock conversion ratios, conversion share and per share amounts, and post-conversion share and per share amounts, as well as common stock option, option per common share, common share and common per share amounts, in these unaudited condensed financial statements and accompanying notes have been retroactively restated to reflect the Stock Split and the Stock Split’s effect on the respective series A convertible preferred stock and series B convertible preferred stock conversion ratios for each series of convertible preferred stock. The Stock Split did not affect the par values per share.

Need for Additional Capital—Since inception, the Company has incurred net losses and negative cash flows from operations, including net losses of \$42.9 million and \$66.4 million during the six months ended June 30, 2024 and the year ended December 31, 2023, respectively. As of June 30, 2024, the Company had cash and cash equivalents of \$175.0 million and an accumulated deficit of \$224.8 million and expects to incur substantial operating losses and negative cash flows from operations for the foreseeable future. During the years ended December 31, 2021 and December 31, 2020, the Company raised aggregate total net proceeds of \$185.0 million in connection with the issuance of series A and series B convertible preferred stock. During the year ended December 31, 2023 the Company raised \$100.3 million of total net proceeds in connection with the closing of its initial public offering ("IPO") on November 7, 2023 and subsequent partial exercise of the underwriters' option to purchase additional shares, as well \$3.9 million of net proceeds from the issuance of a convertible Simple Agreement for Future Equity ("SAFE") note (the "SAFE Note") in August 2023. During the six months ended June 30, 2024, the Company received total net proceeds of \$88.7 million after deducting underwriting commissions and offering expenses in a private placement offering of its common stock (see Note 7). Management estimates that the Company's current cash and cash equivalents balance is sufficient to fund its operations for at least 12 months from the issuance date of these unaudited condensed financial statements.

If the Company is unable to obtain additional funding before achieving sufficient profitability and positive cash flows from operations, if ever, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue plans to obtain additional funding before achieving sufficient profitability and positive cash flows from operations, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

Risks and Uncertainties—The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, successful discovery and development of its product candidates, development by competitors of new technological innovations, dependence on key personnel, the ability to attract and retain qualified employees, protection of proprietary technology, compliance with governmental regulations, the ability to secure additional capital to fund operations, and commercial success of its product candidates. Any of the Company's current product candidates and future product candidates that it may develop will require extensive nonclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel, infrastructure, and extensive compliance- reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

2. Summary of Significant Accounting Policies

There have been no significant changes in the Company's accounting policies from those disclosed in its Annual Financial Statements.

Use of Estimates—The preparation of the financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of income and expense during the reporting period. The most significant estimates relate to the accruals of research and development costs, including accruals of research contract costs, and assumptions used to estimate the fair value of the Company's stock option awards and, prior to its IPO, to determine the fair value of its common stock. Management evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors, including the current economic environment, and makes adjustments when facts and circumstances dictate. These estimates are based on information available as of the date of the financial statements; therefore, actual results could differ from those estimates.

Net Loss per Share—The Company follows the two-class method when computing net income (loss) per common share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per common share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income (loss) available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. The Company considers its convertible preferred stock to be participating securities as, in the event a dividend is paid on common stock, the holders of these securities would be entitled to receive dividends on a basis consistent with the common stockholders. The Company also considers the shares issued upon the early exercise of stock options that are subject to repurchase to be participating securities because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. There is no allocation required under the two-class method during periods of loss since the participating securities do not have a contractual obligation to share in the losses of the Company.

Basic net income (loss) per common share is computed by dividing the net income (loss) per common share by the weighted-average number of common shares outstanding for the period. Diluted net income (loss) per common share is computed by adjusting net income (loss) to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per common share is computed by dividing the diluted net loss by the weighted-average number of common shares outstanding for the period, including potential dilutive common shares. For the purposes of this calculation, shares of convertible preferred stock are considered potential dilutive common shares.

In periods in which the Company reported a net loss, diluted net loss per common share was the same as basic net loss per common share since dilutive common shares were not assumed to have been issued if their effect was anti-dilutive. During (i) the three and six months ended June 30, 2023, 8,070,027 potential common shares related to the conversion of series A convertible preferred stock and 5,489,573 potential common shares related to the conversion of series B convertible preferred stock, which converted into 8,070,027 common shares and 6,386,337 common shares, respectively, in connection with the Company's IPO on November 7, 2023 (see Note 7), and 1,873,093 potential common shares related to the exercise of outstanding stock options, and (ii) the three and six months ended June 30, 2024, 3,728,009 total potential common shares related to the exercise of outstanding stock options and settlement of outstanding restricted stock units ("RSUs") (see Note 8), were excluded from the computation of diluted net loss per common share because including them would have had an anti-dilutive effect as the Company reported net losses for those periods.

Concentrations of Credit Risk—Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and restricted cash. The Company's cash and restricted cash balances exceed Federal Deposit Insurance Corporation insurance limits, and the Company's cash equivalents consist of investments in a U.S. government money market fund. The Company's cash and cash equivalents and restricted cash is held with large financial institutions that management believes to be of high credit quality. To date, the Company has not recognized any losses caused by uninsured balances.

3. Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The three levels of inputs that may be used to measure fair value are as follows:

Level 1—Inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities.

Level 3—Inputs are unobservable inputs for the asset or liability.

The Company's cash equivalents consist of investments in a U.S. government money market fund stated at carrying value, which approximates fair value and is based on quoted prices in active markets for identical securities. Cash is stated at carrying value, which approximates fair value due to its short-term nature. The carrying values of the Company's prepaid expenses, other current assets, accounts payable and accrued expenses approximate their fair values due to their short-term nature.

The following table presents information about the Company's financial assets measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values:

	As of June 30, 2024:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents (money market)	\$ 156,188	\$ -	\$ -	\$ 156,188
	<u>\$ 156,188</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 156,188</u>
	As of December 31, 2023:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents (money market)	\$ 102,484	\$ -	\$ -	\$ 102,484
	<u>\$ 102,484</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 102,484</u>

4. Property and Equipment

The following is the summary of the Company's property and equipment and related accumulated depreciation and amortization as of June 30, 2024 and December 31, 2023:

	Useful Life	June 30, 2024	December 31, 2023
Internal use software	3 years	\$ 309	\$ 296
Furniture and fixtures	5 years	380	380
Lab equipment	7 years	776	514
Leasehold improvements	7 years	267	247
Total property and equipment		1,732	1,437
Less: accumulated depreciation and amortization		(527)	(381)
Total property and equipment, net		\$ 1,205	\$ 1,056

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	June 30, 2024	December 31, 2023
Accrued research and development expenses	\$ 6,909	\$ 6,384
Accrued bonus expenses	1,900	2,810
Accrued general and administrative expenses and other professional fees	872	1,092
Accrued personnel expenses	541	242
Taxes payable	36	157
Other current liabilities	184	155
Total accrued expenses and other current liabilities	\$ 10,442	\$ 10,840

6. Leases

Operating Lease Right-of-Use Asset

In January 2022, the Company entered into a lease agreement for an office facility and laboratory space in New York, New York that commenced in April 2022 and ends in July 2029 with an additional five-year option to extend the lease beyond July 2029 at the then-prevailing effective market rental rate. Upon commencement of this lease, the Company recorded operating lease right-of-use assets and operating lease liabilities of \$11.6 million based on the present value of payments over the lease term using an estimated incremental borrowing rate of 8.53% in accordance with the provisions of ASC Topic 842, *Leases* ("ASC 842"). In connection with the Company's lease of office space and laboratory space, the Company provided a security deposit to the landlord in the form of a letter of credit totaling \$1.2 million. The cash collateralizing the letter of credit was included in long-term restricted cash in the Company's condensed balance sheets as of June 30, 2024 and December 31, 2023. This lease was classified as an operating lease in accordance with the provisions of ASC 842. The Company did not recognize any right-of-use assets and lease liabilities associated with the potential option to renew or extend. The Company's operating lease agreement does not contain any significant residual value guarantees or restrictive covenants.

The remaining lease terms and payment terms as of June 30, 2024 and December 31, 2023 were 5.1 years and 5.6 years, respectively. The components of this operating lease were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating lease expense	\$ 537	\$ 537	\$ 1,074	\$ 1,074
Variable lease expense	115	125	228	194
Total operating lease expense	\$ 652	\$ 662	\$ 1,302	\$ 1,268
Cash paid for amounts included in the measurement of lease liabilities, included in operating cash flows	\$ 520	\$ 507	\$ 1,050	\$ 1,055

The following table provides a reconciliation of the Company's remaining undiscounted contractual rent obligations due within each year ended December 31 to the operating lease liabilities recognized as of June 30, 2024:

Years ended December 31	Operating Leases
2024	\$ 1,073
2025	2,152
2026	2,206
2027	2,261
2028	2,318
Thereafter	1,372
Total lease payments	11,382
Less: present value adjustment	(2,145)
Total operating lease liabilities	\$ 9,237
Included in the balance sheet:	
Current portion of lease liabilities - operating	2,098
Non-current portion of lease liabilities - operating	7,139
Total operating lease liabilities	\$ 9,237

Equipment Finance Leases

Commencing in April 2022, the Company leases certain laboratory equipment under financing arrangements accounted for as finance leases in accordance with the provision of ASC 842 that are classified in the Company's condensed balance sheet as finance lease liabilities with related right-of-use assets recorded and depreciated on a straight-line basis over the estimated useful life of 7 years. The total gross, accumulated amortization, and net book values of equipment finance lease right-of-use assets capitalized under such finance lease arrangements at June 30, 2024 were \$2.2 million, \$0.6 million and \$1.6 million, respectively. Under the terms of the equipment finance lease agreements executed through the issuance of these unaudited condensed financial statements, the principal balances plus interest for the equipment are to be repaid in full after 60 monthly installments following lease commencement, with lease commencement dates ranging from April 1, 2022 to April 1, 2023, annual imputed interest rates ranging from 7.90% to 9.30%, and monthly installment payment amounts ranging from approximately \$4,000 to \$18,000. As of June 30, 2024, the total aggregate monthly installment payment amount was approximately \$49,000 for equipment finance lease agreements executed through the issuance date of these unaudited condensed financial statements.

The weighted-average remaining lease payment term, weighted-average remaining amortization term, and weighted-average effective interest rate for the Company's equipment finance lease agreements as of June 30, 2024 were 3.2 years, 5.3 years, and 8.58%, respectively. The weighted-average remaining lease payment term, weighted-average remaining amortization term, and weighted-average effective interest rate for the Company's equipment finance lease agreements as of December 31, 2023 were 3.7 years, 5.7 years, and 8.59%, respectively. The components of the equipment finance leases were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Reduction in the carrying amount of ROU assets, finance	\$ 80	\$ 79	\$ 165	\$ 148
Interest on finance lease liabilities	23	43	60	93
Total finance lease expense	\$ 103	\$ 122	\$ 225	\$ 241
Cash paid for amounts included in the measurement of lease liabilities, included in financing cash flows	\$ 74	\$ 103	\$ 183	\$ 213

The following table provides a reconciliation of the Company's remaining equipment finance lease obligations due within each year ending December 31 to the equipment finance lease liabilities recognized at June 30, 2024:

Years ended December 31	Equipment Finance Leases
2024	\$ 293
2025	587
2026	587
2027	359
2028	11
Total lease payments	1,837
Less: imputed interest	(222)
Total finance lease liabilities	\$ 1,615
Included in the balance sheet:	
Current portion of lease liabilities - finance	572
Non-current portion of lease liabilities - finance	1,043
Total finance lease liabilities	\$ 1,615

7. Capital Stock

As of June 30, 2024 and December 31, 2023, the Company's amended and restated certificate of incorporation provided that the authorized capital stock of the Company was 510,000,000 shares consisting of 500,000,000 shares of common stock and 10,000,000 shares of undesignated preferred stock, both with a par value of \$0.0001 per share. As of June 30, 2024 and December 31, 2023, 33,054,253 shares and 26,668,485 shares, respectively, of the Company's common stock authorized were issued, including 14,342 shares and 22,107 shares, respectively, that were legally issued upon the early exercise of unvested stock options and that are excluded from the number of shares outstanding until the right to repurchase subsequently lapses upon vesting. The Company repurchased a total of 2,991 shares of common stock issued pursuant to the early exercise of stock options granted under the 2021 Plan for a total of approximately \$13,000 during the three and six months ended June 30, 2024, which was recorded to treasury stock in the Company's condensed balance sheet (see Note 8). Each common share entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, if any, as may be declared by the Company's Board of Directors. No cash dividends have been declared or paid by the Company.

Upon the declaration of effectiveness of the Company's IPO registration statement on November 2, 2023, the Company's outstanding convertible SAFE Note automatically converted into 411,815 shares of common stock. Upon the closing of the Company's IPO on November 7, 2023, the Company issued and sold 9,090,910 shares of its common stock, and subsequently, the underwriters partially exercised their associated 30-day option to purchase additional shares of common stock with 1,048,746 additional shares issued. The net proceeds to the Company from the IPO and subsequent partial exercise of the underwriters' 30-day option to purchase additional shares were approximately \$100.3 million based on the initial offering price of \$11.00 per share, after deducting underwriting discounts, commissions and offering expenses totaling \$11.3 million. Also upon the closing of the Company's IPO on November 7, 2023, all 85,495,722 then outstanding shares of the Company's series A convertible preferred stock and all 58,157,823 then outstanding shares of the Company's series B convertible preferred stock converted into 8,070,027 shares and 6,386,337 shares of common stock, respectively, including 896,764 shares of common stock issued as a result of series B convertible preferred stock antidilution provisions. On March 11, 2024, the Company entered into a common stock purchase agreement to issue and sell an aggregate of 6,278,905 shares of its common stock at a price of \$15.13 per share, in a private placement that closed on March 13, 2024 (the "Private Placement"). The gross and net proceeds received from the Private Placement were approximately \$95.0 million and \$88.7 million, respectively, after deducting approximately \$6.3 million of commissions and other offering costs.

The Company had reserved the following number of shares of common stock for the exercise of outstanding stock options, settlement of outstanding RSUs, and future issuance of stock-based awards:

	June 30, 2024	December 31, 2023
Options to purchase shares of common stock under the 2021 Plan and 2023 Plan	3,459,309	2,415,740
RSUs subject to settlement in shares of common stock under the 2023 Plan	268,700	-
Shares available for issuance under the 2023 Plan	2,207,329	2,293,816
Shares available for issuance under the 2023 ESPP	505,284	238,600
Total shares of common stock reserved for future issuance	<u>6,440,622</u>	<u>4,948,156</u>

8. Stock-based Compensation

In February 2021, the Company adopted the 2021 Equity Incentive Plan (the “2021 Plan”) for the issuance of stock options to the Company’s key directors, officers, employees and consultants, as a means to secure the benefits arising from capital stock ownership. In connection with the Company’s IPO in November 2023, the Company adopted the 2023 Equity Incentive Plan (the “2023 Plan”) and the 2023 Employee Stock Purchase Plan (the “2023 ESPP”) and collectively with the 2021 Plan and 2023 Plan, the “Plans”). The purposes of the Plans are to promote the alignment of the interests of key directors, officers, employees, and consultants with the success of the Company and to provide compensation opportunities to attract, retain and motivate directors, officers, employees, and consultants of the Company.

The maximum number of shares of common stock that may be issued under the 2023 Plan is 4,737,000 shares, which is approximately the sum of (i) 1,803,980 new shares, plus (ii) the 2021 Plan’s available reserve, plus (iii) the number of returning shares, if any, upon the cancellation or forfeiture of equity awards that are outstanding under the 2021 Plan. In addition, the number of shares of common stock reserved for issuance under the 2023 Plan will automatically increase on January 1 of each year, beginning on January 1, 2024, and continuing through and including January 1, 2033, by 5% of the total number of shares of common stock outstanding on December 31 of the immediately preceding calendar year, or a lesser number of shares determined by the Company’s Board of Directors prior to the applicable January 1. The number of shares of common stock reserved for issuance under the 2023 ESPP will automatically increase on January 1 of each calendar year, beginning on January 1, 2024 and continuing through and including January 1, 2033, by the lesser of (i) 1% of the total number of shares of capital stock outstanding on December 31 of the preceding calendar year, (ii) 477,200 shares and (iii) a number of shares determined by the Company’s Board of Directors. Shares subject to purchase rights granted under the 2023 ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under the 2023 ESPP.

On January 1, 2024, the number of shares of common stock reserved for issuance under the 2023 Plan and the 2023 ESPP automatically increased by 1,333,424 shares and 266,684 shares, respectively, to totals of 3,720,103 shares and 505,284 shares, respectively. As of June 30, 2024, 2,207,329 shares and 505,284 shares were available for future issuance under the 2023 Plan and 2023 ESPP, respectively. No shares have been issued under the 2023 ESPP through June 30, 2024.

Stock option activity

Stock options granted under the 2021 Plan generally (i) are subject to requisite service requirements, (ii) vest over a four-year period with 25% of the options granted vesting after one year and the remainder vesting in equal monthly installments over the following 36 months, and (iii) allow for early exercise subject to repurchase. Stock options granted under the 2021 Plan to certain of the Company’s non-employees vest in equal monthly installments over a four-year period or vested upon the achievement of a certain milestone event. The Company repurchased a total of 2,991 shares of common stock issued pursuant to the early exercise of stock options granted under the 2021 Plan for a total of approximately \$13,000 during the three and six months ended June 30, 2024, which was recorded to treasury stock in the Company’s condensed balance sheet (see Note 7).

Stock options granted under the 2023 Plan generally (i) are subject to requisite service requirements, and (ii) vest over a four-year period with 25% of the options granted vesting after one year and the remainder vesting in equal monthly installments over the following 36 months. Stock options granted under the 2023 Plan to certain of the Company’s non-employees vest in equal annual installments over a three-year period or over a one-year period.

The following table summarizes the stock option activity under the 2021 Plan and the 2023 Plan for the three months ended June 30, 2024 (weighted-average remaining contractual term (in years) is not stated in thousands):

	Number of Shares	Weighted-Average Exercise Price (per share)	Weighted-Average Grant Date Fair Value (per share)	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	2,415,740	\$ 8.32	\$ 5.80	7.83	\$ 13,689
Granted	1,382,330	15.85	11.77		
Exercised	(109,854)	3.91	2.51		1,065
Forfeited	(183,116)	10.40	7.59		
Expired	(45,791)	11.06	2.23		
Outstanding as of June 30, 2024	3,459,309	\$ 11.32	\$ 8.24	8.52	\$ 17,512
Vested options outstanding and exercisable as of June 30, 2024	1,037,611	\$ 6.37	\$ 4.34	7.21	\$ 10,210
Unvested options outstanding and exercisable as of June 30, 2024	980,481	\$ 10.16	\$ 7.36	8.32	\$ 5,976
Unvested options outstanding and unexercisable as of June 30, 2024	1,441,217	\$ 15.68	\$ 11.64	9.61	\$ 1,326

The weighted-average grant date fair value of stock options granted during the six months ended June 30, 2023 was \$13.01 per share. The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The total intrinsic value of stock options exercised during the six months ended June 30, 2023 was \$12.

The total grant date fair values of stock options vested during the three months ended June 30, 2024 and June 30, 2023 were \$0.7 million and \$0.3 million, respectively. The total grant date fair values of stock options vested during the six months ended June 30, 2024 and June 30, 2023 were \$1.6 million and \$0.8 million, respectively.

The Company estimated the fair value of options granted using a Black-Scholes option pricing model with the following assumptions presented on a weighted average basis during the six months ended June 30, 2024 (not stated in thousands):

	Six Months Ended June 30, 2024
Weighted average risk-free interest rate	4.14 %
Expected term (in years)	6.02
Expected volatility	85.83 %
Expected dividend yield	0.00 %

The expected dividend yield is 0.00% as the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

RSU activity

RSUs granted under the 2023 Plan generally (i) are subject to requisite service requirements, and (ii) vest over a four-year period with 25% of the RSUs granted vesting after approximately one year and the remainder vesting in equal quarterly installments over the following nine quarters.

The following table summarizes the RSU activity under the 2023 Plan for the six months ended June 30, 2024:

	Number of Shares	Weighted-Average Grant Date Fair Value (per share)
Unvested as of December 31, 2023	-	\$ -
Granted	276,078	15.55
Vested	-	-
Forfeited	(7,378)	14.68
Unvested as of June 30, 2024	268,700	\$ 15.58

Stock-based compensation expense

Stock-based compensation expense was classified as follows in the Company's unaudited condensed statements of operations and comprehensive loss:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development expense	\$ 1,437	\$ 558	\$ 2,520	\$ 716
General and administrative expense	1,409	411	2,657	650
Total stock-based compensation expense	\$ 2,846	\$ 969	\$ 5,177	\$ 1,366

As of June 30, 2024, there was \$23.7 million of unrecognized stock-based compensation expense related to unvested stock options and RSUs estimated to be recognized over a weighted-average period of 1.49 years.

9. Net Loss per Share

Basic and diluted net loss per common share attributable to common stockholders was calculated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Numerator:				
Net loss attributable to common stockholders	\$ (21,238)	\$ (13,441)	\$ (42,920)	\$ (32,099)
Denominator:				
Weighted-average common shares outstanding, basic and diluted	33,001,946	1,619,547	30,490,892	1,615,194
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.64)	\$ (8.30)	\$ (1.41)	\$ (19.87)

10. Commitments and Contingencies

Leases—As of June 30, 2024, the Company had entered into commitments under lease agreements to rent laboratory and office space and finance equipment (see Note 6).

Commitments—As of June 30, 2024, the Company had entered into commitments under license, acquisition, research collaboration and sponsored research agreements with third parties (see Note 11). In addition, the Company has entered into services agreements with third parties for pharmaceutical manufacturing and research activities in the normal course of business, which can generally be terminated by the Company with 30- to 60-days' written notice, unless otherwise indicated. Further, certain of the Company's manufacturing agreements could require early termination and wind-down payments due from the Company upon either the termination of its clinical trials or if the Company terminates such agreements for convenience.

Contingencies—From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business. The Company recognizes any associated legal fees as incurred and accrues a liability for such contingent liability matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated. For all periods presented, the Company was not a party to any pending material litigation or other material legal proceedings, except that on October 12, 2023, Rocket Pharmaceuticals, Inc. ("Rocket") filed a lawsuit in the U.S. District Court for the Southern District of New York against the Company and two individuals claiming, among other things, misappropriation of confidential information and trade secrets. The individual defendants are a current employee and a former employee of the Company's analytical development team, both of whom were employed at Rocket before joining the Company in 2021. The complaint alleges the individual defendants downloaded confidential Rocket company documents and other proprietary materials prior to leaving Rocket in 2021 and that the Company used this information to advance its programs. The complaint seeks unspecified damages and asks the court to enjoin the Company from competing and working in the market for gene therapy treatments targeting cardiac diseases. The Company retained legal counsel to assist with its ongoing review of the allegations in Rocket's complaint and is confident in its defenses to the allegations. On December 7, 2023, the Company filed a motion to dismiss the complaint, which is now fully briefed and pending before the court. While it is not possible to predict the outcome with certainty and an estimate of the possible loss cannot be made, the Company currently does not expect the final outcome will have a material adverse effect on its timelines for development of its product candidates.

Indemnification Agreements—In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its Board of Directors and executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. For all periods presented, the Company has not incurred any material costs as a result of such indemnifications.

11. License, Acquisition, Research and Collaboration and Sponsored Research Agreements

Adverum Biotechnologies—On January 25, 2021, the Company entered into an exclusive license agreement with Adverum Biotechnologies Inc. (“Adverum”) to in-license materials and technology related to the treatment of cardiomyopathy due to Friedreich ataxia (“FA”) (the “Adverum Agreement”). In connection with the Adverum Agreement, the Company gained access to a portfolio of inventions, patent rights, technology, and licensed methods that the Company continues to develop, and the Company will assume all development and commercialization activities worldwide. Pursuant to the Adverum Agreement, the Company paid a one-time up-front non-refundable fee of \$7.5 million, and is obligated to pay aggregate development and regulatory milestones of up to \$17.5 million including a \$3.5 million development milestone that was achieved and paid in the first quarter of 2023, and aggregate sales event and commercialization milestones of up to \$49.0 million. The Company is obligated to pay Adverum tiered royalties ranging from high single-digits to sub teens based on annual aggregate worldwide net sales of Products (as defined in the Adverum Agreement). As of June 30, 2024, there were no research and development expenses recorded by the Company or payments made to Adverum under the terms of the Adverum Agreement other than the one-time up-front non-refundable fee of \$7.5 million and the \$3.5 million development milestone that was achieved and paid in the first quarter of 2023.

The Adverum Agreement remains in effect until termination at the date of the last royalty term to expire. The Company can terminate the Adverum Agreement with 120 days’ written notice. The Adverum Agreement can also be terminated as a result of a patent challenge, material breach of contractual terms, or insolvency by either party.

Cornell University—On May 27, 2020, the Company entered into two exclusive license agreements with Cornell University (“Cornell”) (the “First Cornell License Agreement” and the “Second Cornell License Agreement,” collectively the “May 2020 Cornell License Agreements”). The First Cornell License Agreement is for the in-license of technology related to portfolios for APOE-associated Alzheimer’s disease and Anti-Tau, although the Company’s license is not restricted by such indications and it includes assignment to the Company of Cornell’s IND for the use of AAVrh10.hAPOE2 vector to treat *APOE4* homozygous patients who are at risk for or have Alzheimer’s disease to support development of the Company’s LX1001 program. The Second Cornell License Agreement is for the in-license of technology related to a portfolio for FA although the Company’s license is not restricted by such indications, and it includes assignment to the Company of Cornell’s IND for the use of AAVrh.10cUhCLN2 to treat children with CLN2 Batten disease to support development of the Company’s LX1004 program. Through the May 2020 Cornell License Agreements, the Company gains access to a portfolio of inventions, patent rights, technology, and licensed methods that the Company continues to develop. Under the terms of the May 2020 Cornell License Agreements, the Company has assumed all development and commercialization activities worldwide with respect to the licensed technology.

As initial consideration for the May 2020 Cornell License Agreements, the Company paid Cornell an upfront payment in cash of \$0.3 million and issued \$1.3 million of notes (“Notes”). In November 2020, Notes with outstanding principal of \$1.3 million were cancelled in exchange for 1,337,610 shares of series A convertible preferred stock. As additional consideration, the Company is required to pay Cornell up to \$8.4 million upon the achievement of specific clinical and regulatory milestones under the First Cornell License Agreement and up to \$4.3 million in two portfolios and up to \$0.6 million for a third portfolio upon the achievement of specific clinical and regulatory milestones under the Second Cornell License Agreement. In the second quarter of 2022, a clinical and regulatory milestone of \$0.1 million was recognized and paid to Cornell in connection with the Second Cornell License Agreement. The Company is also required to pay Cornell a flat royalty in the mid-single-digits based on net sales of the products covered by the licenses, subject to certain adjustments.

Upon expiration of the royalty term of a given licensed product in a country, the respective license becomes non-exclusive and royalty-free. In addition, each of the May 2020 Cornell License Agreements may be terminated by the Company for any reason upon ninety (90) days’ advance notice to Cornell and by Cornell upon the Company’s material uncured breach, and all licenses and rights granted by either party under such agreement will concurrently terminate.

On April 21, 2024, the Company entered into the Third License Agreement (the “Third Cornell License Agreement,” together with the May 2020 Cornell License Agreements, the “Cornell License Agreements”) with Cornell. Pursuant to the Third Cornell License Agreement, Cornell has granted the Company an exclusive license to practice under certain patent rights generated in animal studies conducted by Cornell on behalf of the Company and a non-exclusive license to know-how concerning a gene therapy for FA cardiomyopathy and current and future data generated in an ongoing investigator-initiated Phase 1A trial of AAVrh.10hFXN to treat FA cardiomyopathy. Both licenses are worldwide and cover products with human and non-human prophylactic and therapeutic uses. Cornell has also granted the Company a right of reference to Cornell’s Investigation New Drug application for a gene therapy for FA cardiomyopathy.

Under the Third Cornell License Agreement, the Company paid a license issue fee and an initial data transfer fee to Cornell totaling \$0.6 million. Additionally, the Company will be paying an annual data transfer fee of \$50,000 until data is no longer being gathered. The Company has agreed to pay annual license maintenance fees ranging from \$2,500 to \$25,000 until such time the Company commercializes a licensed product. In addition, the Company will pay Cornell up to an aggregate of \$2.1 million in regulatory milestones and up to an aggregate of \$100 million in commercial milestones, plus low single digit royalties on net sales.

The Third Cornell License Agreement contains other customary license terms including terms related to sublicensing, development, commercialization, milestones, royalties, intellectual property, and termination. Upon expiration of the applicable royalty term for a product in a given country, the Company shall retain a non-exclusive, royalty free license to the data and know-how, including to continue selling such product in that country.

Cornell may terminate the Third Cornell License Agreement if the Company (i) breaches the Third Cornell License Agreement (subject to a cure period), (ii) participates in any proceeding challenging the validity of the licensed patents, (iii) publishes the licensed data without Cornell’s prior written consent, or (iv) does not reach certain milestones. Cornell may also terminate the Third Cornell License Agreement in part on product-by-product basis if the Company does not diligently develop and sale a product. The Company may terminate the Third Cornell License Agreement, in whole or in part with respect to the right of reference, or the licensed data, know-how, or patent rights, with 90 days’ prior written notice to Cornell.

During the three and six months ended June 30, 2023, the Company did not incur or pay any research and development expenses in connection with the Cornell License Agreements. The Company incurred and paid \$0.6 million and \$0.6 million of research and development expenses to Cornell in connection with the Cornell License Agreements during the three and six months ended June 30, 2024, respectively.

Stelios Therapeutics, Inc.—Stelios Therapeutics, Inc. (“Stelios”) was an early-stage company developing novel adeno-associated AAV-based gene therapies for rare cardiac conditions including arrhythmogenic cardiomyopathy and TNNI3-associated hypertrophic cardiomyopathy. On July 16, 2021, the Company acquired 100% of the outstanding stock of Stelios that was accounted for as an asset acquisition pursuant FASB ASC 805, *Business Combinations*. The Company is required to pay up to an aggregate of \$20.5 million to the selling shareholders of Stelios upon the achievement of certain development milestones, including a \$2.0 million development milestone that was achieved and paid in the third quarter of 2022.

Regents of the University of California, San Diego—Stelios entered into exclusive worldwide license agreements on April 23, 2020, and August 6, 2020 (the “First UCSD Agreement” and the “Second UCSD Agreement”, respectively) with the Regents of UCSD to in-license materials and intellectual property related to gene therapies for arrhythmogenic right ventricular cardiomyopathy and hypertrophic cardiomyopathy, respectively. The First UCSD Agreement and the Second UCSD Agreement relate to the Company’s development efforts for its LX2021 and LX2022 programs, respectively. In connection with the First UCSD Agreement and the Second UCSD Agreement, the Company gained access to inventions, patent rights, technology, and licensed methods that it continues to develop, and it has assumed all worldwide development and commercialization activities with respect to the licensed technologies. The First UCSD Agreement and Second UCSD Agreement required Stelios to pay one-time up-front non-refundable cash fees of \$20,000 for each agreement and requires the Company to pay aggregate development and commercialization milestones of up to \$4.8 million and \$2.4 million, respectively, and low- to mid-single digit royalties and low-single digit royalties, respectively, based on aggregate net sales. The only research and development expenses incurred by Stelios or the Company and payments made to the Regents of UCSD through June 30, 2024 under the terms of the First UCSD Agreement and the Second UCSD Agreement were the one-time up-front non-refundable cash fees of \$20,000 for each agreement. The Company has the right to terminate the First UCSD Agreement and the Second UCSD Agreement at any time upon sixty (60)-days’ written notice to the Regents of UCSD.

On October 4, 2021, the Company entered into an exclusive worldwide license agreement (the “Third UCSD Agreement” and collectively with the First UCSD Agreement and the Second UCSD Agreement, the “UCSD Agreements”) with the Regents of UCSD to in-license materials and intellectual property related to LX2020, a gene therapy for arrhythmogenic right ventricular cardiomyopathy. The Third UCSD Agreement relates to the Company’s development efforts for its LX2020 program. In connection with the Third UCSD Agreement, the Company gained access to inventions, patent rights, technology, and licensed methods that it continues to develop, and it has assumed all worldwide development and commercialization activities with respect to the licensed technology. The Third UCSD Agreement required the Company to pay a one-time up-front non-refundable cash fee of \$20,000 and requires the Company to pay aggregate development and commercialization milestones of up to \$4.0 million, and low- to mid-single digit royalties based on aggregate net sales. The only research and development expenses incurred by the Company and payments made to the Regents of UCSD under the terms of the Third UCSD Agreement were the one-time up-front non-refundable cash fee of \$20,000. The Company has the right to terminate the Third UCSD Agreement at any time upon sixty (60)-days’ written notice to the Regents of UCSD.

On December 3, 2021, the Company entered into two sponsored research agreements with the Regents of UCSD (the “First UCSD SRA”, the “Second UCSD SRA”, and collectively, the “UCSD SRAs”) for the Company’s LX2020, LX2021 and LX2022 programs in connection with the UCSD Agreements. Under the terms of the UCSD SRAs, the Company has the first rights to obtain non-exclusive or exclusive, sublicensable, royalty-bearing, perpetual and transferable worldwide licenses in any resulting inventions owned by the Regents of UCSD or resulting inventions jointly owned between the Company and the Regents of UCSD, and the Company retains the rights to any resulting inventions owned by the Company. The UCSD SRAs each have a two-year term and may be terminated early by the Company at any time upon the giving of thirty (30) days’ written notice to the Regents of UCSD. The total costs to be invoiced to the Company over the terms of the UCSD SRAs are \$5.6 million, of which the Company incurred \$0.8 million and \$1.1 million of research and development expenses during the three and six months ended June 30, 2023, respectively. The Company paid \$0 and \$0.2 million to the Regents of UCSD in connection with the UCSD SRAs during the three and six months ended June 30, 2023, respectively. The Company did not incur any research and development expenses in connection with the UCSD SRAs during the three and six months ended June 30, 2024. The Company paid \$0.2 million and \$0.7 million to the Regents of UCSD in connection with the UCSD SRAs during the three and six months ended June 30, 2024, respectively. The Company has paid a cumulative total of \$4.0 million to the Regents of UCSD as of June 30, 2024, in connection with the UCSD SRAs.

On April 13, 2024, the Company entered into a third sponsored research agreement with the Regents of UCSD (the “Third UCSD SRA”) for the Company’s LX2022 program in connection with the Second UCSD Agreement. Under the terms of the Third UCSD SRA, the Company has the first rights to obtain non-exclusive or exclusive, sublicensable, royalty-bearing, perpetual and transferable worldwide licenses in any resulting inventions owned by the Regents of UCSD or resulting inventions jointly owned between the Company and the Regents of UCSD, and the Company retains the rights to any resulting inventions owned by the Company. The Third UCSD SRA has a two-year term and may be terminated early by the Company at any time upon the giving of thirty (30) days’ written notice to the Regents of UCSD. The costs to be invoiced to the Company over the term of the Third UCSD SRA are \$0.7 million, and the Company may incur additional costs of \$0.6 million under the Third UCSD SRA if certain study objectives are met. The Company also entered into an amendment to the Second UCSD SRA for the Company’s LX2022 program that extended the term of the Second UCSD SRA to December 2024. During the three and six months ended June 30, 2024, the Company incurred and paid a total of \$0.3 million to the Regents of UCSD in connection with the Third UCSD SRA.

On April 19, 2024, the Company entered into an amendment to the First UCSD SRA (as amended, the “Amended First UCSD SRA”) for the Company’s LX2021 program in connection with the First UCSD Agreement. The Amended First UCSD SRA extends the term of the First UCSD SRA to December 2026 and provides for additional research and development studies and expenses. The total costs to be invoiced to the Company under the Amended First UCSD SRA are \$0.8 million. During the three and six months ended June 30, 2024, the Company incurred a total of \$0.4 million to the Regents of UCSD in connection with the Amended First UCSD SRA. The Company did not make any payments to the Regents of UCSD in connection with the Amended First UCSD SRA during the three and six months ended June 30, 2024.

Weill Cornell Medical College—On February 2, 2021, the Company entered into a Research Collaboration Agreement with Weill Cornell Medical College (“WCM” and the “WCM Agreement”) in connection with the Cornell License Agreements entered on May 27, 2020. The Company committed to fund scientific research at WCM to investigate further and potentially enhance the technology licensed to the Company pursuant to the License Agreements.

Under the terms of the WCM Agreement, each WCM invention, joint invention, and related joint results for which an Improvement, as defined in the WCM Agreement, applies and the Company has made an election to amend the Cornell License Agreements, the Company has the first option to negotiate in good faith with WCM for royalty-bearing, worldwide license, under Cornell patent rights, Cornell rights, and Cornell's interest in joint patent rights, to develop, make, have made, use, offer for sale, sell, have sold, and import derived products in the field. During the three and six months ended June 30, 2023 the Company incurred \$0.3 million and \$0.9 million, respectively, of research and development costs and paid \$0.3 million and \$1.8 million, respectively, to Cornell in connection with the WCM Agreement. During the three and six months ended June 30, 2024 the Company did not incur or pay any research and development expenses in connection with the WCM Agreement. Cumulatively, the Company has incurred and paid total research and development costs of \$9.9 million to WCM in connection with the WCM Agreement as of June 30, 2024.

The WCM Agreement expired in accordance with its terms in February 2024.

12. Subsequent Events

Subsequent events have been evaluated through August 12, 2024, which is the date that these unaudited condensed financial statements were issued and were available to be issued.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q. As a result of many factors, including those factors set forth in the “Risk Factors” section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Please also see the section titled “Special Note Regarding Forward-Looking Statements.” Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to “we,” “us” and “our” refer to Lexeo Therapeutics, Inc.

We are a clinical stage genetic medicine company dedicated to transforming healthcare by applying pioneering science to fundamentally change how disease is treated. By taking aim at the underlying genetic cause of the devastating diseases we target, we seek to create substantial positive impact and reduce the overwhelming burdens placed on people receiving treatment, their caregivers, and healthcare systems. Our current pipeline consists of candidates targeting patient populations that place significant burden on society and are most amenable to our genetic medicine approach.

Our most advanced cardiovascular product candidate, LX2006 for the treatment of patients with Friedreich ataxia, or FA, cardiomyopathy, is currently being evaluated in SUNRISE-FA, an ongoing Phase 1/2 clinical trial. We have observed an increase in frataxin protein expression in the hearts of three patients that have undergone cardiac biopsies across cohort 1 (n=1) and cohort 2 (n=2). In July 2024, we announced interim clinical data of LX2006 from the ongoing Lexeo-sponsored SUNRISE-FA trial and Cornell investigator-initiated trial, providing baseline characteristics from 11 participants that had been treated and follow-up data from 8 participants that had reached at least 6-months of follow-up, showing (i) that LX2006 has been well-tolerated with no treatment-related serious adverse events to date and (ii) improvements in key cardiac biomarkers including left ventricular mass index, lateral wall thickness, and high-sensitivity troponin I. In light of the evidence of treatment effect with improvements across multiple cardiac measures, we recently initiated formal engagements with the FDA to discuss surrogate endpoints for a future registrational study. LX2006 has received Rare Pediatric Disease designation, Orphan Drug designation, and Fast Track designation from the FDA, and Orphan Medicinal Product designation from the European Commission. Our second most advanced cardiovascular product candidate, LX2020 for the treatment of arrhythmogenic cardiomyopathy, or ACM, caused by mutations in the PKP2 gene, referred to as PKP2-ACM, received investigational new drug, or IND, clearance from the U.S. Food and Drug Administration, or FDA, in July 2023 and is currently being evaluated in HEROIC-PKP2, an ongoing Phase 1/2 clinical trial. LX2020 received Fast Track and Orphan Drug designations from the FDA in December 2023. We expect to provide an interim data readout from cohort 1 in the second half of 2024.

Our lead Alzheimer’s disease product candidate, LX1001, for the treatment of *APOE4* homozygous patients with Alzheimer’s disease, is in an ongoing Phase 1/2 trial. In December 2022, we reported that we observed an increase in expression levels of the protective protein, *APOE2*, in the first dose cohort and a consistent trend towards improvement in core Alzheimer’s disease biomarkers in the first dose cohort. We completed enrollment of the trial in the fourth quarter of 2023 and expect to report additional interim data from all cohorts in the Phase 1/2 clinical trial in the second half of 2024.

We are targeting diseases that have seen limited penetration of precision medicine, which we define as medications that treat the underlying molecular mechanism of a disease, and where we believe there is significant opportunity for gene therapy to play a role as a key therapeutic option. We believe the specific indications we are initially targeting, FA cardiomyopathy, PKP2-ACM and *APOE4*-associated Alzheimer’s disease, are highly amenable to gene therapy, where administration of a single dose has the potential to either restore loss-of-function or minimize gain-of-function mutations by treating the underlying genetic cause of the disease. Although few precision medicines are currently approved for the treatment of cardiovascular conditions or Alzheimer’s disease, recent approvals by the FDA suggest a willingness to approve new precision medicines based on biomarkers and functional endpoints. Together with improved diagnostics and increased testing, these developments may offer one of the most substantial opportunities for the uptake of precision medicines in the global pharmaceutical marketplace.

Each of our gene therapy candidates utilizes the vector construct, dose and route of administration that we believe will result in the most favorable biodistribution and safety profile for our product candidate for each disease. Our most advanced cardiovascular and *APOE4*-associated Alzheimer’s disease programs use the AAVrh10 vector due to its high transduction efficiency in both myocardial cells and neurons, potential for lower toxicity given the opportunity to utilize lower doses compared to other well-established AAV serotypes, and low pre-existing immunity.

By specifically tailoring our technological approach to each targeted disease, we believe we can optimize our programs to achieve the highest likelihood of having therapeutic impact. We target genetically defined indications in specific sub-groups of patients that offer the potential to demonstrate therapeutic impact through improvement in functional endpoints or biomarkers, have high unmet need and large market opportunities, have established proof-of-concept in relevant preclinical models, and have organized patient advocacy groups and identifiable patient populations. In addition to targeting cardiovascular diseases and APOE4-associated Alzheimer's disease that we believe can be addressed by our current approach utilizing AAVrh10, we have ongoing discovery efforts to identify next-generation vector technologies with the best potential therapeutic profile. Finally, we continuously seek to bolster our pipeline through relationships with academic institutions, providing us access to cutting edge genetic medicines research which will include not only AAV gene therapy but also other potential therapeutic payload types and non-viral delivery systems. In August 2023, we announced a strategic investment from Sarepta Therapeutics, Inc. to explore collaboration opportunities within our preclinical cardiovascular pipeline.

To date, we have funded our operations primarily through proceeds from the sale of shares of our convertible preferred stock and common stock, including our Private Placement, IPO and the subsequent partial exercise of the underwriters' 30-day option to purchase additional shares of common stock. As of June 30, 2024, we had \$175.0 million of cash and cash equivalents, and we had raised aggregate net proceeds of \$100.3 million from our IPO and the subsequent partial exercise of the underwriters' 30-day option to purchase additional shares of common stock, as well as totals of \$88.7 million, \$185.0 million and \$3.9 million of net proceeds from the Private Placement, the sales of our convertible equity securities, and a convertible SAFE Note, respectively (see Note 7 to the unaudited consolidated financial statements appearing elsewhere in this Quarterly Report for more information). We have incurred significant operating losses since the commencement of our operations. 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 gene therapy candidates or any future gene therapy candidates. Our net losses for the six months ended June 30, 2024 and the year ended December 31, 2023 were \$42.9 million and \$66.4 million, respectively, and our accumulated deficit was \$224.8 million at June 30, 2024. We expect to continue to incur significant losses for the foreseeable future as we advance our current and future product candidates through preclinical and clinical development, continue to build our operations and transition to operating as a public company.

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 to 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 clinical trials as well as research and development of our FA cardiomyopathy (LX2006), APOE-associated Alzheimer's disease (LX1001), and arrhythmogenic cardiomyopathy caused by mutations in the *PKP2* gene, or PKP2-ACM (LX2020) programs and other product candidates;
- initiate preclinical studies and clinical trials for any additional product candidates that we may pursue in the future;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- invest in capital equipment in order to expand our research and development and manufacturing activities;
- attract, hire and retain additional clinical, scientific, quality control, regulatory, and manufacturing management and administrative personnel;
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development;
- 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;
- expand our operations in the United States and to other geographies;

- incur additional legal, accounting, investor relations and other general and administrative expenses associated with operating as a public company; and
- establish a sales, marketing and distribution infrastructure, either ourselves or in partnership with others, to commercialize any product candidates, if approved, and related additional commercial manufacturing costs.

Components of our results of operations

Revenue

To date, we have not generated any revenue from product sales. If our development efforts for LX2006, LX1001, and LX2020 or any future product candidates, are successful and result in regulatory approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from product sales, royalties or payments from such collaboration or license agreements, or a combination of product sales and payments from such agreements.

Operating expenses

Research and development

Research and development expenses consist of costs incurred for our research activities, including our discovery efforts and the preclinical and clinical development of our programs. These expenses include:

- employee-related expenses, including salaries, benefits, and stock-based compensation expense for employees engaged in research and development functions;
- expenses incurred under agreements with third parties, such as consultants, clinical investigators, contractors and CROs that assist with (i) identification of potential product candidates in discovery platforms and (ii) the preclinical and clinical studies of our product candidates;
- the cost of developing and scaling our manufacturing process and manufacturing product candidates for use in our research, preclinical studies and clinical trials, including under agreements with third parties, such as consultants, contractors and contract manufacturing organizations, or CMOs;
- costs to maintain compliance with FDA and other regulatory requirements;
- laboratory supplies and research materials;
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities;
- payments made under our licensing agreements with third parties, including milestone payments; and
- other expenses incurred as a result of research and development activities.

We expense research and development costs as incurred. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. When third-party service providers' billing terms do not coincide with our period-end, we are required to make estimates of our obligations to those third parties incurred in a given accounting period and record accruals at the end of the period. We base these estimates on our knowledge of the research and development programs, services performed for the period, past history for related activities and the expected duration of the third-party service contract, where applicable. If timelines or contracts are modified based upon changes in the scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis; therefore, actual results could differ from our estimates. Upfront payments under license agreements are expensed upon receipt of the license, and annual maintenance fees under license agreements are expensed in the period in which they are incurred. Milestone payments under license agreements are accrued, with a corresponding expense being recognized, in the period in which the milestone is determined to be probable of achievement and the related amount is reasonably estimable.

Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of external costs, such as fees paid to CROs, CMOs, central laboratories and certain outside consultants in connection with our research and discovery, preclinical development, process development, manufacturing, clinical development, clinical trials, regulatory and quality assurance activities. We do not allocate professional services costs and licensing fees and other similar costs to specific programs because these costs are deployed across multiple programs.

Research and development activities are central to our business model and account for a significant portion of our operating expenses. 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. As a result, we expect our research and development expenses to increase substantially in absolute dollars for the foreseeable future as we further advance LX2006, LX2020, LX1001, and any other future product candidates that we may develop, into and through preclinical studies and clinical trials and pursue regulatory approvals. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of our product candidates due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future research, preclinical studies and clinical trials, regulatory developments and our assessments as to each product candidate's commercial potential. In addition, we cannot forecast whether any of our current or future product candidates will be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. We are also unable to predict when, if ever, we will generate revenue from our product candidates to offset our expenses.

General and administrative

General and administrative expenses consist primarily of personnel expenses, including salaries, benefits and stock-based compensation expense, for personnel in executive, accounting, business development, legal, human resources and administrative functions. General and administrative expenses also include corporate facility costs not otherwise included in research and development expenses, depreciation, and other expenses, which include direct or allocated expenses for rent and maintenance of facilities and insurance, not otherwise included in research and development expenses, as well as professional fees for legal, consulting, investor and public relations, accounting and audit services.

We expect that our general and administrative expenses will increase significantly in the near-to-medium term as we incur additional expenses associated with operating as a public company, including increased expenses for insurance premiums and audit, legal, regulatory, and tax-related services associated with maintaining compliance with the rules and regulations of the Securities and Exchange Commission, or SEC, and standards applicable to companies listed on a national securities exchange, investor relations activities and other administrative and professional services. We also plan to increase our general and administrative headcount to support the continued research and development of our programs and the growth of our business.

Other income (expense)

Other income (expense) includes net foreign exchange gains and (losses).

Interest expense

Interest expense is primarily associated with our finance right of use asset equipment leases.

Interest income

Interest income is primarily related to interest earned from our investment in a U.S. government money market fund, as well as interest earned on interest-bearing demand deposit cash accounts.

Income taxes

Provision for income taxes consists of U.S. federal and state income taxes in which we conduct business. Since our inception, we have not recorded any income tax benefits for the net losses we have incurred in each year or for our research and development tax credits, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss, or NOL, carryforwards and tax credits will not be realized. Accordingly, we have recorded a full valuation allowance against our net deferred tax assets at June 30, 2024, December 31, 2023, June 30, 2023 and December 31, 2022. As of June 30, 2024, December 31, 2023, June 30, 2023 and December 31, 2022, we had no unrecognized tax benefits.

Results of operations

Comparison of the three months ended June 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended June 30, 2024 and 2023 (in thousands):

	Three Months Ended June 30,		
	2024	2023	Change
Operating expenses			
Research and development	\$ 16,560	\$ 11,236	\$ 5,324
General and administrative	6,990	2,739	4,251
Total operating expenses	<u>23,550</u>	<u>13,975</u>	<u>9,575</u>
Operating loss	<u>(23,550)</u>	<u>(13,975)</u>	<u>(9,575)</u>
Other income and expense			
Other income (expense), net	(1)	(3)	2
Interest expense	(35)	(53)	18
Interest income	2,348	590	1,758
Total other income and expense	<u>2,312</u>	<u>534</u>	<u>1,778</u>
Loss from operations before income taxes	<u>(21,238)</u>	<u>(13,441)</u>	<u>(7,797)</u>
Income taxes	-	-	-
Net loss and comprehensive loss	<u>\$ (21,238)</u>	<u>\$ (13,441)</u>	<u>\$ (7,797)</u>

Research and development expenses

The following table summarizes our research and development expenses incurred for the three months ended June 30, 2024 and 2023 (in thousands):

	Three Months Ended June 30,		
	2024	2023	Change
Direct external research and development expenses by program:			
LX2020	\$ 4,582	\$ 2,759	\$ 1,823
LX2006	3,909	888	3,021
LX1001	(782)	2,267	(3,049)
Other programs	1,383	773	610
Total direct external research and development expenses by program	<u>9,092</u>	<u>6,687</u>	<u>2,405</u>
Unallocated research and development expenses:			
Employee and stock-based compensation expenses	5,751	3,264	2,487
Lab-related costs and supplies	278	371	(93)
Professional fees	453	450	3
Other unallocated costs, including facilities	986	464	522
Total unallocated research and development expenses:	<u>7,468</u>	<u>4,549</u>	<u>2,919</u>
Total research and development expenses	<u>\$ 16,560</u>	<u>\$ 11,236</u>	<u>\$ 5,324</u>

The net increase of \$5.3 million in total research and development expenses for the three months ended June 30, 2024 compared to the three months ended June 30, 2023 was primarily due to increases in (i) clinical trial costs of \$2.6 million excluding an adjustment reducing estimated accrued clinical trial expenses by \$2.2 million for our LX1001 program recorded in the second quarter of 2024, (ii) employee compensation and stock-based compensation expenses of \$2.5 million primarily due to increased headcount and equity awards granted since June 30, 2023, (iii) chemistry, manufacturing and controls, or CMC, expenses of \$2.5 million, and (iv) license fees of \$0.6 million related to the Third Cornell License Agreement. These increases were partially offset by an adjustment reducing estimated accrued clinical trial expenses by \$2.2 million for our LX1001 program recorded in the second quarter of 2024 and a decrease in non-clinical and preclinical expenses of \$0.8 million primarily related to our early stage cardiovascular and central nervous system, or CNS, disease programs.

General and administrative expenses

The net increase of \$4.3 million in general and administrative expenses for the three months ended June 30, 2024 compared to the three months ended June 30, 2023 was primarily due to increases in (i) third-party legal fees and associated costs of \$1.8 million, (ii) employee compensation and stock-based compensation expenses of \$1.8 million primarily due to increased headcount and equity awards granted since June 30, 2023, and (iii) third-party audit, accounting, investor relations, public relations and other professional service provider fees, as well as insurance expenses, of \$0.4 million primarily due to our becoming a publicly traded company in November 2023.

Interest income

We recognized interest income of \$2.3 million and \$0.6 million for the three months ended June 30, 2024 and June 30, 2023, respectively, primarily related to interest earned on our investment in a U.S. government money market fund with an increased average invested balance in 2024 primarily due to the net proceeds received from our IPO and the subsequent partial exercise of the underwriters' option to purchase additional shares in November 2023, as well as the net proceeds received from our Private Placement offering in March 2024.

Comparison of the six months ended June 30, 2024 and 2023

The following table summarizes our results of operations for the six months ended June 30, 2024 and 2023 (in thousands):

	2024	Six Months Ended June 30, 2023	Change
Operating expenses			
Research and development	\$ 32,302	\$ 27,674	\$ 4,628
General and administrative	14,539	5,592	8,947
Total operating expenses	46,841	33,266	13,575
Operating loss	(46,841)	(33,266)	(13,575)
Other income and expense			
Other income (expense), net	(6)	(7)	1
Interest expense	(72)	(103)	31
Interest income	3,999	1,277	2,722
Total other income and expense	3,921	1,167	2,754
Loss from operations before income taxes	(42,920)	(32,099)	(10,821)
Income taxes	-	-	-
Net loss and comprehensive loss	\$ (42,920)	\$ (32,099)	\$ (10,821)

Research and development expenses

The following table summarizes our research and development expenses incurred for the six months ended June 30, 2024 and 2023 (in thousands):

	2024	Six Months Ended June 30, 2023	Change
Direct external research and development expenses by program:			
LX2020	\$ 8,688	\$ 6,373	\$ 2,315
LX2006	7,121	5,298	1,823
LX1001	837	4,857	(4,020)
Other programs	1,928	1,771	157
Total direct external research and development expenses by program	18,574	18,299	275
Unallocated research and development expenses:			
Employee and stock-based compensation expenses	10,761	6,072	4,689
Lab-related costs and supplies	631	700	(69)
Professional fees	794	1,001	(207)
Other unallocated costs, including facilities	1,542	1,602	(60)
Total unallocated research and development expenses:	13,728	9,375	4,353
Total research and development expenses	\$ 32,302	\$ 27,674	\$ 4,628

The net increase of \$4.6 million in total research and development expenses for the six months ended June 30, 2024 compared to the six months ended June 30, 2023 was primarily due to increases in (i) employee compensation and stock-based compensation expenses of \$4.7 million primarily due to increased headcount and equity awards granted since June 30, 2023, (ii) CMC expenses of \$4.3 million, (iii) clinical trial costs of \$3.4 million excluding an adjustment reducing estimated accrued clinical trial expenses by \$2.2 million for our LX1001 program recorded in the second quarter of 2024, (iv) license fees of \$0.6 million related to the Third Cornell License Agreement, and (v) quality and program and portfolio management costs of \$0.6 million. These increases were partially offset by (i) a decrease in milestone expense that consisted of a \$3.5 million development milestone achieved and paid to Adverum in 2023, (ii) a decrease in non-clinical and preclinical expenses of \$3.3 million primarily related to our early stage cardiovascular and CNS disease programs, and (iii) an adjustment reducing estimated accrued clinical trial expenses by \$2.2 million for our LX1001 program recorded in the second quarter of 2024.

General and administrative expenses

The net increase of \$8.9 million in general and administrative expenses for the six months ended June 30, 2024 compared to the six months ended June 30, 2023 was primarily due to increases in (i) third-party legal fees and associated costs of \$4.5 million, (ii) employee compensation and stock-based compensation expenses of \$3.0 million primarily due to increased headcount and equity awards granted since June 30, 2023, (iii) third-party audit, accounting, investor relations, public relations and other professional service provider fees, as well as insurance expenses, of \$0.9 million primarily due to our becoming a publicly traded company in November 2023, and (iv) travel expenses of \$0.2 million.

Interest income

We recognized interest income of \$4.0 million and \$1.3 million for the six months ended June 30, 2024 and June 30, 2023, respectively, primarily related to interest earned on our investment in a U.S. government money market fund with an increased average invested balance in 2024 primarily due to the net proceeds received from our IPO and the subsequent partial exercise of the underwriters' option to purchase additional shares in November 2023, as well the net proceeds received from our Private Placement offering in March 2024.

Liquidity and capital resources

Sources of liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. We expect to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of our product candidates. Since our inception through June 30, 2024, we funded our operations primarily with total net proceeds from sales of our common stock, convertible SAFE Note and convertible equity securities of \$377.9 million. As of June 30, 2024 and December 31, 2023, we had cash and cash equivalents of \$175.0 million and \$121.5 million, respectively.

Based on our current operating plans, we expect the net proceeds from the IPO and subsequent partial exercise of the underwriters' option to purchase additional shares in November 2023 and Private Placement offering in March 2024, together with our existing cash and cash equivalents, will be sufficient to fund our planned operating expenses and capital expenditure requirements into 2027. Our total future capital requirements will depend on many factors and is subject to the risks and uncertainties set forth in the section titled “*Risk Factors*.”

Cash flows

The following table summarizes our sources and uses of cash for the six months ended June 30, 2024 and June 30, 2023 (in thousands):

	<u>Six Months Ended June 30,</u>	
	<u>2024</u>	<u>2023</u>
Net cash used in operating activities	\$ (35,019)	\$ (31,566)
Net cash used in investing activities	(411)	(39)
Net cash provided by (used in) financing activities	88,945	(192)
Net increase (decrease) in cash	\$ 53,515	\$ (31,797)

Operating activities

During the six months ended June 30, 2024, net cash used in operating activities consisted primarily of our net loss of \$42.9 million, which was partially offset by \$5.2 million of stock-based compensation expense, \$1.8 million of net cash provided by changes in operating assets and liabilities, and \$1.0 million of depreciation and amortization of operating and finance right-of-use assets.

During the six months ended June 30, 2023, net cash used in operating activities consisted primarily of our net loss of \$32.1 million and \$1.7 million of net cash used by changes in operating assets and liabilities, which were partially offset by \$1.4 million of stock-based compensation expense and \$0.9 million of depreciation and amortization of our right-of-use assets for our operating and finance leases

Investing activities

During the six months ended June 30, 2024, net cash used in investing activities was \$0.4 million and consisted primarily of purchases of lab equipment.

During the six months ended June 30, 2023, net cash used in investing activities of \$39,000 consisted primarily of purchases of lab equipment.

Financing activities

During the six months ended June 30, 2024, net cash provided by financing activities consisted primarily of the net proceeds received from the Private Placement offering of \$88.7 million, as well as \$0.4 million of proceeds received from the exercise of stock options, which were partially offset by \$0.2 million of principal payments made on equipment finance leases.

During the six months ended June 30, 2023, net cash used in financing activities consisted primarily of \$0.2 million of principal payments made on equipment finance leases.

Funding requirements

We expect our expenses and capital requirements to increase significantly in connection with our ongoing activities, particularly as we advance our lead product candidates and other development programs, in addition to the costs associated with operating as a public company. Accordingly, and beyond the net proceeds raised in the IPO and the subsequent partial exercise of the underwriters' option to purchase additional shares of common stock, as well as the Private Placement, we will continue to require substantial additional funding to support our continuing operations.

The timing and amount of our future operating and capital requirements will largely depend on many factors, including:

- the initiation, scope, progress, timing, results and costs of product discovery, preclinical studies and clinical trials for our product candidates or any future candidates we may develop;
- our ability to maintain our relationships with Weill Cornell Medicine, Adverum, UCSD, and any other key licensors or collaborators;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more preclinical studies or clinical trials than those that we currently expect or change their requirements on studies that had previously been agreed to;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we have or may enter into;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under collaboration agreements, if any;
- the costs to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production;
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates; and
- our need to implement additional internal systems and infrastructure.

We may be unable to raise additional funds or enter into potential collaborations, strategic partnerships or marketing, distribution, licensing or other similar agreements or arrangements on favorable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted. If we fail to raise capital or enter into such agreements or arrangements as, and when, needed, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Critical accounting policies and significant judgments and estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses, and the disclosure of our contingent liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

Other than as disclosed in Note 2 to the condensed financial statements included in this Quarterly Report on Form 10-Q, there have been no significant changes to our critical accounting estimates from those described in our audited consolidated financial statements as of and for the year ended December 31, 2023 included in our Annual Report on Form 10-K, filed with the SEC on March 11, 2024.

JOBS Act accounting election

We qualify as an "emerging growth company" pursuant to the provisions of the Jumpstart Our Business Startups Act of 2012. As an emerging growth company, we have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies.

Item 3. Quantitative and qualitative disclosures about market risk

We are a smaller reporting company, as defined by Rule 12b-2 under the Exchange Act and are not required to provide the information under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of our internal control over financial reporting to determine whether any change occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Based on the evaluation of our disclosure controls and procedures at June 30, 2024, our principal executive officer and our principal financial officer concluded that, as of such date, our disclosure controls and procedures 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 Exchange Act Rules 13a-15(f) and 15d-15(f)) during the fiscal quarter ended June 30, 2024 that 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. On October 12, 2023, Rocket filed a lawsuit in the U.S. District Court for the Southern District of New York against Lexeo and two individuals claiming, among other things, misappropriation of confidential information and trade secrets. The individual defendants are a current employee and a former employee of Lexeo's analytical development team, both of whom were employed at Rocket before joining Lexeo in 2021. The complaint alleges the individual defendants downloaded confidential Rocket company documents and other proprietary materials prior to leaving Rocket in 2021 and that Lexeo used this information to advance its programs. The complaint seeks unspecified damages and asks the Court to enjoin Lexeo from competing and working in the market for gene therapy treatments targeting cardiac diseases. We retained legal counsel to assist with our ongoing review of the allegations in Rocket's complaint and are confident in our defenses to the allegations. On December 7, 2023, we filed a motion to dismiss the complaint, which is now fully briefed and pending before the court. While it is not possible to predict the outcome with certainty and an estimate of the possible loss cannot be made, we currently do not expect the final outcome will have a material adverse effect on our timelines for development of our product candidates. Regardless of the final outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, harm to our reputation and other factors.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Quarterly Report, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this Quarterly Report, before deciding to invest in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the price of our common stock could decline, and you could lose part or all of your investment. We cannot provide assurance that any of the events discussed below will not occur.

Risk Factors Summary

Investing in our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties, as fully described below. The principal factors and uncertainties that make investing in our common stock risky include, among others:

- we have incurred significant losses since our inception, and we expect to incur significant net losses for the foreseeable future and may not be able to achieve or sustain revenue or profitability in the future;
- we have a limited operating history, have not completed any clinical trials, and have no products approved for commercial sale;
- if we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy;
- raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates;
- our business is dependent on our ability to advance our current and future product candidates through preclinical studies and clinical trials, obtain marketing approval and ultimately commercialize them. If we are unable to or experience significant delays in doing so, our business will be materially harmed;
- we are developing novel gene therapy product candidates, which makes it difficult to predict the time, cost and potential success of product candidate development;
- because gene therapy is novel and the regulatory landscape that governs any product candidates we may develop is rigorous, complex, uncertain and subject to change, we cannot predict with certainty the geographic areas in which we could obtain regulatory approval or the time and cost of obtaining regulatory approval, if we receive it at all, for any product candidates we may develop;

- preclinical studies and clinical trials are expensive, time-consuming, difficult to design and implement and involve an uncertain outcome. Further, we may encounter substantial delays in completing the development of our product candidates;
- the regulatory approval processes of the FDA, EMA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for our product candidates, our business will be substantially harmed;
- success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials;
- interim “top-line” and preliminary results from our clinical trials that we announce, publish or present from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data;
- our preclinical studies and clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates. We may also identify safety and efficacy concerns after the approval of a product candidate which can result in negative consequences to our business and results of operations;
- some of the diseases we initially seek to treat have low prevalence and it may be difficult to identify and enroll patients with these diseases. If we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented;
- we may seek Orphan Drug designation or Rare Pediatric Disease designation for some of our product candidates and we may be unsuccessful, or may be unable to maintain the benefits associated with Orphan Drug designation, including the potential for market exclusivity, for product candidates for which we obtain Orphan Drug designation;
- Fast Track, Breakthrough Therapy, or Regenerative Medicine Advanced Therapy designation that we may receive from the FDA may not actually lead to a faster development or regulatory review or approval process, and does not assure FDA approval of our product candidates;
- we have received Rare Pediatric Disease designation from the FDA for LX2006 for the treatment of FA and we may seek such designation for future product candidates. However, a marketing application for these product candidates, if approved, may not meet the eligibility criteria for a rare pediatric disease priority review voucher;
- we and our contract manufacturers are subject to significant regulation with respect to manufacturing our products. The third-party manufacturing facilities on which we rely, and any manufacturing facility that we may have in the future, may have limited capacity or fail to meet the applicable stringent regulatory requirements;
- gene therapies are novel, complex and difficult to manufacture. We could experience manufacturing problems that result in delays in the development or commercialization of our product candidates or otherwise harm our business;
- we depend on third-party suppliers for materials used in the manufacture of our product candidates, and the loss of these third-party suppliers or their inability to supply us with adequate materials could harm our business;
- even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success;
- we rely on our collaborations with Cornell and UCSD to conduct research and development for many of our pipeline programs, including conducting preclinical and IND-enabling studies for portions of our near-term future pipeline. Failure or delay of Cornell or UCSD to fulfill all or part of their respective obligations to us under our agreements, a breakdown in collaboration between the parties or a complete or partial loss of either of these relationships could materially harm our business;
- we intend to continue to rely on third parties to conduct a significant portion of our existing clinical trials and potential future clinical trials for product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials;

- if we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market; and
- we are currently subject to a lawsuit claiming, among other things, that we misappropriated the confidential information and trade secrets of Rocket, and which seeks unspecified damages and asks the court to enjoin us from competing and working in the market for gene therapy treatments targeting cardiac diseases. In the future, we may be subject to additional claims that we and our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information or trade secrets of third parties.

Risks related to our financial position and capital needs

We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

Since our inception, we have incurred significant net losses, and we expect to continue to incur significant expenses and operating losses for the foreseeable future. We incurred net losses of \$66.4 million for the year ended December 31, 2023, and \$21.2 million and \$42.9 million for the three and six months ended June 30, 2024, respectively. As of June 30, 2024, we had an accumulated deficit of \$224.8 million. We have primarily financed our operations with approximately \$100.3 million of net proceeds raised in our IPO and the subsequent partial exercise of the underwriters' 30-day option to purchase additional shares of common stock, as well as totals of \$88.7 million, \$185.0 million and \$3.9 million of net proceeds from the Private Placement, sales of our convertible equity securities and a convertible SAFE Note, respectively. We have no products approved for commercialization and have never generated any revenue from product sales.

We are still in the early clinical stages of development of our lead product candidates. We expect to continue to incur significant expenses and operating losses over the next several years. Our operating expenses and net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue to advance the preclinical and clinical development of our product candidates and discovery programs;
- initiate and complete additional clinical trials of our current and future product candidates;
- seek regulatory approval for any product candidates that successfully complete clinical trials;
- continue to develop our gene therapy product candidate pipeline;
- scale up our clinical and regulatory capabilities;
- work with our third party manufacturing partners to produce material in accordance with current good manufacturing practices, or cGMP, for clinical trials or potential commercial sales;
- establish, either alone or with a third party, a commercialization infrastructure and scale up manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio and patent claims;
- hire additional clinical, quality control, regulatory, manufacturing, scientific and administrative personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting and other expenses in operating as a public company.

To date, we have not generated any revenue from the commercialization of our product candidates. To become and remain profitable, we must succeed in developing and eventually commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, obtaining regulatory approval, and manufacturing, marketing and selling any product candidates for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We are only in the preliminary stages of most of these activities and all of our product candidates are in early clinical trials or preclinical development. We may never succeed in these activities and, even if we do, may never generate any revenue or revenue that is significant enough to achieve profitability.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We have a limited operating history and no history of commercializing products, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.

We are a clinical stage genetic medicine company with a limited operating history. We commenced substantive business operations in 2020, and our operations to date have been largely focused on organizing and staffing our company, business planning, raising capital, entering into collaboration and license agreements for conducting preclinical and clinical research and development activities for our product candidates and gene therapy pipeline, and conducting clinical trials for our product candidates through CROs and other third parties. To date, we have not yet demonstrated our ability to successfully complete internally sponsored clinical trials, complete pivotal clinical trials, manufacture a product on a commercial scale or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

We will need substantial additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

We will require substantial future capital in order to complete planned and future clinical development for our lead product candidates, preclinical development for our other product candidates, and potential commercialization of these product candidates, if any are approved. We expect our spending levels to significantly increase in connection with our planned clinical trials of our lead product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant expenses related to product sales, medical affairs, marketing, manufacturing and distribution. We also expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate certain of our clinical trials, our research and development programs or other operations.

As of June 30, 2024, we had cash and cash equivalents of \$175.0 million. Following the \$88.7 million of net proceeds received upon the closing of the Private Placement in March 2024, we believe that our cash and cash equivalents will be sufficient to fund our operating expenses and capital requirements into 2027. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities, acquisitions of additional product candidates, and changes in regulation. Our future capital requirements will depend on many factors, including:

- the costs of and investment in ongoing and future development of our gene therapy product candidates;
- the scope, progress, costs and results of discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the extent to which we develop, in-license or acquire other product candidates and technologies in our product candidate pipeline;
- the costs and timing of process development and manufacturing scale-up activities associated with our product candidates and other programs as we advance them through preclinical and clinical development;
- the number of, and development requirements for, product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;

- our headcount growth and associated costs as we expand our research and development capabilities and establish a commercial infrastructure;
- the costs of establishing and maintaining commercial-scale cGMP manufacturing capabilities, either internally or with third parties;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our ability to establish and maintain additional collaborations on favorable terms, if at all;
- the success of any collaborations that we may establish and our license agreements;
- the outcome of any legal proceedings involving us;
- the achievement of milestones or occurrence of other developments that trigger payments under our collaboration agreement or any additional collaboration agreements we may enter into; and
- the costs of operating as a public company.

We will require additional capital to achieve our business objectives. While the long-term economic impact of either the COVID-19 pandemic or the ongoing geopolitical conflicts in Ukraine and Israel is difficult to assess or predict, each of these events has caused significant disruptions to the global financial markets and contributed to a general global economic slowdown. Furthermore, inflation rates, particularly in the United States, have increased recently to levels not seen in decades. Increased inflation may result in increased operating costs and may affect our operating budgets, specifically with respect to increased labor costs and associated difficulties in recruiting qualified personnel. In addition, the U.S. Federal Reserve has raised, and may further raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten these risks. If the disruptions and slowdown deepen or persist, we may not be able to access additional capital on favorable terms, or at all, which could in the future negatively affect our financial condition and we could be forced to curtail our planned operations and the pursuit of our growth strategy.

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

Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, government or private party grants, debt financings and license and collaboration agreements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making 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 be required to relinquish valuable rights to our technologies, future revenue streams or product candidates, grant licenses on terms that may not be favorable to us or commit to future payment streams. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our 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.

Risks related to the development of our product candidates

Our business is dependent on our ability to advance our current and future product candidates through preclinical studies and clinical trials, obtain marketing approval and ultimately commercialize them. If we are unable to or experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our time and financial resources in the development of our product candidates and technology platforms. Our business is dependent on our ability to successfully complete preclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize LX2006, LX1001, LX2020 and any other product candidates in a timely manner.

Each of our product candidates and programs will require additional preclinical and/or clinical development, regulatory approval and significant marketing efforts, and we will be required to obtain manufacturing supply and expertise and to build a commercial organization or successfully outsource commercialization before we generate any revenue from product sales. We do not have any products that are approved for commercial sale, and we may never be able to develop or commercialize marketable products.

Our ability to generate revenue from our product candidates, which we do not expect to occur for several years, if ever, will depend heavily on the successful development, regulatory approval and eventual commercialization of our product candidates. The success of our lead product candidates, or any other product candidates that we develop or otherwise may acquire will depend on several factors, including:

- timely and successful completion of preclinical studies, including toxicology studies, biodistribution studies and minimally efficacious dose studies in animals, where applicable, under the FDA's good laboratory practices;
- the availability or development of suitable animal disease models for nonclinical studies to enable us to proceed into clinical development or support the submission of a marketing application;
- effective IND applications from the FDA, or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for our product candidates;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- successful enrollment and completion of clinical trials, including under the FDA's current Good Clinical Practices, or cGCPs;
- establishment of our own manufacturing capabilities and/or arrangements with third-party manufacturers for our commercial manufacturing processes for any of our product candidates that receive regulatory approval;
- receipt of timely marketing approvals from applicable regulatory authorities;
- launch of commercial sales of products, if approved, whether alone or in collaboration with others;
- acceptance of the benefits and use of our products, including method of administration, if and when approved, by patients, the medical community and third-party payors, for their approved indications;
- the prevalence and severity of adverse events experienced with any of our product candidates;
- the availability, perceived advantages, cost, safety and efficacy of alternative therapies for any diseases for which we are developing our product candidates;
- our ability to produce our product candidates on a commercial scale;
- attainment and maintenance of patent, trademark and trade secret protection and regulatory exclusivity for our product candidates and otherwise protecting our rights in our intellectual property portfolio;
- maintenance of compliance with regulatory requirements such as cGMPs;
- attainment and maintenance of third-party coverage and adequate reimbursement for our product candidates and patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement; and

- maintenance of a continued acceptable safety, tolerability and efficacy profile of our products following approval.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for any product candidate we develop, we may not be able to continue our operations.

We are developing novel gene therapy product candidates, which makes it difficult to predict the time, cost and potential success of product candidate development.

Our future success depends on the successful development of a novel therapeutic approach. To date, very few products that utilize gene transfer have been approved in the United States or Europe. There have been a limited number of clinical trials using AAVrh10. Although gene therapies have been studied in human clinical trials for over 30 years, only a limited number of AAV-based gene therapy products have been approved by the FDA.

We cannot be certain that our AAVrh10-based gene therapy product candidates will successfully complete clinical trials or that any future product candidates utilizing this or other vector constructs will successfully complete preclinical studies or clinical trials. We may not be successful in developing product candidates that avoid triggering toxicities or other side effects in preclinical studies or clinical trials. Our intravenous and intrathecal routes of administration may cause unforeseen side effects or present other challenges. Any such results could impact our ability to develop a product candidate, including our ability to enroll patients in our clinical trials. As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of our approach to gene therapy, or any similar or competitive programs, will result in the identification, development, and regulatory approval of any product candidate, or that other gene therapy programs will not be considered better or more favorable. There can be no assurance that any development problems we experience in the future related to our current gene therapy product candidates or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience delays and challenges in achieving sustainable, reproducible, and scalable production. Any of these factors may prevent us from completing our preclinical studies or clinical trials or commercializing any product candidates we may develop on a timely or profitable basis, if at all.

Because gene therapy is novel and the regulatory landscape that governs any product candidates we may develop is rigorous, complex, uncertain and subject to change, we cannot predict with certainty the geographic areas in which we could obtain regulatory approval nor the time and cost of obtaining regulatory approval, if we receive it at all, for any product candidates we may develop.

The regulatory requirements that will govern any novel gene therapy product candidates we develop are not entirely clear and are subject to change. The novel nature of our capsids makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in the United States, the European Union or other jurisdictions. Within the broader genetic medicine field, very few gene therapy products have received marketing authorization from the FDA or the European Medicines Agency, or EMA. Even with respect to gene therapies, the regulatory landscape is still developing. Regulatory requirements governing gene therapy products have changed frequently and will likely continue to change in the future, including with respect to those responsible for regulation of existing gene therapy products. For example, in 2016, the FDA established the Office of Tissues and Advanced Therapies, or OTAT, within the Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and to advise the CBER on its review. In September 2022, the FDA announced retitling of OTAT to the Office of Therapeutic Products, or OTP, and elevation of OTP to a “Super Office” to meet its growing cell and gene therapy workload.

Our product candidates will need to meet safety and efficacy standards applicable to any new biologic being pursued for a given disease under the regulatory framework administered by the FDA. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies, including Institutional Review Boards, or IRBs, can impede or delay the initiation of a clinical trial.

The same applies in the European Union. The EMA’s Committee for Advanced Therapies, or CAT, is responsible for assessing the quality, safety and efficacy of advanced-therapy medicinal products. Advanced-therapy medicinal products include gene therapy medicines, somatic-cell therapy medicines and tissue-engineered medicines. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a gene therapy medicinal candidate that is submitted to the EMA. In the European Union, the development and evaluation of a gene therapy product must be considered in the context of the relevant European Union guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for gene therapy products and require that we comply with these new guidelines. This could mean that any gene therapy product candidate we may develop in the future could be required to comply with additional and/or more stringent gene therapy guidelines in the European Union.

Adverse developments in preclinical studies or clinical trials conducted by others in the field of gene therapy and gene regulation products may cause the FDA, the EMA and other regulatory bodies to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing gene regulation technologies, either of which could harm our business. In addition, the clinical trial requirements of the FDA, the EMA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for product candidates such as ours can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates. Further, as we are developing novel potential treatments for diseases in which, in some cases, there is little clinical experience with potential new endpoints and methodologies, there is heightened risk that the FDA, the EMA or other regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. In addition, we may not be able to identify or develop appropriate animal disease models to enable or support planned clinical development. Any natural history studies that we may rely upon in our clinical development may not be accepted by the FDA, EMA or other regulatory authorities. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing gene regulation technology in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays, or other impediments to our research programs or the commercialization of resulting products. Further, approvals by one regulatory agency may not be indicative of what other regulatory agencies may require for approval.

The regulatory review committees and advisory groups described above and any new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment product candidates, or lead to significant post-approval limitations or restrictions. As we advance our research programs and develop future product candidates, we will be required to consult with these regulatory and advisory groups and to comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of any product candidates we identify and develop. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

Preclinical studies and clinical trials are expensive, time-consuming, difficult to design and implement and involve an uncertain outcome. Further, we may encounter substantial delays in completing the development of our product candidates.

All of our product candidates are in preclinical or early clinical development, and the risk of failure is high. The preclinical studies, clinical trials and manufacturing of our product candidates are, and the manufacturing and marketing of our products, if approved, will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we may test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target disease. In particular, because our product candidates are subject to regulation as biologics, we will need to demonstrate that they are sufficiently safe and of sufficient purity and potency for use in their target diseases. Each product candidate must demonstrate an adequate risk-versus-benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive, can take many years to complete and is subject to uncertainty. We cannot guarantee that any clinical trials will be initiated on schedule, conducted as planned or completed on schedule, if at all. To date, we are sponsoring clinical trials of LX1001, LX2006 and LX2020, but we have not successfully completed any clinical trial that we have internally sponsored. Failure can occur at any time during the clinical trial process. Even if our ongoing and future clinical trials are completed as planned, we cannot be certain that their results will support the safety and effectiveness of our product candidates for their targeted diseases or support continued clinical development of such product candidates. Our future clinical trial results may not be successful.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. This is particularly true for clinical trials in rare diseases, where the small patient populations make it difficult or impossible to conduct two traditional, adequate and well-controlled trials, and therefore the FDA or comparable foreign regulatory authorities are often required to exercise flexibility in approving therapies for such diseases. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

We may experience delays in initiating and conducting clinical trials of our lead product candidates and we do not know whether our clinical trials will begin on time, need to be redesigned, recruit and enroll patients on time or be completed on schedule, or at all. Events that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;
- delays in sourcing or qualifying ancillaries required for administration of our clinical drug product (such as vials, stoppers, or tubing);
- delays in developing suitable assays for screening patients for eligibility for trials with respect to certain product candidates;
- delays in reaching agreement with the FDA, EMA or other regulatory authorities as to the design or implementation of our clinical trials;
- failure to obtain regulatory approval to commence a clinical trial;
- failure to reach an agreement on acceptable terms with clinical trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- inability to obtain IRB approval for each clinical trial site;
- inability to recruit suitable patients to participate in a clinical trial in a timely manner;
- failure to have patients complete a clinical trial or return for post-treatment follow-up;
- deviations by clinical trial sites, CROs or other third parties from trial protocol;
- failure to perform our planned clinical trials in accordance with the FDA's cGCP requirements, or applicable regulatory guidelines in other countries;
- inability to address patient-safety concerns that arise during the course of a trial, including occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- failure to initiate a sufficient number of clinical trial sites; or
- delays in manufacturing sufficient quantities of a product candidate for use in clinical trials.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates or significantly increase the cost of such trials, including:

- we may experience changes in regulatory requirements or guidance, or receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or halt development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- we, our investigators or regulators may suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate, and we may not have funds to cover the costs;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- any future collaborators that conduct clinical trials may face any of the above issues and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully initiate or complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for diseases or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings or Risk Evaluation and Mitigation Strategies, or REMS;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA, EMA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

All of our product candidates will require extensive clinical testing before we are prepared to submit a biologics license application, or BLA, or marketing authorization application, or MAA, for regulatory approval. We cannot predict with any certainty if or when we might complete the clinical development for our product candidates and submit a BLA or MAA for regulatory approval of any of our product candidates or whether any such BLA or MAA will be approved. We may also seek feedback from the FDA, EMA or other regulatory authorities on our clinical development program, and the FDA, EMA or such regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development programs.

We cannot predict with any certainty whether or when we might complete a given clinical trial. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be harmed, and our ability to generate revenues from our product candidates may be delayed or lost. In addition, any delays in our clinical trials could increase our costs, slow down the development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The regulatory approval processes of the FDA, EMA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval or other marketing authorizations by the FDA, EMA and comparable foreign authorities is unpredictable, and it typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, and the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that we may never obtain regulatory approval for any product candidates we may seek to develop in the future. Neither we nor any collaborator is permitted to market any of our biologic product candidates in the United States until we receive regulatory approval of a BLA from the FDA, and we cannot market any of our product candidates in the European Union until we receive approval for an MAA from the EMA, or other required regulatory approval in other countries.

Prior to obtaining approval to commercialize any product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe, effective and of sufficient purity for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates meet regulatory standards, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or after approval, or it may object to elements of our clinical development programs, or require changes to our manufacturing approaches.

Of the large number of products in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval and marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval and marketing authorization to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

We have invested a significant portion of our time and financial resources in the development of our product candidates and technology platforms. Our business is dependent on our ability to successfully complete preclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize LX2006, LX2020, LX1001 and our other product candidates in a timely manner.

Even if we eventually complete clinical testing and receive approval of a BLA or foreign marketing application for any of our product candidates, the FDA, EMA or the applicable foreign regulatory agency may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-marketing clinical trials. The FDA, EMA or the applicable foreign regulatory agency also may approve or authorize for marketing a product candidate for a more limited disease or patient population than we originally request, and the FDA, EMA or applicable foreign regulatory agency may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

In addition, the FDA, EMA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained. Recently, the Supreme Court overruled the *Chevron* doctrine, which had given deference to regulatory agencies' statutory interpretations of ambiguous regulations in litigation against federal government agencies, such as the FDA. The overruling of the *Chevron* doctrine may significantly increase the number of challenges brought by companies and other stakeholders against federal agencies such as the FDA and its longstanding decisions and policies, including the FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for drug approvals, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action.

Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical tests and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical or animal studies and early clinical trials does not ensure that later larger-scale efficacy and safety trials will be successful, nor does it predict final results. For example, we may be unable to identify suitable animal disease models for our product candidates, which could delay or frustrate our ability to proceed into clinical trials or obtain marketing approval. In addition, the preclinical studies conducted by Stelios (an entity that we acquired in 2021), and UCSD for our product candidates LX2021 and LX2022 employed an AAV9-based formulation and studies using this vector may not be predictive of future testing we intend to conduct using an AAVrh10-based formulation or other potential capsid serotypes.

Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. Furthermore, our currently ongoing and most future clinical trials involve or will involve a small patient population. Because of the small sample sizes studied in our trials thus far, the results of these trials may not be indicative of results of future clinical trials.

Additionally, some of our ongoing and planned clinical trials utilize, or may utilize, an “open-label” trial design. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results when studied in a controlled environment with a placebo or active control.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

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

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

Our preclinical studies and clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates. We may also identify safety and efficacy concerns after the approval of a product candidate which can result in negative consequences to our business and results of operations.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, effective and of sufficient purity for use in each target disease, and failures can occur at any stage of testing. Preclinical studies and clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target disease. While we have developed our AAVrh10-mediated gene therapy product candidates to leverage the low seropositivity of AAVrh10, any gene therapy product based on viral vectors carries the risks of immunogenicity, elevated liver enzymes and insertional oncogenesis, which is the process whereby the insertion of a functional gene near a gene that is important in cell growth or division results in uncontrolled cell division, which could potentially enhance the risk of malignant transformation. In one of our preclinical studies of LX2006, we observed four cases of hepatocellular carcinoma, or HCC, in wild-type mice at 10 months post-treatment. Although data reported by the FDA Cellular, Tissue, and Gene Therapies Advisory Committee in September 2021 suggests that HCC observed in mice after AAV treatment is unlikely to translate to risks for humans, any future instances of HCC in our clinical trials could result in delays or the abandonment of our trials. Health authorities also ask that sponsors closely monitor the risk of elevated liver enzymes and abnormal liver ultrasound on a routine basis in patients participating in gene therapy clinical trials.

Possible adverse side effects that could occur with treatment with gene therapy products include an immunologic reaction early after administration, which, while not necessarily adverse to the patient's health, could substantially limit the effectiveness of the treatment. For example, in previous third-party clinical trials involving AAV capsids for gene therapy, some subjects experienced the development of a T-cell antibody response, whereby after the vector is within the target cell types, the cellular immune response system triggers the removal of transduced cell types by activated T-cells. If any of our product candidates demonstrate a similar effect, we may decide or be required to perform additional preclinical studies or to halt or delay further clinical development of our product candidates.

In addition to side effects caused by the product candidate, the administration process or related procedures also can cause adverse side effects. Our APOE-associated Alzheimer's disease product candidates are designed to be delivered via intracisternal administration. While the intracisternal method of administration has been available for some years, its use for gene therapies is new and no gene therapy is currently approved for this method of administration. Intracisternal administration may have greater risk and/or be perceived as having greater risk than more common methods of administration, such as intravenous injection. Other gene therapy product candidates in clinical development utilizing intracisternal delivery could also generate data that could adversely affect the clinical, regulatory or commercial perception of our product candidates.

If adverse events occur, either as a result of the product candidate or administration process, our clinical trials could be suspended or terminated. If we cannot demonstrate that any adverse events were not caused by the drug or administration process or related procedures, the FDA, EMA or foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted diseases. Even if we are able to demonstrate that serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly. Furthermore, negative results in our development of LX2006, LX1001, or LX2020 could be interpreted as a failure to achieve proof of concept for our technology and result in the abandonment of other development programs.

In addition, gene therapy is still a relatively new approach to disease treatment and additional adverse side effects could develop. There also is the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biologic activity of the genetic material or other components of products used to carry the genetic material. If our product candidates are associated with side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The FDA or an IRB may also require that we suspend, discontinue, or limit our clinical trials based on safety information, or that we conduct additional animal or human studies regarding the safety and efficacy of our product candidates which we have not planned or anticipated. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates or limiting the scope of the approved indication, if approved. Many product candidates that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the product candidate.

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

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the labels;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or other requirements subject to a REMS;
- we could be sued and held liable for harm caused to patients;
- we may not be able to obtain or maintain third-party payor coverage and adequate reimbursement; and
- our reputation and physician or patient acceptance of our products may suffer.

There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or foreign regulatory agency in a timely manner or at all. Moreover, any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Some of the diseases we initially seek to treat have low prevalence and it may be difficult to identify and enroll patients with these diseases. If we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population and competition for patients with other trials. The rare genetic diseases which some of our product candidates are designed to target have low incidence and prevalence and may be difficult to diagnose. In particular, because we are focused on patients with specific genetic mutations, our ability to enroll eligible patients may be limited or enrollment may be slower than we anticipate. For example, we estimate that approximately 6,600 people in the United States have FA and that approximately 80% of these patients will develop the cardiac manifestation of FA, or FA cardiomyopathy, and accordingly it may be difficult for us to identify and timely recruit a sufficient number of eligible patients to conduct our clinical trials. While the patient population for LX2020, our program targeting PKP2-ACM, is significantly larger than FA, we may face challenges in identifying and recruiting eligible patients to conduct our clinical trial given competing clinical trials. Even for more prevalent conditions such as Alzheimer's disease, it may be difficult to recruit patients to clinical trials due to the number of approved products, difficulty identifying patients with the specific genotype we are studying, and the number of clinical trials being conducted in this indication.

Our trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, EMA or other foreign regulatory authorities. We cannot predict how successful we will be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the trial in question;
- the size of the patient population and process for identifying patients;
- the perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the diseases we are investigating;
- the availability of competing commercially available therapies and other competing therapeutic product candidates' clinical trials;

- the efforts to facilitate timely enrollment in clinical trials;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion of their treatment;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we rely on CROs and clinical trial sites to help ensure the proper and timely conduct of our clinical trials and we may have limited influence over their performance. For additional information, see the risk factor in this section under the heading “*We intend to continue to rely on third parties to conduct a significant portion of our existing clinical trials and potential future clinical trials for product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.*”

Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

We may seek Orphan Drug designation or Rare Pediatric Disease designation for some of our product candidates and we may be unsuccessful, or may be unable to maintain the benefits associated with Orphan Drug designation, including the potential for market exclusivity, for product candidates for which we obtain Orphan Drug designation.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs or biologics intended to treat relatively small patient populations as orphan drug products. Under the Orphan Drug Act, the FDA may designate a drug or biologic as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population of 200,000 or more in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States.

In the United States, Orphan Drug designation entitles a party to potential financial incentives such as tax advantages and user fee waivers. Opportunities for grant funding toward clinical trial costs may also be available for clinical trials of drugs or biologics for rare diseases, regardless of whether the drugs or biologics are designated for the orphan use. In addition, if a drug or biologic with an Orphan Drug designation subsequently receives the first marketing approval for the disease for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug and disease for that time period, except in limited circumstances. If our competitors are able to obtain orphan drug exclusivity prior to us, for products that constitute the “same drug” and treat the same diseases as our product candidates, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

Similarly, in the European Union, the European Commission, upon the recommendation of the EMA’s Committee for Orphan Medicinal Products, grants Orphan Drug designation to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions and either the prevalence of the condition is not more than 5 in 10,000 persons in the European Union, or, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug. In each case, there must be no satisfactory method of diagnosis, prevention or treatment of the condition that has been authorized, or, if such a method exists, the product in question must be of significant benefit to those affected by such condition. In the European Union, Orphan Drug designation entitles a party to financial incentives such as reduction of fees or fee waivers.

We have obtained from the FDA Orphan Drug designation for LX2006 for the treatment of FA cardiomyopathy and for LX2020 for the treatment of PKP2-ACM. LX2006 has also received Orphan Medicinal Product designation from the European Commission. We may seek orphan designation for some or all of our product candidates in orphan indications in which there is a medically plausible basis for the use of these product candidates. However, we may be unsuccessful in obtaining Orphan Drug designation and may be unable to maintain the benefits associated with such designations. Even if we obtain orphan drug exclusivity for any of our product candidates, that exclusivity may not effectively protect those product candidates from competition because different drugs can be approved for the same condition, and orphan drug exclusivity does not prevent the FDA from approving the same or a different drug in another indication. Even after an orphan drug is granted orphan exclusivity and approved, the FDA can subsequently approve a later application for the same drug for the same condition before the expiration of the seven-year exclusivity period if the FDA concludes that the later drug is clinically superior in that it is shown to be safer in a substantial portion of the target populations, more effective or makes a major contribution to patient care. On August 3, 2017, Congress passed the FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified the FDA's preexisting regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The statute supplants prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. Moreover, in the Consolidated Appropriations Act of 2021, Congress clarified that the interpretation of orphan drug exclusivity codified in FDARA would apply in cases where the FDA issued an orphan designation before the enactment of FDARA but where product approval came after the enactment of FDARA. In addition, a designated Orphan Drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the disease for which it received orphan designation. In *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the court disagreed with the FDA's longstanding position that orphan drug exclusivity only applies to the approved use or indication within an eligible disease. This decision created uncertainty in the application of orphan drug exclusivity. In January 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. The FDA may further reevaluate its regulations and policies under the Orphan Drug Act. We do not know if, when, or how the FDA, Congress or future judicial challenges may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. Moreover, orphan drug-exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan Drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Fast Track, Breakthrough Therapy, or Regenerative Medicine Advanced Therapy designation that we may receive from the FDA may not actually lead to a faster development or regulatory review or approval process, and does not assure FDA approval of our product candidates.

We may seek Fast Track, Breakthrough Therapy or Regenerative Medicine Advanced Therapy, or RMAT, designation from the FDA for some or all of our product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with such designations. The FDA's Fast Track, Breakthrough Therapy, and RMAT designation programs are intended to expedite the development of certain qualifying product candidates intended for the treatment of serious diseases and conditions. If a product candidate is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the product's potential to address an unmet medical need for this condition, the sponsor may apply for FDA Fast Track designation.

A product candidate may be designated as a breakthrough therapy if it is intended, alone or in combination with one or more other drugs or biologics to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs and biologics designated as breakthrough therapies by the FDA may also be eligible for accelerated approval.

A product candidate may receive RMAT designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate has the potential to address an unmet medical need for such condition. RMAT designation allows companies developing regenerative medicine therapies to work more closely and frequently with the FDA, and RMAT-designated product candidates may be eligible for priority review and accelerated approval. FDA has confirmed that gene therapies, including genetically modified cells, that lead to a sustained effect on cells or tissues may meet the definition of a regenerative medicine therapy. For product candidates that have received an RMAT designation, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

We have received Fast Track designation for LX1001 for the treatment of patients with early Alzheimer’s disease who are *APOE4* homozygous, to slow disease progression, for LX2006 for the treatment of FA cardiomyopathy, and for LX2020 for the treatment of PKP2-ACM. While we may seek Fast Track, Breakthrough Therapy and/or RMAT designation for some or all of our product candidates, there is no guarantee that we will be successful in obtaining any such designation. Even if we do obtain such designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A Fast Track, Breakthrough Therapy, or RMAT designation does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular time frame. In addition, the FDA may withdraw Fast Track, Breakthrough Therapy, or RMAT designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track, Breakthrough Therapy and/or RMAT designation alone does not guarantee qualification for the FDA’s priority review procedures.

We have received Rare Pediatric Disease designation from the FDA for LX2006 for the treatment of FA and we may seek such designation for future product candidates. However, a marketing application for these product candidates, if approved, may not meet the eligibility criteria for a rare pediatric disease priority review voucher.

We have received Rare Pediatric Disease designation from the FDA for LX2006 for the treatment of FA and LX1004 for the treatment of CLN2 disease and we may seek Rare Pediatric Disease designation for future product candidates. The FDA defines “rare pediatric disease” as a (i) serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and (ii) a rare disease or condition within the meaning of the Orphan Drug Act. Designation of a product candidate as a product for a rare pediatric disease does not guarantee that a marketing application for such product candidate will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Under the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA, we will need to request a rare pediatric disease priority review voucher in our original marketing application for our product candidates for which we have received Rare Pediatric Disease designation. The FDA may determine that a marketing application for any such product candidates, if approved, does not meet the eligibility criteria for a priority review voucher, including for the following reasons:

- the rare pediatric disease that received such designation no longer meets the definition of a “rare pediatric disease”;
- the marketing application contains an active ingredient (including any ester or salt of the active ingredient) that has been previously approved in a marketing application;
- the marketing application is not deemed eligible for priority review;
- the marketing application does not rely on clinical data derived from studies examining a pediatric population and dosages of the product intended for that population (that is, if the marketing application does not contain sufficient clinical data to allow for adequate labeling for use by the full range of affected pediatric patients); or
- the marketing application is approved for a different adult indication than the rare pediatric disease for which our product candidates are designated.

Under the current statutory sunset provisions, after September 30, 2024, the FDA may only award a priority review voucher for an approved rare pediatric disease product application if the sponsor has Rare Pediatric Disease designation for the drug or biologic that is the subject of such application, and that designation was granted by September 30, 2024. After September 30, 2026, the FDA may not award any rare pediatric disease priority review vouchers. However, it is possible the authority for FDA to award rare pediatric disease priority review vouchers will be further extended by Congress. As such, if we do not obtain approval of a marketing application for LX2006 in patients with FA on or before September 30, 2026, and if the priority review voucher program is not extended by Congressional action, we may not receive a priority review voucher.

Where appropriate, we may seek approval from the FDA, EMA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, EMA or comparable regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA, EMA or such other regulatory authorities may seek to withdraw accelerated approval.

Where possible, we may pursue accelerated development strategies in areas of high medical need. We may seek an accelerated approval pathway for one or more of our therapeutic product candidates from the FDA, EMA or comparable foreign regulatory authorities. Under the accelerated approval provisions in the FDCA and the FDA's implementing regulations, the FDA may grant accelerated approval to a therapeutic candidate that is designed to treat a serious or life-threatening condition, generally provides a meaningful therapeutic benefit over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as IMM. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on IMM that is reasonably likely to predict an effect on IMM or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new product over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. If such post-approval studies fail to confirm the product's clinical benefit, the FDA may withdraw its approval of the product. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product.

Prior to seeking accelerated approval, we would seek feedback from the FDA, EMA or comparable foreign regulatory authorities and would otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA, EMA or comparable foreign regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval, there can be no assurance that such application will be accepted or that any approval will be granted on a timely basis, or at all. The FDA, EMA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type, including, for example, if other products are approved via the accelerated pathway and subsequently converted by FDA to full approval. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our therapeutic candidate would result in a longer time period to commercialization of such therapeutic candidate, could increase the cost of development of such therapeutic candidate and could harm our competitive position in the marketplace.

Priority review designation by the FDA may not lead to a faster regulatory review or approval process and, in any event, does not assure FDA approval of our product candidates.

If the FDA determines that a product candidate is intended to treat a serious disease or condition and, if approved, would provide a significant improvement in the safety or effectiveness of the treatment, prevention, or diagnosis of such disease or condition, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review a marketing application is six months from filing of the application, rather than the standard review period of ten months. We may request priority review for certain of our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may disagree and decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or thereafter.

We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and management resources, we must focus on development programs and product candidates that we identify for specific diseases. As such, currently we are primarily focused on the development of our current pipeline of product candidates. As a result, we may forego or delay pursuit of opportunities with other product candidates. For example, we are evaluating strategic alternatives to find the appropriate partner to advance our LX1004 program. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific diseases may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We may not be successful in our efforts to build a pipeline of additional product candidates.

Our business model is centered on developing product candidates targeting patient populations that place significant burden on society and are most amenable to our genetic medicine approach. We are targeting diseases that have seen limited penetration of precision medicine and where we believe there is significant opportunity for gene therapy to play a role as a key therapeutic option. We aim to select, develop and advance product candidates that we believe will have a high probability of technical and regulatory success through development into commercialization. We may not be able to continue to identify and develop new product candidates. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development. For example, they may be shown to have side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our approach, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

If we are unable to successfully validate, develop and obtain regulatory approval for companion diagnostic tests for our product candidates that require or would commercially benefit from such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these product candidates.

In connection with the clinical development of our product candidates for certain indications, we intend to work with collaborators to develop or obtain access to *in vitro* companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from our product candidates. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. The FDA and comparable foreign regulatory authorities regulate *in vitro* companion diagnostics as medical devices and, under that regulatory framework, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of any diagnostics we may develop, which we expect will require separate regulatory clearance or approval prior to commercialization. The FDA generally will require approval or clearance of the diagnostic at the same time that the FDA approves the therapeutic product if the FDA determines that safe and effective use of a therapeutic product depends on an *in vitro* companion diagnostic. The clearance or approval of a companion diagnostic as part of the product label will also limit the use of the product candidate to patients who have met the screening criteria tested for by the companion diagnostic.

We intend to rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our therapeutic candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for these product candidates, or experience delays in doing so, the development of these product candidates may be adversely affected, these product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these product candidates that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

Risks related to the manufacturing of our product candidates

We and our contract manufacturers are subject to significant regulation with respect to manufacturing our products. The third-party manufacturing facilities on which we rely, and any manufacturing facility that we may have in the future, may have limited capacity or fail to meet the applicable stringent regulatory requirements.

We currently have relationships with a limited number of suppliers for the manufacturing of all components of our product candidates. However, if we experience slowdowns or problems with our manufacturing partners and are unable to establish or scale our internal manufacturing capabilities, we will need to continue to contract with manufacturers that can produce the preclinical, clinical and commercial supply of our products. Each supplier may require licenses to manufacture such components if such processes are not owned by the supplier or in the public domain and we may be unable to license such intellectual property rights on reasonable commercial terms or to transfer or sublicense the intellectual property rights we may have with respect to such activities.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for components of our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials in the United States and European Union must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including recordkeeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA or an MAA on a timely basis. Our potential manufacturing facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted, and they could put a hold on one or more of our clinical trials if the facilities of our CMOs do not pass such audit or inspections. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, inspect or audit our manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could harm our business.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be harmed. Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. An alternative manufacturer would need to be qualified through a BLA and/or an MAA supplement which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully, if approved. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed, or we could lose potential revenue.

Gene therapies are novel, complex and difficult to manufacture. We could experience manufacturing problems that result in delays in the development or commercialization of our product candidates or otherwise harm our business.

The manufacture of gene therapy products is technically complex and necessitates substantial expertise and capital investment. Production difficulties caused by unforeseen events may delay the availability of material for our clinical studies.

We rely on third-party manufacturers to manufacture our product candidates for preclinical studies and clinical trials. The manufacturers of pharmaceutical products must comply with strictly enforced cGMP requirements, state and federal regulations, as well as foreign requirements when applicable. Any failure of us or our CMOs to adhere to or document compliance to such regulatory requirements could lead to a delay or interruption in the availability of our product candidate materials for clinical trials or enforcement action from the FDA, EMA or foreign regulatory authorities. If we or our manufacturers fail to comply with the requirements of the FDA, EMA or other regulatory authority, sanctions could be imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

There can be no assurances that our third-party manufacturers will be able to meet our timetable and requirements. If any third party with whom we contract fails to perform its obligations, we may be forced to either manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different third-party manufacturer, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials and future commercial supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original third-party manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidates according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates or commercialize our products, if approved, in a timely manner or within budget.

If we are unable to arrange for alternative third-party manufacturing sources on commercially reasonable terms or in a timely manner, we may be delayed in the development of our product candidates. Our dependence upon others for the manufacture of our product candidates may also adversely affect our future profit margins and our ability to commercialize any product candidates that receive regulatory approval on a timely and competitive basis.

Our product candidates require processing steps that are more complex than those required for most chemical pharmaceuticals. Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic such as our modified virus generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Although we believe that the manufacture of our product candidates may be simplified due to their shared raw materials and other similarities, we cannot be certain that this will be the case and we may be required to develop manufacturing methods that ultimately differ significantly between product candidates, which would require that we invest substantial time and capital to develop suitable manufacturing methods. Our program materials are manufactured using technically complex processes requiring specialized equipment and facilities, highly specific raw materials, cell types and reagents, and other production constraints. Our production process also requires a number of highly specific raw materials, cell types and reagents with limited suppliers. Even though we aim to have backup supplies of raw materials, cell types and reagents whenever possible, we cannot be certain they will be sufficient if our primary sources are unavailable. A shortage of a critical raw material, cell line, or reagent, or a technical issue during manufacturing may lead to delays in clinical development or commercialization plans. We are particularly susceptible to any shortages, delays or our inability to obtain suitable raw materials for our lead product candidates. Any changes in the manufacturing of components of the raw materials we use could result in unanticipated or unfavorable effects in our manufacturing processes, resulting in delays.

In addition, if any of our product candidates obtain approval, the FDA, EMA and other regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, EMA or other regulatory authorities may require that we not distribute a lot until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

We depend on third-party suppliers for materials used in the manufacture of our product candidates, and the loss of these third-party suppliers or their inability to supply us with adequate materials could harm our business.

We rely on third-party suppliers for the materials and components required for the production of our product candidates. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of materials involve several risks, including limited control over pricing, availability, and delivery schedules. There is substantial demand and limited supply for certain of the raw materials used to manufacture gene therapy products. As a small company, our negotiation leverage is limited, and we may get lower priority than our competitors that are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials within the timelines that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole-sourced raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

Any contamination or interruption in our manufacturing process, shortages of raw materials or failure of our suppliers of viruses to deliver necessary components could result in delays in our clinical development or marketing schedules.

Given the nature of gene therapy manufacturing, there is a risk of contamination occurring during the manufacturing process. Any contamination could adversely affect our ability to produce product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage. Some of the raw materials required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could adversely affect our development timelines and our business, financial condition, results of operations and prospects.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and product characteristics. Such changes carry the risk that they will not achieve our intended objectives. Any such changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay the initiation and completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue. In addition, we may be required to make significant changes to our upstream and downstream processes across our pipeline, which could delay the development of our future product candidates. Regulatory agencies, and in particular the FDA and EMA, have demonstrated increased caution in their regulation of gene therapies, including increased scrutiny related to CMC issues. This increased regulatory scrutiny around gene therapy CMC may result in us being required to conduct additional preclinical studies or clinical trials with respect to any of our product candidates, which may result in delays and increased costs in the development or commercialization of our product candidates and ultimately could lead to the failure to obtain approval for any gene therapy product.

Risks related to the commercialization of our product candidates

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- their efficacy, safety and potential advantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- their convenience and ease of administration compared to alternative treatments;

- product labeling or product insert requirements of the FDA or foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any boxed warning or REMS;
- the willingness of the target patient population to try new treatments, such as gene therapy as a novel modality for treatment of our target indications and of physicians to prescribe these treatments;
- our ability to hire and retain a sales force in the United States;
- the strength of marketing and distribution support;
- the availability of coverage and adequate reimbursement for our product candidates, once approved, from third-party payors and government authorities;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

Negative public opinion of gene therapy and increased regulatory scrutiny of gene therapy and genetic research may adversely impact the development or commercial success of our current and future product candidates.

Our product candidates involve introducing genetic material into a patient's cells via intrathecal and intravenous administration. The clinical and commercial success of our potential products will depend in part on public acceptance of the use of gene therapy and gene regulation for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy and gene regulation are unsafe, unethical or immoral, and consequently, our products may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products once approved. In recent years, sponsors of other clinical trials involving gene therapies have announced imposition of clinical holds by the FDA to evaluate safety issues arising during the trials. Among the risks in any gene therapy product based on viral vectors are the risks of immunogenicity, elevated liver enzymes and insertional oncogenesis. If any of our vectors demonstrate a similar effect, we may decide or be required to halt or delay further clinical development of any product candidates that utilize that vector. Adverse events in our or others' clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. The risk of cancer remains a concern for gene therapy, and we cannot assure that it will not occur in any of our planned or future clinical trials or in any clinical trials conducted by other companies. In addition, there is the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of products used to carry the genetic material. In addition, for our regulated gene replacement therapy product candidates which require that the expression of a therapeutic transgene be tightly regulated, we may inadvertently cause overexpression, which could lead to numerous issues, including safety and toxicity concerns. Furthermore, one of our regulatory gene replacement therapy candidates, LX1020, requires the insertion of microRNA, or miRNA, targets into the viral genome, which is a technology that to our knowledge is not present in any approved gene therapy products. If any such adverse events occur, commercialization of our product candidates or further advancement of our clinical trials could be halted or delayed, which would have a negative impact on our business and operations.

The affected populations for our other product candidates may be smaller than we or third parties currently project, which may affect the addressable markets for our product candidates.

We currently focus our research and product development on several indications that are larger-rare diseases. However, our projections of the number of people who have the diseases we are seeking to treat, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are estimates based on our knowledge and understanding of these diseases. These estimates may prove to be incorrect and new studies may further reduce the estimated incidence or prevalence of this disease. The number of patients in the United States, the European Union and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our product candidate or patients may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects.

The total addressable market opportunity for our product candidates will ultimately depend upon a number of factors, including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access and product pricing and reimbursement. Incidence and prevalence estimates are frequently based on information and assumptions that are not exact and may not be accurate, and the methodology is forward-looking and potentially speculative. The process we have used in developing an estimated incidence and prevalence range for the indications we are targeting has involved collating limited data from multiple sources. Accordingly, the incidence and prevalence estimates included in this Quarterly Report should be viewed in that context. Further, the data and statistical information used in this Quarterly Report, including estimates derived from them, may differ from information and estimates made by our competitors or from current or future studies conducted by independent sources.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

Drug development, particularly in the gene therapy field, is highly competitive and subject to rapid and significant technological advancements. As a significant unmet medical need exists in the cardiovascular disease and Alzheimer's disease areas, there are several large and small pharmaceutical companies focused on delivering therapeutics for the treatment of these diseases, including those that we are initially targeting. It is likely that additional drugs will become available in the future for the treatment of our target diseases.

We are aware that our competitors are developing product candidates for the treatment of diseases that our product candidates will target. With respect to LX2006, we are aware of preclinical gene therapy programs in development at Solid Biosciences Inc., Lacerta Therapeutics, Inc. and Astellas Pharma Inc., and those being developed in collaborations between Voyager Therapeutics, Inc. and Neurocrine Biosciences, Inc. Additionally, we are aware that Prime Medicine, Inc. and Tune Therapeutics, Inc. have early-stage gene editing discovery efforts. Among other treatment modalities for FA, we are aware that Larimar Therapeutics, Inc. is developing a clinical stage product candidate, CTI-1601, that Design Therapeutics, Inc. is developing a product candidate, DT-216P2, and that Reata Pharmaceuticals, Inc.'s omaveloxolone (Skyclarys) was approved by the FDA in 2023. In 2023 Biogen Inc. acquired Reata Pharmaceuticals, Inc. for approximately \$7.3 billion and is currently commercializing Skyclarys.

With respect to LX2020, both Rocket Pharmaceuticals, Inc. and Tenaya Therapeutics Inc. are developing an AAV-based gene therapy candidate designed to deliver a functional *PKP2* gene to patients with PKP2-ACM.

With respect to our portfolio of gene therapy programs for the treatment of homozygous APOE4-associated Alzheimer's disease, we are aware that uniQure, N.V. is pursuing AMT-240, a preclinical gene therapy candidate for autosomal dominant Alzheimer's disease intended to silence the *APOE4* variant while expressing the protective variant, and Novartis has a gene therapy candidate for Alzheimer's disease that is in the early preclinical stages of development. Many large and small pharmaceutical companies and academic institutions are developing potential treatments for the condition given the significant unmet need and the large population suffering from Alzheimer's disease. There are multiple FDA-approved treatments for Alzheimer's disease, including donepezil (Aricept), memantine (Namenda), and in January of 2023, lecanemab was granted accelerated approval by the FDA for the treatment of Alzheimer's disease based on the observed reduction of amyloid beta plaque and was granted full approval by the FDA in June 2023. In addition, Eli Lilly and Company's donanemab (Kisunla) received FDA approval in July 2024 for the treatment of Alzheimer's disease. Finally, we are aware that Voyager Therapeutics, Inc. is pursuing Alzheimer's disease treatments and have early-stage discovery efforts ongoing based on vectorized antibodies.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Our current and potential future competitors may also have significantly more experience commercializing drugs, particularly gene therapy and other biologics, that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors.

We will face competition from other drugs or from other non-drug products currently approved or that will be approved in the future in the cardiac and neurology fields, including for the treatment of diseases and diseases in the therapeutic categories we intend to target. Therefore, our ability to compete successfully will depend largely on our ability to:

- develop and commercialize drugs that are advantageous as compared to other products in the market;
- demonstrate through our clinical trials that our product candidates are differentiated from existing and future therapies;
- attract qualified scientific, product development and commercial personnel;
- obtain patent or other proprietary protection for our product candidates;
- obtain required regulatory approvals;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully collaborate with other pharmaceutical companies in the discovery, development and commercialization of new medicines.

The availability of our competitors' products could limit the demand, and the price we are able to charge, for any product candidate we develop. The inability to compete with existing or subsequently introduced drugs would have an adverse impact on our business, financial condition and prospects. In addition, the reimbursement structure of approved gene therapies by other companies could impact the anticipated reimbursement structure of our gene therapies, if approved, and our business, financial condition, results of operations and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving regulatory and marketing approval for, or commercializing, drugs before we do, which would have an adverse impact on our business and results of operations.

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biologics that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have an adverse effect on the future commercial prospects for our biologics.

There is a risk that any of our product candidates approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologics is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain marketing approval for biosimilars referencing our product candidates, if approved, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences.

The success of our product candidates will depend significantly on coverage and adequate reimbursement or the willingness of patients, commercial and government payors to pay for these procedures.

We believe our success depends on obtaining and maintaining coverage and adequate reimbursement for our product candidates, including LX2006, LX1001 and LX2020, and the extent to which patients will be willing to pay out-of-pocket for such products, in the absence of reimbursement for all or part of the cost. In the United States and in other countries, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. The availability of coverage and adequacy of reimbursement for our products by third-party payors, including government health care programs (e.g., Medicare, Medicaid, TRICARE), managed care providers, private health insurers, health maintenance organizations and other organizations is essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor-by-payor basis. One payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage, and adequate reimbursement.

The principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

Third-party payors determine which products and procedures they will cover and establish reimbursement levels. Even if a third-party payor covers a particular product or procedure, the resulting reimbursement payment rates may not be adequate. Patients who are treated in-office for a medical condition generally rely on third-party payors to reimburse all or part of the costs associated with the procedure, including costs associated with products used during the procedure, and may be unwilling to undergo such procedures in the absence of such coverage and adequate reimbursement. Physicians may be unlikely to offer procedures for such treatment if they are not covered by insurance and may be unlikely to purchase and use our product candidates, if approved, for our stated diseases unless coverage is provided and reimbursement is adequate. In addition, for products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Further, coverage policies and third-party reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a procedure is a covered benefit under its health plan; safe, effective and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental, nor investigational. Further, increasing efforts by third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may nonetheless not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. We expect to experience pricing pressures from third-party payors in connection with the potential sale of any of our product candidates.

Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and we cannot be sure that coverage and adequate reimbursement will be made available with respect to the treatments in which our products are used under any foreign reimbursement system.

There can be no assurance that LX2006, LX1001, LX2020 or any other product candidates, if approved for sale in the United States or in other countries, will be considered medically reasonable and necessary, that it will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, if they are approved for sale.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or drugs caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or drugs that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards paid to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks related to our dependence on third parties

Currently, we rely on our collaborations with Cornell and UCSD to conduct research and development for many of our pipeline programs, including conducting preclinical and IND-enabling studies for portions of our near-term future pipeline. Failure or delay of Cornell or UCSD to fulfill all or part of their respective obligations to us under our agreements, a breakdown in collaboration between the parties or a complete or partial loss of either of these relationships could materially harm our business.

Our collaboration with Cornell is critical to our business and in May 2020, we entered into two separate license agreements with Cornell pursuant to which we obtained rights under certain patents, know-how and data to exploit products and technologies covered by such intellectual property. As part of our first license agreement, as amended, we assumed oversight for the conduct of the Phase 1/2 clinical trial of LX1001 that was initiated by Cornell at the end of 2019. As part of our second license agreement with Cornell, as amended, we received an in-license for technology related to portfolios for infantile neuronal ceroid lipofuscinosis type 2 (also called CLN2 Batten disease) and FA cardiomyopathy, as well as an assignment of Cornell's IND to support the development of our LX1004 program. In February 2021, we further expanded our collaboration and entered into a research collaboration agreement with Cornell to conduct preclinical research to develop the licensed technology, which expired pursuant to its terms in February 2024. We entered into a third license agreement with Cornell in April 2024 pursuant to which we obtained certain rights for FA cardiomyopathy, including rights to current and future clinical data from an ongoing Cornell investigator-initiated Phase 1A trial of a gene therapy candidate AAVrh10.hFXN, known as LX2006 at Lexeo. Pursuant to these license agreements, we are obligated to diligently proceed with the development, manufacture, and sale of licensed products. If Cornell delays or fails to perform its obligations under the license agreements terminates any of the license agreements in accordance with its terms, or a dispute otherwise arises between the parties concerning the terms of the agreements or our respective rights to licensed technology, our pipeline of product candidates would be significantly adversely affected and our prospects may be materially harmed.

Our collaboration with UCSD is also highly important to our business, as we have licensed from UCSD intellectual property rights related to our LX2020, LX2021 and LX2022 programs under three separate license agreements, and we have entered into sponsored research agreements with UCSD for preclinical research and development for these programs. If UCSD delays or fails to perform its obligations under either of the sponsored research agreements or any of the license agreements, disagrees with our interpretation of the terms of the sponsored research agreements, license agreements or our discovery plan or terminates any of our existing license agreements, our pipeline of product candidates would be significantly adversely affected and our prospects may be materially harmed.

We intend to continue to rely on third parties to conduct a significant portion of our existing clinical trials and potential future clinical trials for product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We engage CROs to help conduct our ongoing clinical trials. We expect to continue to rely on third parties, including clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials and any future clinical trials. Any of these third parties may terminate their engagements with us, some in the event of an uncured material breach and some at any time for convenience. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. Switching or adding a CRO involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

In addition, any third parties conducting our clinical trials will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

We rely on these parties for execution of our preclinical studies and clinical trials, and generally do not control their activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with cGCP regulations, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, www.clinicaltrials.gov, within specified time frames. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If we or any of our CROs or other third parties, including trial sites, fail to comply with applicable cGCPs, or experience material protocol deviations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. If the FDA or any regulatory authority determines that our clinical data are not reliable for any reason, or if we encounter any data integrity issues, the FDA or other regulatory authorities may require us to exclude such data, which may cause the trial to be underpowered and fail to meet the trial endpoints. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with cGCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of LX2006, LX1001, LX2020 or any other product candidates.

We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential revenue.

We may seek collaborations with non-academic third parties for the development or commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We may seek third-party collaborators for the development and commercialization of our product candidates, including for the commercialization of any of our product candidates that are approved for marketing outside the United States. Our likely collaborators for any such arrangements include regional and national pharmaceutical companies and biotechnology companies. If we enter into any additional such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar diseases that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue.

Risks related to intellectual property

If we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates, including LX2006, LX2020, LX2021, LX2022, LX1001, LX1020, LX1021, and other programs, their respective components, formulations, therapies, methods used to manufacture them and methods of treatment. Furthermore, we currently do not have any patents or patent applications covering our LX1004 product candidate.

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and product candidates.

We cannot offer any assurances about which of our patent applications will issue, the breadth of any resulting patent or whether any of the issued patents will be found invalid and unenforceable or will be threatened by third parties. We cannot offer any assurances that the breadth of our granted patents will be sufficient to stop a competitor from developing and commercializing a product, including a biosimilar product that would be competitive with one or more of our product candidates. Furthermore, any successful challenge to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any of our product candidates. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

The patent prosecution process is expensive and time-consuming. We may not be able to prepare, file and prosecute all necessary or desirable patent applications at a commercially reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in the public domain. In some cases, the work of certain academic researchers in the gene therapy field has entered the public domain, which may preclude our ability to obtain patent protection for certain inventions relating to such work. Although we enter into nondisclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we would not be able to prevent any third party from using any technology that is in the public domain to compete with our product candidates. In addition, as the licensee of university patents from Cornell and UCSD, we have less control over the prosecution and enforcement of those patents than we would if we owned the patents. While we do have typical rights with respect to those patents under university license agreements, our ability to enforce those patents to maintain exclusivity in our markets may be limited by the terms of our agreements with Cornell and UCSD. In addition, to the extent the federal government provided research funding to the licensor university for any technology licensed under the license agreements, then if the federal government elects to exercise any of its overriding rights which may apply as a result of provision of such funding, we may be subject to changes in market exclusivity or other material business requirements or constraints. Moreover, depending on the terms of any future in-licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any patent rights are highly uncertain. Our owned and licensed pending and future patent applications may not result in issued patents which protect our technology or product candidates, effectively prevent others from commercializing competitive technologies and product candidates or otherwise provide any competitive advantage. In fact, patent applications may not issue as patents at all. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold or in-license may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether any of our technologies and product candidates will be protectable or remain protected by valid and enforceable patents. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing technologies and products, and the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Any failure to obtain, maintain or defend our patents and other intellectual property could have a material adverse effect on our business, financial conditions, results of operations and prospects.

We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority or entitlement disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Since patent applications in the United States and other countries are confidential for a period of time after filing, at any moment in time, we cannot be certain that we were in the past or will be in the future the first to file any patent application related to our product candidates. For example, some patent applications in the United States may be maintained in secrecy until the patents are issued. Further, publications in the scientific literature often lag behind actual discoveries. Consequently, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor, were the first to invent or first to file an application for the technology.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

In addition to the protection provided by our patent estate, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not amenable to patent protection. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, or that our trade secrets and other confidential proprietary information will not be disclosed. In addition, while we have undertaken reasonable efforts to ensure such agreements are enforceable and that employees and third parties comply with their obligations thereunder, these agreements may be found insufficient by a court of law or may be breached, or we may not enter into sufficient agreements with such individuals in the first instance, in either case potentially resulting in the unauthorized use or disclosure of our trade secrets and other intellectual property, including to our competitors, which could cause us to lose any competitive advantage resulting from this intellectual property. Individuals not subject to invention assignment agreements may make adverse ownership claims to our current and future intellectual property. Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products, if approved, and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable, and we may not be able to obtain adequate remedies for such breaches.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, our agreements or security measures may be breached, and we may not have adequate remedies for any breach. Also, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA is considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and if we do not obtain protection under the Hatch-Waxman Amendments and similar non-United States legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business.

We in-license key intellectual property necessary for the development of each of our current product candidates. If we fail to comply with our obligations in our current and future intellectual property licenses with third parties, resulting in the termination of such licenses, we could lose rights that are important to our business.

We are heavily reliant upon licenses to certain patent rights and proprietary technology for the development of each of our current product candidates. In particular, we in-license key patents, patent applications and know-how from Adverum related to LX2006, we in-license patent applications and know-how from Cornell related to our LX1001, LX1020 and LX1021 product candidates, and we in-license patent applications and know-how from UCSD, related to our LX2020, LX2021 and LX2022 product candidates. Our license agreements impose diligence and milestone and royalty payment obligations on us, and also contain certain development requirements. If we fail to comply with our obligations, our licensors may have the right to terminate our licenses, in which event we will not be able to develop, manufacture or market any product using the intellectual property under any such terminated agreement and may face other penalties. Such an occurrence would materially adversely affect our business prospects.

Certain of our licenses may not provide us with exclusive rights to use the licensed intellectual property and technology, or may not provide us with exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and product candidates in the future. In addition, the intellectual property rights licensed to us by our licensors, including certain intellectual property licensed by Cornell, UCSD, and Adverum, at least in some respects, may be used by such licensors or licensed to third parties, and such third parties may have certain enforcement rights with respect to such intellectual property. Thus, patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against our licensors or another licensee or in administrative proceedings brought by or against our licensors or another licensee in response to such litigation or for other reasons. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products, including in territories covered by our licenses.

Licenses to additional third-party technology and materials that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms, or at all, which could have a material adverse effect on our business and financial condition. In such events, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology or product candidates. Even if we are able to obtain such additional licenses, they may be non-exclusive thereby giving our competitors and other third parties access to the same technology licensed to us.

If we or our licensors fail to adequately protect our licensed intellectual property, our ability to commercialize our product candidates and technology could suffer. Although we have oversight rights, Cornell and UCSD generally control the prosecution, maintenance and enforcement of our in-licensed patents and patent applications. Therefore, we cannot be certain that the prosecution, maintenance and enforcement of these patent rights will be in a manner consistent with the best interests of our business, or in compliance with applicable laws and regulations, or will result in valid and enforceable patents and other intellectual property rights. It is possible that our licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves or may not be conducted in accordance with our best interests. If we or our licensors fail to maintain such patents or patent applications, or if we or our licensor lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that we license from third parties will also apply to patent rights we may own in the future.

Further, if we fail to comply with our development obligations under our license agreements, we may lose our patent rights with respect to such agreement on a territory-by-territory basis, which would affect our patent rights worldwide. In spite of our efforts, our current and future licensors might conclude that we have materially breached our obligations under our license agreements and might therefore terminate such license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial and other obligations under the license agreement;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;

- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations;
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected technology or product candidates. In addition, if any such disputes result in the termination of our intellectual property licenses, this could result in the loss of our ability to develop and commercialize our lead product candidates, or we could lose other significant rights, experience significant delays in the development and commercialization of our other product candidates, or incur liability for damages, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with our product candidates.

Some of our future agreements with certain of our third-party research partners may provide that improvements developed in the course of our relationship may be owned solely by either us or our third-party research partner. If we determine that rights to such improvements owned solely by a third-party research partner or other third party with whom we collaborate are necessary to commercialize our therapeutic product candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to use the improvements and continue developing, manufacturing or marketing our drug candidates. We may not be able to obtain such a license on an exclusive basis, on commercially reasonable terms, or at all, which could prevent us from commercializing our product candidates or allow our competitors or others the chance to access technology that is important to our business.

Termination of our current or any future license agreements would reduce or eliminate our rights under these agreements and may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. Any of the foregoing could prevent us from commercializing our other product candidates, which could have a material adverse effect on our operating results and overall financial condition.

In addition, intellectual property rights that we in-license in the future may be sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

In addition, a third party may in the future bring claims that our performance under our license agreements, including our sponsoring of clinical trials, interferes with such third party's rights under its agreement with one of our licensors. If any such claim were successful, it may adversely affect our rights and ability to advance our product candidates as clinical candidates or subject us to liability for monetary damages, any of which would have an adverse effect on our business, financial condition, results of operations and prospects.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described above and below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer. We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Presently, we have obtained rights to certain intellectual property rights through licenses from third parties to develop, manufacture and commercialize our lead product candidates and other potential product candidates in our pipeline. Because the commercialization of our product candidates may require the use of additional intellectual property rights held by third parties, the growth of our business likely will depend, in part, on our ability to acquire or license these intellectual property rights. Our product candidates also require specific formulations and manufacturing processes to work effectively and efficiently, and some of these rights are held by others.

We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary, important or more expedient to further our business operations. In addition, even if we are able to obtain such licenses, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, which would harm our business. Were that to happen, we may need to cease use of the product candidates and technologies covered by those third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe, misappropriate or violate those intellectual property rights, which may entail additional costs and development delays if we are able to develop such alternatives, or which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

If we are unable to successfully obtain rights to required third-party intellectual property or maintain the existing intellectual property rights we have licensed, we may be required to expend significant time and resources to redesign our product candidates, or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis, and we may have to abandon development of our product candidates, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our intellectual property licenses with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

We currently depend, and will continue to depend, on our license agreements, including the license agreements with Cornell and Adverum related to LX2006, with Cornell related to our LX1001, LX1020 and LX1021 product candidates, and with UCSD related to LX2020, LX2021 and LX2022 product candidates. The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If any of our licenses or material relationships or any in-licenses upon which our licenses are based are terminated or breached, we may:

- lose our rights to develop and market our products;
- lose patent protection for our products;
- experience significant delays in the development or commercialization of our products;
- not be able to obtain any other licenses on acceptable terms, if at all; or
- incur liability for damages.

These risks apply to any agreements that we may enter into in the future for our products or for any future product candidates. If we experience any of the foregoing, it could have a material adverse effect on our business, financial condition, results or operations and prospects.

We cannot be certain that any of our or licensed pending patent applications or our future owned or licensed patent applications will result in issued patent claims covering such aspects of our product candidates.

Composition-of-matter patents on the active pharmaceutical ingredient, or API, in prescription drug products are generally considered to be the strongest form of intellectual property protection for drug products because those types of patents provide protection without regard to any particular method of use or manufacture or formulation of the API used. Although we intend to file patent applications in the future that cover these product candidates, we cannot be certain that our future owned or licensed patent applications will cover our current or future product candidates.

Method-of-use patents protect the use of a product for the specified method and formulation patents cover formulations of the API. These types of patents do not prevent a competitor or other third party from developing or marketing an identical product for an indication that is outside the scope of the patented method or from developing a different formulation that is outside the scope of the patented formulation. Moreover, with respect to method-of-use patents, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, physicians may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method-of-use patents, the practice is common, and this type of infringement is difficult to prevent or prosecute. In addition, there are numerous publications and other prior art that may be relevant to our owned or in-licensed method-of-use patents and patent applications and may be used to challenge the validity of these owned or in-licensed patents and patent applications in litigation or other intellectual property-related proceedings. If these types of challenges are successful, our owned or in-licensed patents and patent applications may be narrowed or found to be invalid, and we may lose valuable intellectual property rights. Any of the foregoing could have a material adverse effect on our business, financial conditions, prospects and results of operations.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other countries. Even if patents do successfully issue, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and third parties may challenge the validity, enforceability or scope of our owned and licensed patents in courts or patent offices in the United States and abroad, which may result in those patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our owned and licensed patents and pending patent applications, if issued, may not adequately protect our intellectual property or prevent competitors or others from designing around our patent claims to circumvent our owned or licensed patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. If the breadth or strength of protection provided by the patents and patent applications we own or license with respect to our product candidates is not sufficient to impede such competition or is otherwise threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe the patents for which we have applied. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. If we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. In an infringement proceeding, a court may decide that the patent claims we are asserting are invalid and/or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover the technology in question. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could have a material adverse impact on our business.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patent applications. An unfavorable outcome could require us to cease using the related technology or force us to take a license under the patent rights of the prevailing party, if available. Furthermore, our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Even if we establish infringement of any of our patents by a competitive product, a court may decide not to grant an injunction against further infringing activity, thus allowing the competitive product to continue to be marketed by the competitor. It is difficult to obtain an injunction in U.S. litigation and a court could decide that the competitor should instead pay us a “reasonable royalty” as determined by the court, and/or other monetary damages. A reasonable royalty or other monetary damages may or may not be an adequate remedy. Loss of exclusivity and/or competition from a related product would have a material adverse impact on our business.

For certain of our in-licensed patent rights, such as patent rights in-licensed from Cornell and Adverum, we may not have the right to file a lawsuit for infringement and may have to rely on a licensor to enforce these rights for us. If we are not able to directly assert our licensed patent rights against infringers or if a licensor does not vigorously prosecute any infringement claims on our behalf, we may have difficulty competing in certain markets where such potential infringers conduct their business, and our commercialization efforts may suffer as a result.

In addition, we or our licensors, as the case may be, may not be able to detect infringement against our owned or in-licensed patents, which may be especially difficult for manufacturing processes or formulation patents. Even if we or our licensors detect infringement by a third party of our owned or in-licensed patents, we or our licensors, as the case may be, may choose not to pursue litigation against or settlement with the third party. If we or our licensors later sue such third party for patent infringement, the third party may have certain legal defenses available to it that otherwise would not be available but for the delay between when the infringement was first detected and when the suit was brought. These legal defenses may make it impossible for us or our licensors to enforce our owned or in-licensed patents, as the case may be, against that third party.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain.

As our current and future product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. We cannot provide any assurance that our current and future product candidates do not infringe other parties’ patents or other proprietary rights, and competitors or other parties may assert that we infringe their proprietary rights in any event. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and future product candidates, including interference or derivation proceedings before the USPTO, or oppositions and other proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates, manufacturing methods, formulations, administration methods and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights.

Numerous issued patents and pending patent applications that are owned by third parties exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, the claim scope that may issue from pending patent applications owned by third parties or which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties, including our competitors, may allege they have patent rights encompassing our product candidates, technologies or methods and that we are employing their proprietary technology without authorization.

If we were sued for patent infringement, we would need to demonstrate that the relevant product or methods of using the product either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. In order to successfully challenge the validity of any such United States patent in federal court, we would need to overcome a presumption of validity. As this burden is high and requires us to present clear and convincing evidence as to the invalidity of any such United States patent claim, there is no assurance that a court of competent jurisdiction would agree with us and invalidate the claims of any such United States patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future.

While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes that one of our product candidates infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the drug or product candidate that is the subject of the actual or threatened suit.

If any third-party patents are held by a court of competent jurisdiction to be valid and enforceable and to cover any of our technology or product candidates, including the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product. If we were required to obtain a license to continue to manufacture or market the affected product, we may be required to pay substantial royalties or grant cross-licenses to our patents. We cannot, however, assure that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Furthermore, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us; alternatively, or additionally, it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing a product or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

We are currently, and may in the future be, subject to claims that we and our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information or trade secrets of third parties.

We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, harm to our reputation and other factors. For example, on October 12, 2023, Rocket filed a lawsuit against us and two individuals claiming, among other things, misappropriation of confidential information and trade secrets. The individual defendants are a current employee and a former employee of our analytical development team, both of whom were employed at Rocket before joining us in 2021. The complaint alleges the individual defendants downloaded confidential Rocket company documents and other proprietary materials prior to leaving Rocket in 2021 and that we used this information to advance our programs. The complaint seeks unspecified damages and asks the court to enjoin us from competing and working in the market for gene therapy treatments targeting cardiac diseases. We retained legal counsel to assist with our ongoing review of the allegations in Rocket's complaint and are confident in our defenses to the allegations. On December 7, 2023, we filed a motion to dismiss the complaint, and the motion is fully briefed and pending before the court. It is not possible to predict the outcome with certainty and an estimate of the possible loss cannot be made. For additional information regarding this litigation, see "*Item 1 - Legal Proceedings*".

Even if we are successful in defending against these types of claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. Some of our competitors may be able to sustain the costs of this type of litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

We may be subject to claims challenging the inventorship or ownership of our future patents and other intellectual property.

We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patent applications, our future patents, or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates and platform discovery. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

If we rely on third parties to manufacture or commercialize our product candidates, or if we collaborate with additional third parties for the development of such product candidates, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make or use capsids, nucleic acids and vectors that are similar to the biological compositions of our products that are the same as or similar to our product candidates but that are not covered by the claims of owned or in-licensed patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that others may circumvent our owned or in-licensed patents;
- others, including inventors or developers of our owned or in-licensed patented technologies who may become involved with competitors, may independently develop similar technologies that function as alternatives or replacements for any of our technologies without infringing our intellectual property rights;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) who should be listed as inventor(s) or include individual(s) who should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we or our licensors or our other collaboration partners might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license;
- we or our licensors or our other collaboration partners might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license;

- we or our licensors may fail to meet obligations to the U.S. government with respect to in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- it is possible that our pending patent applications will not result in issued patents;
- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs;
- no patent protection may be available with regard to formulation or method of use;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- issued patents that we own or exclusively license may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may not exclusively license our patents and, therefore, may not have a competitive advantage if such patents are licensed to others;
- our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- the laws of other countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may, under certain circumstances, force us or our licensors to grant a license under our patents to a competitor, thus allowing the competitor to compete with us in that jurisdiction or forcing us to lower the price of our drug in that jurisdiction;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not successfully commercialize the product candidates, if approved, before our relevant patents expire;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or technologies we develop may be covered by third parties' patents or other exclusive rights;
- ownership, validity or enforceability of our or our licensors' patents or patent applications may be challenged by third parties; and
- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business.

We may have limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as that in the United States or Europe. These products may compete with our product candidates, and our future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

While we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

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

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and/or applications and any patent rights we may obtain in the future. Furthermore, the USPTO and various non-United States government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse of a patent or patent application can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patents or patent applications, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market, which could have a material adverse effect on our business.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology and genetic medicine industries involve both technological and legal complexity. Therefore, obtaining and enforcing biotechnology and genetic medicine patents is costly, time-consuming and inherently uncertain. In addition, the Leahy-Smith America Invents Act (AIA), which was passed in September 2011, resulted in significant changes to the U.S. patent system.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned from a “first-to-invent” to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors’ patent applications and the enforcement or defense of our or our licensors’ issued patents.

We may become involved in opposition, interference, derivation, inter partes review or other proceedings challenging our or our licensors’ patent rights, and the outcome of any proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our owned or in-licensed patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights.” March-in rights allows the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself. Some of our licensed patents are subject to the provisions of the Bayh-Dole Act. If our licensors fail to comply with the regulations of the Bayh-Dole Act, they could lose title to any patents subject to such regulations, which could affect our license rights under the patents and our ability to stop others from using or commercializing similar or identical technology and products, or limit patent protection for our technology and products.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations, and there are other open questions under patent law that courts have yet to decisively address. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution, but the complexity and uncertainty of European patent laws has also increased in recent years. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Risks related to legal and regulatory compliance matters

Our current and future relationships with customers, healthcare providers, including physicians, and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

We are currently or will in the future be subject to healthcare regulation and enforcement by the U.S. federal government and the states in which we will conduct our business once our product candidates are approved by the FDA and commercialized in the United States. In addition to the FDA's restrictions on marketing of pharmaceutical products, the U.S. healthcare laws and regulations that may affect our ability to operate include: the federal fraud and abuse laws, including the federal anti-kickback and false claims laws; federal data privacy and security laws; and federal transparency laws related to payments and/or other transfers of value made to physicians and other healthcare professionals and teaching hospitals. Many states have similar laws and regulations that may differ from each other and federal law in significant ways, thus complicating compliance efforts. For example, states have anti-kickback and false claims laws that may be broader in scope than analogous federal laws and may apply regardless of payor. In addition, state data privacy laws that protect the security of health information may differ from each other and may not be preempted by federal law. Moreover, several states have enacted legislation requiring pharmaceutical manufacturers to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales and marketing activities, report information related to drug pricing, require the registration of sales representatives, and prohibit certain other sales and marketing practices. These laws may adversely affect our sales, marketing and other activities with respect to any product candidate for which we receive approval to market in the United States by imposing administrative and compliance burdens on us. It is possible that governmental authorities will conclude that our current or future business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, any of which could harm our business.

The risk of being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Even if we obtain FDA or EMA approval for any of our product candidates in the United States or European Union, we may never obtain approval for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy.

Approval by the FDA in the United States or the EMA in the European Union does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming.

Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

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

Any product candidate for which we obtain marketing approval will be subject to ongoing regulatory requirements for, among other things, manufacturing processes, submission of post-approval clinical data and safety information, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising, promotional activities and product tracking and tracing. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, applicable tracking and tracing requirements, continued compliance with cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and cGCP requirements for any clinical trials that we conduct post-approval.

Any regulatory approvals that we receive for our product candidates or any future product candidates may also be subject to a REMS, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or requirements that we conduct potentially costly post-marketing testing, including Phase 4 trials and surveillance to monitor the quality, safety and efficacy of the product. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval. We will further be required to immediately report any serious and unexpected adverse events and certain quality or production problems with our products to regulatory authorities along with other periodic reports.

The FDA and EMA closely regulate the post-approval marketing and promotion of genetic therapy medicines to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we market our products for uses beyond their approved diseases, we may be subject to enforcement action for off-label marketing. Violations of the FDCA, relating to the promotion of prescription drugs for unapproved uses may lead to enforcement actions and investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws. The holder of an approved BLA must submit new or supplemental applications and obtain prior approval for certain changes to the approved product, product labeling, or manufacturing process. A company that is found to have improperly promoted off-label uses of their products may be subject to significant civil, criminal and administrative penalties.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such products;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- refusal to allow entry into supply contracts, including government contracts;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters, or holds on clinical trials;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;

- refusal to permit the import or export of our products;
- product seizure or detention; or
- injunctions or the imposition of administrative, civil or criminal penalties or monetary fines.

The FDA's policies, and the policies of foreign regulatory agencies, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, executive orders or other actions could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. If such executive actions were to impose restrictions on FDA's ability to engage in oversight and implementation activities in the normal course, our business could be negatively impacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our current product candidates or any future product candidates and harm our business, financial condition, results of operations and prospects.

Enacted and future healthcare legislation may increase the difficulty and cost for us to progress our clinical programs and obtain marketing approval of and commercialize our product candidates and may affect the prices we may set.

In the United States, the European Union and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our product candidates, if approved;
- the ability to set a price that we believe is fair for any of our product candidates, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical and biologic products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. presidential executive orders, Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures and could negatively affect our customers and accordingly, our financial operations.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved.

In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Our business depends upon the ability of the FDA to accept and review our potential regulatory filings. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our ability to advance clinical development of our product candidates.

If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing our product candidates or realizing the synergies in the target diseases of our programs, even if they are approved.

We do not have any infrastructure for the sales, marketing or distribution of our products, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. We expect to build a focused sales, distribution and marketing infrastructure to market our product candidates in the United States and European Union, if approved. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact the commercialization of our product candidates. Additionally, if the commercial launch of our product candidates for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We may not have the resources in the foreseeable future to allocate to the sales and marketing of our product candidates in certain international markets. Therefore, our future sales in these markets will largely depend on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator's strategic interest in the product and such collaborator's ability to successfully market and sell the product. We may pursue collaborative arrangements regarding the sale and marketing of LX2006, LX1001 or LX2020, if approved, for certain markets overseas; however, we cannot assure that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces.

If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of LX2006, LX1001 or LX2020, or any of our other product candidates, if approved, we may be forced to delay the potential commercialization of LX2006, LX1001 or LX2020 or any of our other product candidates or reduce the scope of our sales or marketing activities for LX2006, LX1001 or LX2020 or any of our other product candidates. If we elect to increase our expenditures to fund commercialization activities internationally, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. We could enter into arrangements with collaborative partners at an earlier stage than otherwise would be ideal and we may be required to relinquish rights to LX2006, LX1001 or LX2020 or any of our other product candidates or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

If we are unable to establish adequate sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing LX2006, LX1001 or LX2020 or any of our other product candidates, if approved, and may not become profitable and may incur significant additional losses. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we obtain approval to commercialize any products outside of the United States or the European Union, a variety of risks associated with international operations could adversely affect our business.

If LX2006, LX1001, LX2020 or any of our other product candidates are approved for commercialization, we may seek to enter into agreements with third parties to market them in certain jurisdictions outside the United States and the European Union. We expect that we would be subject to additional risks related to international pharmaceutical operations, including:

- different regulatory requirements for drug and biologic approvals and rules governing drug and biologic commercialization in foreign countries;
- reduced protection for intellectual property rights;
- foreign reimbursement, pricing and insurance regimes;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;

- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires, or from economic or political instability;
- greater difficulty with enforcing our contracts;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, or the FCPA, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

In addition, there are complex regulatory, tax, labor and other legal requirements imposed by individual countries in Europe with which we will need to comply. If we are unable to successfully manage the challenges of international expansion and operations, our business and operating results could be harmed.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

We are subject to a variety of privacy and data security laws, rules, regulations, policies, industry standards and contractual obligations, and our failure to comply with them could harm our business.

We maintain a large quantity of sensitive information, including confidential business and personal information in connection with the conduct of our clinical trials and related to our employees, and we are subject to laws and regulations governing the privacy and security of such information. In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws and federal and state consumer protection laws. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues, which may affect our business and is expected to increase our compliance costs and exposure to liability. In the United States, numerous federal and state laws and regulations could apply to our operations or the operations of our partners, including state and federal data breach notification laws, state health information privacy laws and federal and state consumer protection laws and regulations that govern the collection, use, disclosure and protection of health-related and other personal information. Among these regulations are: Section 5 of the Federal Trade Commission Act, which prohibits unfair or deceptive commercial practices; new rules adopted by the SEC in July 2023, which require public companies to disclose material cybersecurity incidents they experience and to disclose on an annual basis material information regarding their cybersecurity risk management, strategy, and governance; and HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and the regulations promulgated thereunder.

We may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, and depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use or disclose individually identifiable health information in a manner that is not authorized or permitted by HIPAA.

In the European Economic Area, or EEA, and the UK, the collection, use, disclosure, transfer or other processing of personal data, including clinical trial data, of individuals is governed by the General Data Protection Regulation, or European Union GDPR (with regards to the EEA) and UK GDPR (with regards to the UK), as well as applicable national data protection legislation and requirements. In this document, “GDPR” refers to both the European Union GDPR and the UK GDPR, unless specified otherwise. The GDPR is wide ranging in scope imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR imposes substantial fines for breaches and violations (up to the greater of €20 million (£17.5 million for the UK) or 4% of our consolidated annual worldwide gross revenue), and confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.

The GDPR also includes restrictions on cross-border data transfers of personal data to countries outside the EEA and the UK that are not considered by the European Commission and UK government as providing “adequate” protection to personal data, or third countries, including the United States, unless a valid GDPR transfer mechanism (for example, the European Commission approved Standard Contractual Clauses, or SCCs, and the UK International Data Transfer Agreement/Addendum, or UK IDTA) has been put in place. Where relying on the SCCs or UK IDTA for data transfers, we may also be required to carry out transfer impact assessments to assess whether the recipient is subject to local laws which allow public authority access to personal data. The international transfer obligations under the EEA and UK data protection regimes will require significant effort and cost, and may result in us needing to make strategic considerations around where EEA and UK personal data is transferred and which service providers we can utilize for the processing of EEA and UK personal data. Although the UK is regarded as a third country under the European Union GDPR, the European Commission has issued a decision recognizing the UK as providing adequate protection under the European Union GDPR, or Adequacy Decision, and, therefore, transfers of personal data originating in the EEA to the UK remain unrestricted.

The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. The UK Government has also now introduced a Data Protection and Digital Information Bill, or UK Bill, into the UK legislative process. The aim of the UK Bill is to reform the UK’s data protection regime following Brexit. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EEA data protection regime and threaten the UK Adequacy Decision from the European Commission. This may lead to additional compliance costs and could increase our overall risk. The respective provisions and enforcement of the European Union GDPR and UK GDPR may further diverge in the future and create additional regulatory challenges and uncertainties.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly. In addition, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California enacted the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020, became enforceable by the California Attorney General on July 1, 2020 and has been dubbed the first “GDPR-like” law in the United States. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act, or CPRA, which became effective as of January 1, 2023, amended the CCPA and imposes additional data protection obligations on companies doing business in California, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data and opt outs for certain uses of sensitive data. The amendments introduced by the CPRA also created a new California data protection agency authorized to issue substantive regulations, and it is anticipated that this development could result in increased privacy and information security enforcement. Although the CCPA, as amended by the CPRA, currently exempts certain health-related information, including clinical trial data, the CCPA may increase our compliance costs and potential liability if we expand our operations into California. Similar broad consumer privacy laws have been enacted in Colorado, Connecticut, Virginia, Utah, Iowa and Indiana and have been proposed in numerous other states and at the federal level. If passed, these bills may have potentially conflicting requirements that would make compliance challenging.

In addition to these consumer privacy laws, the state of Washington recently enacted a comprehensive privacy bill, called the My Health My Data Act. Effective March 2024, this new law will impose strict requirements on the collection, use and processing of health related information that is not subject to HIPAA. Other states are considering bills with similar requirements. The Washington law and, if passed, the other state bills, will add additional complexity to our existing compliance obligations.

With the GDPR, CCPA and other laws, regulations and other obligations relating to privacy and data protection imposing new and relatively burdensome obligations, and with the substantial uncertainty over the interpretation and application of these and other obligations, we may face challenges in addressing their requirements and making necessary changes to our policies and practices and may incur significant costs and expenses in an effort to do so. We will continue to assess, develop, update, and adapt our practices, procedures, and policies in order to address existing and new requirements under applicable data privacy and protection laws and regulations. However, it is possible that both existing and new laws, regulations, and other obligations to which we are or may be subject, may be interpreted and applied in a manner that is inconsistent with our existing or future privacy and data protection practices. Any failure or perceived failure by us to comply with our obligations may result in governmental investigations or enforcement actions, litigation, claims, or public statements against us and could result in significant liability, cause harm to our brand and reputation, and otherwise materially and adversely affect our reputation and business. We do not currently have any formal data privacy policies and procedures in place and have not completed formal assessments of whether we are in compliance with all applicable data privacy laws and regulations. Additionally, if third parties with which we work, such as vendors or service providers, violate applicable laws, rules or regulations or our policies, such violations may also put our or our clinical trial and employee data, including personal data, at risk, which could in turn have an adverse effect on our business.

We are subject to U.S. and certain foreign anti-corruption laws and regulations, export and import controls, sanctions and embargoes. We could face liability and other serious consequences for violations.

We are subject to anti-corruption laws and regulations, including the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act and other state and national anti-bribery laws in the countries in which we may conduct activities in the future. Anti-corruption laws are interpreted broadly and generally prohibit companies and their employees, agents, contractors and other third-party collaborators from offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly through third parties, to any person in the public or private sector to obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls.

Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-United States governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and therefore will be considered foreign officials for purposes of the FCPA. We also expect to rely on third parties for research, preclinical studies and clinical trials and/or to obtain necessary permits, licenses, patent registrations and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities.

We are also subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions.

There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors or collaborators, or those of our affiliates, will comply with all applicable anti-corruption, export and import control, and sanctions laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results and financial condition.

Risks related to employee matters and managing our growth

Our future success depends on our ability to attract and retain key executives and advisors and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, development, clinical, financial and business development expertise of our executive officers, particularly R. Nolan Townsend, our Chief Executive Officer and a member of our board of directors, Eric Adler, M.D., our Chief Medical Officer and Head of Research, Sandi See Tai, M.D., our Chief Development Officer, Jose Manuel Otero, our Chief Technical Officer, and Jenny R. Robertson, our Chief Business and Legal Officer, as well as on the scientific expertise of our founder, Ronald G. Crystal, M.D., Professor and Chairman of Weill Cornell Medicine's Department of Genetic Medicine. Each of our executive officers may currently terminate their employment with us at any time and we do not have an employment contract with Dr. Crystal. We do not maintain "key person" insurance for any of our executives or employees.

Recruiting and retaining qualified executives, scientists and clinical personnel and, if we progress the development of our product pipeline toward scaling up for commercialization, manufacturing and sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key employees, or our inability to recruit certain executives, could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, recruiting executive officers, or replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize gene therapy products.

Competition to hire from this limited pool is intense, and we have experienced and may continue to experience challenges filling certain executive roles. We may be unable to hire, train, retain or motivate key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our clinical development, manufacturing and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of June 30, 2024, we had 69 full-time employees. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical product development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our choice to focus on multiple therapeutic areas may negatively affect our ability to develop adequately the specialized capability and expertise necessary for operations. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may be improperly classified and may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We endeavor to properly classify our employees as exempt or non-exempt with respect to wage and hour laws (including, but not limited to, for purposes of minimum wage, overtime and applicable meal and rest periods), and we monitor and evaluate such classifications. Although there are no current, pending, or threatened claims or investigations against us asserting that any employees have been incorrectly classified as exempt, the possibility nevertheless exists that certain job roles could be deemed to have been incorrectly classified as exempt. In addition, we endeavor to classify our workforce properly, and we monitor and evaluate such classifications. Although there are no current, pending, or threatened claims or investigations against us asserting that any independent contractors have been incorrectly classified, the possibility nevertheless exists that certain contractors could be deemed to be employees.

We are exposed to the risk that our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Although we have adopted a code of business conduct and ethics, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

The administrator of the 2023 Plan is authorized to exercise its discretion to reprice stock options and stock appreciation rights, and if a repricing occurs, there may be adverse consequences to our business.

The administrator of the 2023 Plan, which is our compensation committee, is authorized, subject to the consent of any award holder whose award is materially impaired by such action, to reduce the exercise price of a stock option or stock appreciation right; to cancel a stock option or stock appreciation right in exchange for a different award, cash or other consideration; or to take any other action that is treated as a repricing under generally accepted accounting principles, or each such action, a repricing.

We have no current expectation that a repricing will occur. However, if the administrator were to implement a repricing without seeking prior stockholder approval, certain proxy advisory firms and/or institutional investors may express a lack of support for the repricing, and proxy advisory firms may recommend an “against” or “withhold” vote for members of our compensation committee or our board of directors. In addition, if we are required to hold an advisory vote on named executive officer compensation (known as a “say on pay” vote) at the time of, or subsequent to, any such repricing, it is likely, based on their current policies, that proxy advisory firms would issue an “against” recommendation on our say on pay proposal. Defending against negative recommendations with respect to our directors and/or say on pay proposal would require management attention, and could be costly and time-consuming.

If our stockholders agree with proxy advisory firms’ recommendations, we may need to make changes to our compensation and corporate governance practices, and perhaps the composition of our board of directors and its committees, potentially leading to business disruptions and a negative impact on our stock price. Even absent negative reactions from proxy advisory firms and institutional investors, we may be required to recognize a compensation expense and the repricing will require management’s time and attention and the payment of administrative costs and attorney and accounting firm fees. As such, a repricing could cause a negative impact on our stock price, and adverse consequences to our business.

Risks related to ownership of our common stock and status as a public company

The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The trading price for our common stock may be influenced by many factors, including those discussed in this “Risk Factors” section and elsewhere in this Quarterly Report on Form 10-Q and:

- the reporting of unfavorable preclinical and clinical results;
- the commencement, enrollment or results of our clinical trials of LX2006, LX1001, LX2020 or any future clinical trials we may conduct, or changes in the development status of our product candidates;

- any delay in our regulatory filings for LX2006, LX1001, LX2020 or any other product candidate we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results from, delays in or termination of clinical trials;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- unanticipated serious safety concerns related to the use of LX2006, LX1001 or LX2020 or any other product candidates;
- changes in financial estimates by us or by any equity research analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock trading price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- our relationships with our collaborators;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation or employee or independent contractor litigation;
- changes in the structure of healthcare payment systems;
- unfavorable geopolitical and economic conditions; and
- other events or factors, many of which are beyond our control.

The global economy, including credit and financial markets and the banking sector, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, supply chain shortages, increases in inflation rates, bank failures, higher interest rates and uncertainty about economic stability. For example, the ongoing wars in Ukraine and Israel have created volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets continue to deteriorate, it may make any necessary debt or equity financings more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs. In addition, higher inflation and macro turmoil and uncertainty could also adversely affect our buyers and sellers, which could reduce demand for our products. These factors may negatively affect the trading price of our common stock, regardless of our actual operating performance.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the trading prices of these companies' stock. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources, which could harm our business.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. As a newly public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the trading price of our common stock. While we currently have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

We are an "emerging growth company" and a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the last day of the fiscal year ending after the fifth anniversary of the IPO, or, if earlier, (i) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.235 billion, (ii) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30, or (iii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

In addition, we have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult. As a result of these elections, the information that we provide in this Quarterly Report may be different than the information investors may receive from other public companies in which they hold equity interests. In addition, it is possible that some investors will find our common stock less attractive as a result of these elections, which may result in a less active trading market for our common stock and higher volatility in our trading price.

Even after we no longer qualify as an emerging growth company, we may, under certain circumstances, still qualify as a “smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, or DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws;
- any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our restated certificate or our amended and restated bylaws;
- any claim or cause of action as to which the DGCL confers jurisdiction on the Court of Chancery of the state of Delaware; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may result in increased costs for investors to bring a claim. Further, these exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the trading price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only a portion of our directors stand for election at any given annual stockholder meeting;
- allow the authorized number of our directors to be changed from time to time by our shareholders or our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish requirements for stockholder proposals that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and allow actions by our stockholders by written consent, with certain requirements;
- limit who may call stockholder meetings; and
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

General risks

Unstable market and economic conditions may have serious adverse consequences on our business and financial condition.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions recently, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military conflict between Russia and Ukraine and increasing tensions between China and Taiwan have created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our service providers, manufacturers or other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget. We have experienced and may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in initiating or expanding clinical trials and manufacturing sufficient quantities of materials. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting.

Commencing with our fiscal year ending December 31, 2024, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We have never been required to test our internal control within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We may identify weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we fail to remediate our identified material weakness, or identify additional material weaknesses, in our internal control over financial reporting, if we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the trading price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC, or other regulatory authorities.

Our ability to utilize our net operating loss carryforwards and research tax credits to offset future taxable income may be subject to limitations.

As of December 31, 2023, we had approximately \$70.2 million of U.S. federal net operating loss carryforwards, or NOLs, \$139.3 million of U.S. state and local NOLs, and \$7.1 million of federal tax credits. U.S. federal NOLs generated in taxable years beginning after December 31, 2017, do not expire and may be carried forward indefinitely, but the deductibility of such NOLs is limited to no more than 80% of current year taxable income. Our U.S. state and local NOLs begin to expire in 2040 and our federal research tax credits begin to expire in 2041.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership by certain stockholders over a rolling three-year period, the corporation’s ability to use its pre-change NOLs and certain other pre-change tax attributes (such as research tax credits) to offset its post-change taxable income or taxes may be limited. If we undergo an ownership change, and our ability to use our pre-change NOLs and other pre-change tax attributes (such as tax credits) to offset our post-change income or taxes is limited, it would harm our future results of operations by effectively increasing our future tax obligations. U.S. state and local NOLs may be similarly limited. In addition, at the U.S. state and local level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase U.S. state and local taxes owed.

Irrespective of the above, our ability to utilize our NOLs and research tax credits to offset future taxable income or taxes is conditioned on our attaining profitability and generating taxable income. We do not know if and when we will generate sufficient taxable income to utilize our NOLs and research tax credits.

Changes in tax laws or regulations that are applied adversely to us or our customers may materially harm our business.

New tax laws, statutes, rules, regulations, or ordinances could be enacted at any time. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted differently, changed, repealed, or modified at any time. Any such enactment, interpretation, change, repeal, or modification could adversely affect us, possibly with retroactive effect. The Inflation Reduction Act, or IRA, enacted a 15% minimum tax on the adjusted financial statement income of certain large U.S. corporations for taxable years beginning after December 31, 2022, as well as a 1% excise tax on stock repurchases made by public corporations after December 31, 2022. Further, the Tax Cuts and Jobs Act of 2017, or the Tax Act, enacted many significant changes in U.S. federal tax laws, some of which were further modified by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, and may be modified in the future by the current or a future presidential administration. Among other changes, the Tax Act amended the Code to require that certain research and experimental expenditures be capitalized and amortized over five years if incurred in the United States or fifteen years if incurred in foreign jurisdictions for taxable years beginning after December 31, 2021. Although the U.S. Congress has considered legislation that would defer, modify, or repeal the capitalization and amortization requirement, there is no assurance that such changes will be made. If the requirement is not deferred, repealed, or otherwise modified, it may increase our cash taxes and effective tax rate. In addition, it is uncertain if and to what extent various states will conform to the IRA, the Tax Act, the CARES Act, or any future U.S. federal tax laws. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets, result in significant one-time charges, and increase our future U.S. tax expenses.

Our business and operations would suffer in the event of system failures, cyberattacks or a deficiency in our or our CMOs’, CROs’, manufacturers’, contractors’, consultants’ or collaborators’ cybersecurity.

Despite the implementation of security measures, our internal computer systems, as well as those of third parties on which we rely, are vulnerable to damage from, among other things, computer viruses, malware, unauthorized access, natural disasters, terrorism, war telecommunication and electrical failures, system malfunctions, cyberattacks or cyber-intrusions over the Internet, attachments to emails, phishing attacks, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could lead to the loss, destruction, alteration, prevention of access to, disclosure, dissemination of, or damage or unauthorized access to, our data (including trade secrets or other confidential information, intellectual property, proprietary business information and personal data) or data that is processed or maintained on our behalf, and cause interruptions in our operations, which could result in a material disruption of our product candidate development programs. For example, the loss of preclinical study or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, we cannot ensure that our information technology and infrastructure will prevent breakdowns or breaches in our or their systems or other cybersecurity incidents that cause loss, destruction, unavailability, alteration, dissemination of, or damage or unauthorized access to, our data, including personal data, assets and other data processed or maintained on our behalf, that could have a material adverse effect upon our reputation, business, operations or financial condition. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, and such an event could disrupt our operations, damage our reputation, and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay clinical development of our product candidates.

To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information or personal data, we could incur material legal claims and liability and damage to our reputation, and the further development of our product candidates could be delayed. Any such event could also compel us to comply with federal and state breach notification laws, and foreign law equivalents, subject us to mandatory corrective action and otherwise subject us to substantial liability under laws, rules, regulations and standards that protect the privacy and security of personal data, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Notifications and follow-up actions related to a data breach or other security incident could impact our reputation and cause us to incur significant costs, including significant legal expenses and remediation costs. We expect to incur significant costs in an effort to detect and prevent security incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security incident. However, we cannot guarantee that we will be able to detect or prevent any such incidents, or that we can remediate any such incidents in an effective or timely manner. Our efforts to improve security and protect data from compromise may also identify previously undiscovered instances of data breaches or other cybersecurity incidents. To the extent that any data breach, disruption or security incident were to result in any loss, destruction, or alteration of, damage, unauthorized access to or inappropriate or unauthorized disclosure or dissemination of, our data, including personal data, or other information that is processed or maintained on our behalf, we could be exposed to litigation and governmental investigations and inquiries, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with applicable state, federal and foreign privacy and security laws, rules, regulations and standards.

We incur increased costs and demands upon management as a result of being a public company.

As a public company listed in the United States, we incur significant additional legal, accounting and other expenses that we did not incur as a private company, including the cost of director and officer liability insurance. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the Nasdaq Stock Market, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors, or as members of senior management.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

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

Recent Sales of Unregistered Securities; Use of Proceeds

We did not issue any unregistered equity securities during the three months ended June 30, 2024.

Purchases of Equity Securities by the Issuer

Period	Total Number of Shares (or Units) Purchased	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
April 1, 2024 to April 30, 2024	779	\$ 4.87	—	—
May 1, 2024 to May 31, 2024	—	—	—	—
June 1, 2024 to June 30, 2024	2,212 ⁽¹⁾	\$ 4.18	—	—
Total	<u>2,991</u>	<u>\$ 13,046</u>	<u>—</u>	<u>—</u>

⁽¹⁾ We repurchased shares of our common stock that were previously issued upon the early exercise of employee stock options in connection with the exercise of our repurchase right upon cessation of service of certain of our employees.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The following exhibits are filed as part of this report:

<u>Exhibit Number</u>	<u>Description</u>	<u>Form</u>	<u>File No.</u>	<u>Number</u>	<u>Filing Date</u>
3.1	Amended and Restated Certificate of Incorporation of the Registrant (as amended and currently in effect)	8-K	001-41855	3.1	November 7, 2023
3.2	Amended and Restated Bylaws of the Registrant (as amended and currently in effect)	8-K	001-41855	3.2	November 7, 2023
10.1†*	2021 Equity Incentive Plan, as amended from time to time and Form of Stock Option Agreement, Early Exercise Notice and Restricted Stock Purchase Agreement, and Exercise Notice.				
10.2†*	Employment Agreement, dated April 10, 2024, by and between the Company and Jose Manuel Otero.				
10.3^*	Third License Agreement, dated April 21, 2024, by and between Cornell University and the Company.				
31.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1#	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	Inline XBRL Instance Document-the Instance Document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema Document				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101)				

* Filed herewith.

The information in Exhibit 32.1 shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act (including this Quarterly Report), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

† Indicates a management contract or any compensatory plan, contract or arrangement.

^ Portions of this agreement have been omitted pursuant to Item 601 of Regulation S-K.

SIGNATURES

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

LEXEO THERAPEUTICS, INC.

August 12, 2024

By: /s/ R. Nolan Townsend

R. Nolan Townsend
Chief Executive Officer and
Director (Principal Executive Officer and Principal
Financial Officer)

LEXEO THERAPEUTICS, INC.

2021 EQUITY INCENTIVE PLAN

1. Purposes of the Plan. The purposes of this Plan are (a) to attract and retain the best available personnel to ensure the Company's success and accomplish the Company's goals; (b) to incentivize Employees, Directors and Independent Contractors with long-term equity-based compensation to align their interests with the Company's stockholders, and (c) to promote the success of the Company's business. The Plan permits the grant of Incentive Stock Options, Nonstatutory Stock Options and Restricted Stock.

2. Definitions. As used herein, the following definitions will apply:

(a) "**Administrator**" means the Board or any of its Committees as will be administering the Plan, in accordance with Section 4 of the Plan.

(b) "**Affiliate**" means (i) an entity other than a Subsidiary which, together with the Company, is under common control of a third person or entity and (ii) an entity other than a Subsidiary in which the Company and/or one or more Subsidiaries own a controlling interest.

(c) "**Applicable Laws**" means all applicable laws, rules, regulations and requirements, including, but not limited to, all applicable U.S. federal or state laws, rules and regulations, the rules and regulations of any stock exchange or quotation system on which the Common Stock is listed or quoted, and the applicable laws, rules and regulations of any other country or jurisdiction where Awards are, or will be, granted under the Plan or Participants reside or provide services to the Company or any Parent or Subsidiary of the Company, as such laws, rules, and regulations shall be in effect from time to time.

(d) "**Award**" means, individually or collectively, a grant under the Plan of Options or Restricted Stock.

(e) "**Award Agreement**" means any written or electronic agreement setting forth the terms and provisions applicable to each Award granted under the Plan. All Award Agreements are subject to the terms and conditions of the Plan.

(f) "**Board**" means the Board of Directors of the Company.

(g) **“Cause”** means, with respect to the termination of a Participant’s status as a Service Provider, except as otherwise defined in an Award Agreement, (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or similar agreement in effect between the Company or an Affiliate of the Company and the Participant at the time of the grant of the Award (or where there is such an agreement but it does not define “cause” (or words of like import) or where it only applies upon the occurrence of a change in control and one has not yet taken place): (A) any material breach by Participant of any material written agreement between Participant and the Company; (B) any failure by Participant to comply with the Company’s material written policies or rules as they may be in effect from time to time; (C) neglect or persistent unsatisfactory performance of Participant’s duties; (D) Participant’s repeated failure to follow reasonable and lawful instructions from the Board or Chief Executive Officer; (E) Participant’s indictment for, conviction of, or plea of guilty or nolo contendere to, any felony or crime that results in, or is reasonably expected to result in, a material adverse effect on the business or reputation of the Company; (F) Participant’s commission of or participation in an act of fraud against the Company; (G) Participant’s intentional material damage to the Company’s business, property or reputation; or (H) Participant’s unauthorized use or disclosure of any proprietary information or trade secrets of the Company or any other party to whom the Participant owes an obligation of nondisclosure as a result of his or her relationship with the Company; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or similar agreement in effect between the Company or an Affiliate and the Participant at the time of the grant of the Award that defines “cause” (or words of like import), “cause” as defined under such agreement; provided, however, that with regard to any agreement under which the definition of “cause” only applies on occurrence of a change in control, such definition of “cause” shall not apply until a change in control actually takes place and then only with regard to a termination thereafter. For purposes of clarity, a termination without “Cause” does not include any termination that occurs solely as a result of Participant’s death or Disability. The determination as to whether a Participant’s status as a Service Provider for purposes of the Plan has been terminated for Cause shall be made in good faith by the Company and shall be final and binding on the Participant. The foregoing definition does not in any way limit the Company’s ability (or that of any Parent or Subsidiary or any successor thereto, as appropriate) to terminate a Participant’s employment or consulting relationship at any time, subject to Applicable Laws.

(h) **“Change in Control”** except as may otherwise be provided in an Award Agreement or other applicable agreement, means the occurrence of any of the following:

(i) The consummation of a merger or consolidation of the Company with or into another entity or any other corporate reorganization, if the Company’s stockholders immediately prior to such merger, consolidation or reorganization cease to directly or indirectly own immediately after such merger, consolidation or reorganization at least a majority of the combined voting power of the continuing or surviving entity’s securities outstanding immediately after such merger, consolidation or reorganization;

(ii) The consummation of the sale, transfer or other disposition of all or substantially all of the Company’s assets (other than (x) to a corporation or other entity of which at least a majority of its combined voting power is owned directly or indirectly by the Company, (y) to a corporation or other entity owned directly or indirectly by the shareholders of the Company in substantially the same proportions as their ownership of Common Stock or (z) to a continuing or surviving entity described in Section 2(h)(i) in connection with a merger, consolidation or reorganization which does not result in a Change in Control under Section 2(h)(i));

(iii) A change in the effective control of the Company which occurs on the date that a majority of members of the Board is replaced during any twelve (12) month period by Directors whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election; or

(iv) The consummation of any transaction as a result of which any Person becomes the “beneficial owner” (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing at least fifty percent (50%) of the total voting power represented by the Company’s then outstanding voting securities. For purposes of this Section 2(h), the term “Person” shall have the same meaning as when used in Sections 13(d) and 14(d) of the Exchange Act but shall exclude:

(1) a trustee or other fiduciary holding securities under an employee benefit plan of the Company or an affiliate of the Company;

(2) a corporation or other entity owned directly or indirectly by the stockholders of the Company in substantially the same proportions as their ownership of Common Stock;

(3) the Company; and

(4) a corporation or other entity of which at least a majority of its combined voting power is owned directly or indirectly by the Company.

A transaction shall not constitute a Change in Control if its sole purpose is to change the state of the Company's incorporation or to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transactions. In addition, if any Person (as defined above) is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same Person will not be considered to cause a Change in Control. If required for compliance with Code Section 409A, in no event will a Change in Control be deemed to have occurred if such transaction is not also a "change in the ownership or effective control of" the Company or "a change in the ownership of a substantial portion of the assets of" the Company as determined under Treasury Regulation Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder).

(i) "**Code**" means the Internal Revenue Code of 1986, as amended. Reference to a specific section of the Code or regulation thereunder shall include such section or regulation, any valid regulation promulgated under such section, and any comparable provision of any future legislation or regulation amending, supplementing or superseding such section or regulation.

(j) "**Code Section 409A**" means Section 409A of the Code, as amended from time to time, including the guidance and regulations promulgated thereunder and successor provisions, guidance and regulations thereto.

(k) "**Committee**" means a committee of Directors or of other individuals satisfying Applicable Laws appointed by the Board in accordance with Section 4 hereof.

(l) "**Common Stock**" means the common stock of the Company.

(m) "**Company**" means Lexeo Therapeutics, Inc., a Delaware corporation, or any successor thereto.

(n) "**Director**" means a member of the Board.

(o) "**Disability**" means total and permanent disability as defined in Section 22(e)(3) of the Code, provided that in the case of Awards other than Incentive Stock Options, the Administrator in its discretion may determine whether a permanent and total disability exists in accordance with uniform and non-discriminatory standards adopted by the Administrator from time to time.

(p) "**Effective Date**" means February 12, 2021.

(q) "**Employee**" means any person employed by the Company or any Parent or Subsidiary of the Company. Neither service as a Director nor payment of a director's fee by the Company will be sufficient to constitute "employment" by the Company.

(r) "**Exchange Act**" means the Securities Exchange Act of 1934, as amended.

(s) "**Exchange Program**" means a program under which outstanding Awards are amended to provide for a lower exercise price or surrendered or cancelled in exchange for (i) Awards with a lower exercise price, (ii) a different type of award under a different equity incentive plan, (iii) cash, or (iv) a combination of (i), (ii) and/or (iii). Notwithstanding the preceding, the term Exchange Program does not include (A) any action described in Section 10 or any action taken in connection with a Change in Control transaction nor (B) any transfer or other disposition permitted under Section 9. For the purpose of clarity, each of the actions described in the prior sentence, none of which constitute an Exchange Program, may be undertaken (or authorized) by the Administrator in its sole discretion without approval by the Company's stockholders.

(t) “**Fair Market Value**” means, as of any date, the value of Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or a national market system, its Fair Market Value will be the closing sales price for such stock (or the closing bid, if no sales were reported) as quoted on such exchange or system on the day of determination, as reported in such source as the Administrator deems reliable;

(ii) If the Common Stock is regularly quoted by a recognized securities dealer but selling prices are not reported, the Fair Market Value of a Share will be the mean between the high bid and low asked prices for the Common Stock on the day of determination, as reported in such source as the Administrator deems reliable; or

(iii) In the absence of an established market for the Common Stock, the Fair Market Value will be determined in good faith by the Administrator in compliance with Applicable Laws and regulations and in a manner that complies with Code Section 409A.

(u) “**Family Member**” means any child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law (including adoptive relationships) of a Participant, any person sharing the Participant’s household (other than a tenant or employee), a trust in which these persons (or the Participant) have more than 50% of the beneficial interest, a foundation in which these persons (or the Participant) control the management of assets, and any other entity in which these persons (or the Participant) own more than 50% of the voting interests.

(v) “**Fiscal Year**” means the fiscal year of the Company.

(w) “**Incentive Stock Option**” means an Option that by its terms qualifies and is intended to qualify as an incentive stock option within the meaning of Section 422 of the Code and the regulations promulgated thereunder.

(x) “**Independent Contractor**” means any person, including an advisor, consultant or agent, engaged by the Company or a Parent or Subsidiary to render services to such entity or who renders, or has rendered, services to the Company, or any Parent, Subsidiary or Affiliate and is compensated for such services.

(y) “**Nonstatutory Stock Option**” means an Option that by its terms does not qualify or is not intended to qualify as an Incentive Stock Option.

(z) “**Option**” means a stock option granted pursuant to the Plan.

(aa) “**Parent**” means any corporation (other than the Company) in an unbroken chain of corporations ending with the Company if each of the corporations other than the Company owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other corporations in such chain. A corporation that attains the status of a Parent on a date after the adoption of the Plan shall be considered a Parent commencing as of such date.

(bb) “**Participant**” means the holder of an outstanding Option.

(cc) “**Period of Restriction**” means the period during which the transfer of Shares of Restricted Stock are subject to restrictions and therefore, the Shares are subject to a substantial risk of forfeiture.

(dd) “**Plan**” means this 2021 Equity Incentive Plan, as it may be amended from time to time.

(ee) “**Service Provider**” means an Employee, Director or Independent Contractor.

(ff) “**Share**” means a share of the Common Stock, as adjusted in accordance with Section 10 of the Plan.

(gg) “**Subsidiary**” means any corporation (other than the Company) in an unbroken chain of corporations beginning with the Company if each of the corporations other than the last corporation in the unbroken chain owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other corporations in such chain. A corporation that attains the status of a Subsidiary on a date after the adoption of the Plan shall be considered a Subsidiary commencing as of such date.

(hh) “**Tax-Related Items**” means income tax, social insurance or other social contributions, national insurance, social security, payroll tax, fringe benefits tax, payment on account or other tax-related items.

3. Stock Subject to the Plan.

(a) **Stock Subject to the Plan**. Subject to the provisions of Section 10 of the Plan, the maximum aggregate number of Shares that may be issued under the Plan shall be [●] Shares. The Shares may be authorized, but unissued, or reacquired Common Stock. Notwithstanding the foregoing, subject to the provisions of Section 10 below, in no event shall the maximum aggregate number of Shares that may be issued under the Plan pursuant to Incentive Stock Options exceed the number set forth in this Section 3(a) plus, to the extent allowable under Section 422 of the Code and the regulations promulgated thereunder, any Shares that again become available for issuance pursuant to Section 3(b).

(b) **Lapsed Awards**. To the extent an Award should expire or be forfeited or become unexercisable for any reason without having been exercised in full, or is surrendered pursuant to an Exchange Program, the unissued Shares that were subject thereto shall, unless the Plan shall have been terminated, continue to be available under the Plan for issuance pursuant to future Awards. In addition, any Shares which are retained by the Company in order to satisfy the exercise or purchase price for any Award or any withholding taxes due with respect to any Award shall be treated as not issued and shall continue to be available under the Plan for issuance pursuant to future Awards. Shares issued under the Plan and later forfeited to the Company due to the failure to vest or repurchased by the Company at the original purchase price paid to the Company for the Shares (including, without limitation, upon forfeiture to or repurchase by the Company in connection with a Participant ceasing to be a Service Provider) shall again be available for future grant under the Plan.

4. Administration of the Plan.

(a) **Procedure**.

(i) **Multiple Administrative Bodies**. Different Committees with respect to different groups of Service Providers may administer the Plan.

(ii) **Other Administration**. Other than as provided above, the Plan will be administered by (A) the Board or (B) a Committee, which committee will be constituted to satisfy Applicable Laws.

(b) **Powers of the Administrator**. Subject to the provisions of the Plan, the Administrator will have the authority, in its discretion:

(i) to determine the Fair Market Value in accordance with Section 2(c);

(ii) to select the Service Providers to whom Awards may be granted hereunder;

(iii) to determine the number of Shares to be covered by each Award granted hereunder;

(iv) to approve forms of Award Agreements for use under the Plan;

(v) to determine the terms and conditions, not inconsistent with the terms of the Plan, of any Award granted hereunder; such terms and conditions include, but are not limited to, the exercise price, the time or times when Options may be exercised (which may be based on performance criteria), any vesting acceleration or waiver of forfeiture restrictions, and any restriction or limitation regarding any Award or the Shares relating thereto, based in each case on such factors as the Administrator will determine;

(vi) to institute and determine the terms and conditions of an Exchange Program; provided, however, that the Administrator shall not implement an Exchange Program without the approval of the holders of a majority of the Shares that are present in person or by proxy and entitled to vote at any annual or special meeting of Company's stockholders;

(vii) to construe and interpret the terms of the Plan and Awards granted pursuant to the Plan;

(viii) to prescribe, amend and rescind rules and regulations relating to the Plan, including rules and regulations established for the purpose of satisfying applicable non-U.S. laws, for qualifying for favorable tax treatment under applicable non-U.S. laws or facilitating compliance with non-U.S. laws (sub-plans may be created for any of these purposes);

(ix) to modify or amend each Award (subject to Section 17 of the Plan), including but not limited to the discretionary authority to extend the post-termination exercisability period of Options, to accelerate vesting and to extend the maximum term of an Option (subject to Section 6(b) of the Plan regarding Incentive Stock Options);

(x) to allow Participants to satisfy tax withholding obligations in such manner as prescribed in Section 11 of the Plan;

(xi) to authorize any person to execute on behalf of the Company any instrument required to effect the grant of an Award previously granted by the Administrator;

(xii) to allow a Participant to defer the receipt of the payment of cash or the delivery of Shares that would otherwise be due to such Participant under an Award; and

(xiii) to make all other determinations deemed necessary or advisable for administering the Plan.

(c) **Effect of Administrator's Decision.** The Administrator's decisions, determinations and interpretations will be final and binding on all Participants and any other holders of Awards.

(d) **Delegation by the Administrator.** To the extent permitted by Applicable Laws, the Administrator, in its sole discretion and on such terms and conditions as it may provide, may delegate all or any part of its authority and powers under the Plan to one or more Directors or officers of the Company.

5. Award Eligibility. Nonstatutory Stock Options and Restricted Stock may be granted to Service Providers. Incentive Stock Options may be granted only to Employees.

6. Stock Options.

(a) **Limitations.** Each Option will be designated in the Award Agreement as either an Incentive Stock Option or a Nonstatutory Stock Option. However, notwithstanding such designation, to the extent that the aggregate Fair Market Value of the Shares with respect to which Incentive Stock Options are exercisable for the first time by the Participant during any calendar year (under all plans of the Company and any Parent or Subsidiary) exceeds one hundred thousand dollars (\$100,000), such Options will be treated as Nonstatutory Stock Options. For purposes of this Section 6(a), Incentive Stock Options will be taken into account in the order in which they were granted. The Fair Market Value of the Shares will be determined as of the date the Option with respect to such Shares is granted. With respect to the Committee's authority in Section 4(b)(ix), if, at the time of any such extension, the exercise price per Share of the Option is less than the Fair Market Value of a Share, the extension shall, unless otherwise determined by the Committee, be limited to the earlier of (1) the maximum term of the Option as set by its original terms, or (2) ten (10) years from the grant date. Unless otherwise determined by the Committee, any extension of the term of an Option pursuant to Section 4(b)(ix) shall comply with Code Section 409A to the extent necessary to avoid taxation thereunder.

(b) **Term of Option.** The term of each Option will be stated in the Award Agreement. In the case of an Incentive Stock Option, the term will be ten (10) years from the date of grant or such shorter term as may be provided in the Award Agreement. Moreover, in the case of an Incentive Stock Option granted to a Participant who, at the time the Incentive Stock Option is granted, owns stock representing more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or any Parent or Subsidiary, the term of the Incentive Stock Option will be five (5) years from the date of grant or such shorter term as may be provided in the Award Agreement.

(c) Option Exercise Price and Consideration.

(i) **Exercise Price.** The per share exercise price for the Shares to be issued pursuant to exercise of an Option will be determined by the Administrator, subject to the following:

(1) In the case of an Incentive Stock Option

(A) granted to an Employee who, at the time the Incentive Stock Option is granted, owns stock representing more than ten percent (10%) of the voting power of all classes of stock of the Company or any Parent or Subsidiary, the per Share exercise price will be no less than one hundred ten percent (110%) of the Fair Market Value per Share on the date of grant.

(B) granted to any Employee other than an Employee described in paragraph (A) immediately above, the per Share exercise price will be no less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant.

(2) In the case of a Nonstatutory Stock Option, the per Share exercise price will be no less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant.

(3) Notwithstanding the foregoing, Options may be granted with a per Share exercise price of less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant pursuant to a transaction described in, and in a manner consistent with, Section 424(a) of the Code.

(ii) **Waiting Period and Exercise Dates.** At the time an Option is granted, the Administrator will fix the period within which the Option may be exercised and will determine any conditions that must be satisfied before the Option may be exercised.

(iii) **Form of Consideration.** The Administrator will determine the acceptable form of consideration for exercising an Option, including the method of payment. In the case of an Incentive Stock Option, the Administrator will determine the acceptable form of consideration at the time of grant. Such consideration for both types of Options may consist entirely of: (1) cash; (2) check (subject to collection); (3) promissory note, to the extent permitted by Applicable Laws; (4) other Shares, provided that such Shares have a Fair Market Value on the date of surrender equal to the aggregate exercise price of the Shares as to which such Option will be exercised and provided that accepting such Shares will not result in any adverse accounting consequences to the Company, as the Administrator determines in its sole discretion; (5) consideration received by the Company under a broker-assisted (or other) cashless exercise program (whether through a broker or otherwise) implemented by the Company in connection with the Plan; (6) by net exercise; (7) such other consideration and method of payment for the issuance of Shares to the extent permitted by Applicable Laws; or (8) any combination of the foregoing methods of payment.

(d) **Exercise of Option.**

(i) **Procedure for Exercise; Rights as a Stockholder.** Any Option granted hereunder will be exercisable according to the terms of the Plan and at such times and under such conditions as determined by the Administrator and set forth in the Award Agreement. An Option may not be exercised for a fraction of a Share.

An Option will be deemed exercised when the Company receives: (i) a notice of exercise (in such form as the Administrator may specify from time to time) from the person entitled to exercise the Option, and (ii) full payment for the Shares with respect to which the Option is exercised (together with full payment of any applicable taxes or other amounts required to be withheld or deducted with respect to the Option). Full payment may consist of any consideration and method of payment authorized by the Administrator and permitted by the Award Agreement and the Plan. Shares issued upon exercise of an Option will be issued in the name of the Participant. Until the Shares are issued (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), no right to vote or receive dividends or any other rights as a stockholder will exist with respect to the Shares subject to an Option, notwithstanding the exercise of the Option. The Company will issue (or cause to be issued) such Shares promptly after the Option is exercised. No adjustment will be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Section 10 of the Plan.

(ii) **Termination of Relationship as a Service Provider.** If a Participant ceases to be a Service Provider, other than upon the Participant's termination as the result of the Participant's death, Disability or Cause, the Participant may exercise his or her Option within such period of time as is specified in the Award Agreement to the extent that the Option is vested on the date of termination (but in no event later than the expiration of the term of such Option as set forth in the Award Agreement). In the absence of a specified time in the Award Agreement, the Option will remain exercisable for three (3) months following the Participant's termination. Unless otherwise provided by the Administrator, if on the date of termination the Participant is not vested as to his or her entire Option, the Shares covered by the unvested portion of the Option will revert to the Plan. If after termination the Participant does not exercise his or her Option within the time specified by the Administrator, the Option will terminate, and the Shares covered by such Option will revert to the Plan.

(iii) **Disability of Participant.** If a Participant ceases to be a Service Provider as a result of the Participant's Disability, the Participant may exercise his or her Option within such period of time as is specified in the Award Agreement to the extent the Option is vested on the date of termination (but in no event later than the expiration of the term of such Option as set forth in the Award Agreement). In the absence of a specified time in the Award Agreement, the Option will remain exercisable for twelve (12) months following the Participant's termination as a result of the Participant's Disability. Unless otherwise provided by the Administrator, if on the date of termination the Participant is not vested as to his or her entire Option, the Shares covered by the unvested portion of the Option will revert to the Plan. If after termination the Participant does not exercise his or her Option within the time specified herein, the Option will terminate, and the Shares covered by such Option will revert to the Plan.

(iv) **Death of Participant.** If a Participant dies while a Service Provider, the Option may be exercised following the Participant's death within such period of time as is specified in the Award Agreement to the extent that the Option is vested on the date of death (but in no event may the Option be exercised later than the expiration of the term of such Option as set forth in the Award Agreement), by the Participant's designated beneficiary, provided such beneficiary has been designated prior to Participant's death in a form acceptable to the Administrator. If no such beneficiary has been designated by the Participant, then such Option may be exercised by the personal representative of the Participant's estate or by the person(s) to whom the Option is transferred pursuant to the Participant's will or in accordance with the laws of descent and distribution. In the absence of a specified time in the Award Agreement, the Option will remain exercisable for twelve (12) months following the Participant's death. Unless otherwise provided by the Administrator, if on the date of termination the Participant is not vested as to his or her entire Option, the Shares covered by the unvested portion of the Option will revert to the Plan. If the Option is not so exercised within the time specified herein, the Option will terminate, and the Shares covered by such Option will revert to the Plan.

(v) **Termination for Cause.** If a Participant ceases to be a Service Provider as a result of being terminated for Cause, any outstanding Option (including any vested portion thereof) held by such Participant shall immediately terminate in its entirety upon the Participant being first notified of his or her termination for Cause and the Participant will be prohibited from exercising his or her Option from and after the date of such termination. All the Participant's rights under any Option, including the right to exercise the Option, may be suspended pending an investigation of whether Participant will be terminated for Cause.

7. Restricted Stock.

(a) **Grant of Restricted Stock.** Restricted Stock may be granted at any time and from time to time as determined by the Administrator. After the Administrator determines that it will grant Restricted Stock under the Plan, it will advise the Participant in an Award Agreement of the terms, conditions, and restrictions (if any) related to the grant, including the number of Shares of Restricted Stock.

(b) **Restricted Stock Agreement.** Each Award of Restricted Stock will be evidenced by an Award Agreement that will specify the Period of Restriction, the number of Shares granted, and such other terms and conditions as the Administrator, in its sole discretion, will determine. Unless the Administrator determines otherwise, the Company as escrow agent will hold Shares of Restricted Stock until the restrictions on such Shares have lapsed.

(c) **Transferability.** Except as provided in this Section 7 or the Award Agreement, Shares of Restricted Stock may not be sold, transferred, pledged, assigned, or otherwise alienated or hypothecated until the end of the applicable Period of Restriction.

(d) **Other Restrictions.** The Administrator, in its sole discretion, may impose such other restrictions on Shares of Restricted Stock as it may deem advisable or appropriate.

(e) **Removal of Restrictions.** Except as otherwise provided in this Section 7, Shares of Restricted Stock covered by each Restricted Stock grant made under the Plan will be released from escrow as soon as practicable after the last day of the Period of Restriction or at such other time as the Administrator may determine. The Administrator, in its discretion, may accelerate the time at which any restrictions will lapse or be removed.

(f) **Voting Rights.** During the Period of Restriction, Service Providers holding Shares of Restricted Stock granted hereunder may exercise full voting rights with respect to those Shares, unless the Administrator determines otherwise.

(g) **Dividends and Other Distributions.** During the Period of Restriction, any dividends or distributions paid with respect to Shares of Restricted Stock will be subject to the same restrictions, including without limitation restrictions on transferability and forfeitability, as the Shares of Restricted Stock with respect to which they were paid.

(h) **Return of Restricted Stock to Company.** On the date set forth in the Award Agreement, the Restricted Stock for which restrictions have not lapsed will be cancelled and returned as unissued shares to the Company and again will become available for grant under the Plan.

8. Leaves of Absence/Transfer Between Locations. The Administrator shall have the discretion to determine at any time whether and to what extent the vesting of Awards shall be suspended during any leave of absence; provided, however, that in the absence of such determination, vesting of Awards shall continue during any paid leave and shall be suspended during any unpaid leave of greater than thirty (30) days (unless otherwise required by Applicable Laws). A Participant will not cease to be an Employee in the case of (a) any leave of absence approved by the Participant's employer or (b) transfers between locations of the Company or between the Company, its Parent, or any Subsidiary. If an Employee is holding an Incentive Stock Option and such leave exceeds three (3) months then, for purposes of Incentive Stock Option status only, such Employee's service as an Employee shall be deemed terminated on the first (1st) day following such three (3) month period and the Incentive Stock Option shall thereafter automatically treated for tax purposes as a Nonstatutory Stock Option in accordance with Applicable Laws, unless reemployment upon the expiration of such leave is guaranteed by contract or statute, or unless provided otherwise pursuant to a written Company policy.

9. Non-Transferability of Awards and Shares Underlying Awards.

(a) **Non-Transferability of Awards.**

(i) **General.** Except as set forth in this Section 9, Awards (or any rights of such Awards) may not be sold, pledged, encumbered, assigned, hypothecated, or disposed of or otherwise transferred in any manner other than by will or by the laws of descent or distribution. The designation of a beneficiary by a Participant pursuant to this Plan and the applicable Award Agreement will not constitute a transfer. An Option may be exercised, during the lifetime of the holder of the Option, only by such holder or a transferee permitted by this Section 9.

(ii) **Limited Transferability Rights.** Notwithstanding anything else in this Section 9, the Administrator may in its sole discretion provide that any Nonstatutory Stock Options may be transferred by instrument to an inter vivos or testamentary trust in which the Options are to be passed to beneficiaries upon the death of the trustor (settlor) or by gift to Family Members. Further, beginning with (1) the period when the Company begins to rely on the exemption described in Rule 12h-1(f)(1) promulgated under the Exchange Act, as determined by the Board in its sole discretion, and (2) ending on the earlier of (x) the date when the Company ceases to rely on such exemption, as determined by the Board in its sole discretion, or (y) the date when the Company becomes subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act, an Option, or prior to exercise, the Shares subject to the Option, may not be pledged, hypothecated or otherwise transferred or disposed of, in any manner, including by entering into any short position, any "put equivalent position" or any "call equivalent position" (as defined in Rule 16a-1(h) and Rule 16a-1(b) of the Exchange Act, respectively), other than to persons who are Family Members through gifts or domestic relations orders, or to an executor or guardian of the Participant upon the death or disability of the Participant. Notwithstanding the foregoing sentence, the Board, in its sole discretion, may permit transfers of Nonstatutory Stock Options to the Company or in connection with a Change in Control or other acquisition transactions involving the Company to the extent permitted by Rule 12h-1(f).

(b) **Non-Transferability of Stock Underlying Awards.**

(i) **General.** Notwithstanding anything to the contrary, no Participant or other stockholder shall Transfer (as such term is defined below) any Shares (or any rights of or interests in such Shares) acquired pursuant to any Award to any person or entity unless such Transfer is approved by the Company prior to such Transfer, which approval may be granted or withheld in the Company's sole and absolute discretion. "Transfer" shall mean, with respect to any security, the direct or indirect assignment, sale, transfer, tender, pledge, hypothecation, or the grant, creation or suffrage of a lien or encumbrance in or upon, or the gift, placement in trust, or the Constructive Sale (as such term is defined below) or other disposition of such security (including transfer by testamentary or intestate succession, merger or otherwise by operation of law) or any right, title or interest therein (including, but not limited to, any right or power to vote to which the holder thereof may be entitled, whether such right or power is granted by proxy or otherwise), or the record or beneficial ownership thereof, the offer to make such a sale, transfer, Constructive Sale or other disposition, and each agreement, arrangement or understanding, whether or not in writing, to effect any of the foregoing. "Constructive Sale" shall mean, with respect to any security, a short sale with respect to such security, entering into or acquiring an offsetting derivative contract with respect to such security, entering into or acquiring a futures or forward contract to deliver such security, or entering into any other hedging or other derivative transaction that has the effect of materially changing the economic benefits and risks of ownership. Any purported Transfer effected in violation of this Section 13 shall be null and void and shall have no force or effect and the Company shall not be required (x) to transfer on its books any Shares that have been sold or otherwise transferred in violation of any of the provisions of the Plan or (y) to treat as owner of such Shares or to accord the right to vote or pay dividends to any purchaser or other transferee to whom such Shares shall have been so transferred.

(ii) **Approval Process.** Any Participant or stockholder seeking the approval of the Company to Transfer some or all of its Shares shall give written notice thereof to the Secretary of the Company that shall include: (1) the name of the stockholder; (2) the proposed transferee; (3) the number of shares of the Transfer of which approval is thereby requested; and (4) the purchase price, if any, of the shares proposed for Transfer. The Company may require the Participant to supplement its notice with such additional information as the Company may request or as may otherwise be required by the applicable Award Agreement or other applicable written agreement. In addition, such request for Transfer shall be subject to such right of first refusal, transfer provisions and any other terms and conditions as may be set forth in the applicable Award Agreement or other applicable written agreement.

10.Adjustments; Dissolution or Liquidation; Merger or Change in Control.

(a) **Adjustments.** In the event of a stock split, reverse stock split, stock dividend, combination, consolidation, recapitalization (including a recapitalization through a large nonrecurring cash dividend) or reclassification of the Shares, subdivision of the Shares, a rights offering, a reorganization, merger, spin-off, split-up, repurchase, or exchange of Common Stock or other securities of the Company or other significant corporate transaction, or other change affecting the Common Stock occurs, the Administrator, in order to prevent dilution, diminution or enlargement of the benefits or potential benefits intended to be made available under the Plan, will, in such manner as it may deem equitable, adjust the number, kind and class of securities that may be delivered under the Plan and/or the number, class, kind and price of securities covered by each outstanding Award. Notwithstanding the forgoing, all adjustments under this Section 10 shall be made in a manner that does not result in taxation under Code Section 409A.

(b) **Dissolution or Liquidation.** In the event of the proposed winding up, dissolution or liquidation of the Company, the Administrator will notify each Participant as soon as practicable prior to the effective date of such proposed transaction. To the extent it has not been previously exercised, an Award will terminate immediately prior to the consummation of such proposed action.

(c) **Change in Control.** In the event of a Change in Control, each outstanding Award (vested or unvested) will be treated as the Administrator determines, which determination may be made without the consent of any Participant and need not treat all outstanding Awards (or portion thereof) in an identical manner. Such determination, without the consent of any Participant, may provide (without limitation) for one or more of the following in the event of a Change in Control: (i) the continuation of such outstanding Awards by the Company (if the Company is the surviving corporation); (ii) the assumption of such outstanding Awards by the surviving corporation or its parent; (iii) the substitution by the surviving corporation or its parent of new options or other equity awards for such Awards; (iv) the cancellation of such Awards in exchange for a payment to the Participants equal to the excess, if any, of (1) the Fair Market Value of the Shares subject to such Awards as of the closing date of such Change in Control over (2) the exercise or purchase price paid or to be paid for the Shares subject to the Awards; provided that at the discretion of the Administrator, such payment may be subject to the same conditions that apply to the consideration that will be paid to holders of Shares in connection with the transaction; provided, however, that any payout in connection with a terminated award shall comply with Code Section 409A to the extent necessary to avoid taxation thereunder; or (E) the opportunity for Participants to exercise the Options prior to the occurrence of the Change in Control and the termination (for no consideration) upon the consummation of such Change in Control of any Options not exercised prior thereto.

11. Tax.

(a) **Withholding Requirements.** Prior to the delivery of any Shares or cash pursuant to an Award (or exercise thereof) or prior to any time the Awards or Shares are subject to taxation or other Tax-Related Items, the Company and/or the Participant's employer will have the power and the right to deduct or withhold, or require a Participant to remit to the Company, an amount sufficient to satisfy any Tax-Related Items or other items that are required to be withheld or deducted or otherwise applicable with respect to such Award.

(b) **Withholding Arrangements.** The Administrator, in its sole discretion and pursuant to such procedures as it may specify from time to time, may permit a Participant to satisfy such withholding or deduction obligations or any other Tax-Related Items, in whole or in part by (without limitation) (i) paying cash, (ii) electing to have the Company withhold otherwise deliverable cash or Shares, or (iii) delivering to the Company already-owned Shares; provided that, unless specifically permitted by the Company, any proceeds derived from a cashless exercise must be an approved broker-assisted cashless exercise or the cash or Shares withheld or delivered must be limited to avoid financial accounting charges under applicable accounting guidance or Shares must have been previously held for the minimum duration required to avoid financial accounting charges under applicable accounting guidance. Except as otherwise determined by the Administrator, the Fair Market Value of the Shares to be withheld or delivered will be determined as of the date that the amounts are required to be withheld or deducted.

(c) **Compliance With Code Section 409A.** Awards will be designed and operated in such a manner that they are either exempt from the application of, or comply with, the requirements of Code Section 409A such that the grant, payment, settlement or deferral will not be subject to the additional tax or interest applicable under Code Section 409A. The Plan and each Award Agreement under the Plan is intended to meet the requirements of Code Section 409A (or an exemption therefrom) and will be construed and interpreted in accordance with such intent, except as otherwise determined in the sole discretion of the Administrator. To the extent that an Award or payment, or the settlement or deferral thereof, is subject to Code Section 409A the Award will be granted, paid, settled or deferred in a manner that will meet the requirements of Code Section 409A (or an exemption therefrom), such that the grant, payment, settlement or deferral will not be subject to the additional tax or interest applicable under Code Section 409A. In no event will the Company be responsible for or reimburse a Participant for any taxes or other penalties incurred as a result of the application of Code Section 409A.

12. No Effect on Employment or Service. Neither the Plan nor any Award will confer upon a Participant any right with respect to continuing the Participant's relationship as a Service Provider with the Company or any Subsidiary or Affiliate, nor will they interfere in any way with the Participant's right or the Company's or any Subsidiary or Affiliate's right to terminate such relationship at any time, with or without cause, to the extent permitted by Applicable Laws.

13. Date of Grant. The date of grant of an Award will be, for all purposes, the date on which the granting of an Award is authorized, or such other date as may be specified in such authorization.

14. Corporate Records Control. In the event that the corporate records (e.g., Board consents, resolutions or minutes) documenting the corporate action constituting the grant contain terms (e.g., exercise price, vesting schedule or number of shares) that are inconsistent with those in the Award Agreement or related grant documents as a result of a clerical error in the papering of the Award Agreement or related grant documents, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Award Agreement or related grant documents.

15. Clawback/Recovery. All Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the U.S. Dodd-Frank Wall Street Reform and Consumer Protection Act or other Applicable Laws. In addition, the Board may impose such other clawback, recovery or recoupment provisions in an Award Agreement as the Board determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired Shares or other cash or property upon the occurrence of an event constituting Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for "good reason" or "constructive termination" (or similar term) under any agreement with the Company.

16. Term of Plan. Subject to Section 20 of the Plan, this Plan will become effective as of the Effective Date. The Plan will continue in effect until terminated under Section 17 of the Plan.

17. Amendment and Termination of the Plan.

(a) **Amendment and Termination.** The Administrator may at any time amend, alter, suspend or terminate the Plan.

(b) **Stockholder Approval.** The Company will obtain stockholder approval of any Plan amendment to the extent necessary and desirable to comply with Applicable Laws.

(c) **Effect of Amendment or Termination.** No amendment, alteration, suspension or termination of the Plan will materially impair the rights of any Participant, unless mutually agreed otherwise between the Participant and the Administrator, which agreement must be in writing and signed by the Participant and the Company. Termination of the Plan will not affect the Administrator's ability to exercise the powers granted to it hereunder with respect to Awards granted under the Plan prior to the date of such termination.

18. Conditions Upon Issuance of Shares.

(a) **Legal Compliance.** Shares will not be issued pursuant to the exercise or vesting (as applicable) of an Award unless the exercise or vesting of such Award and the issuance and delivery of such Shares will comply with Applicable Laws and will be further subject to the approval of counsel for the Company with respect to such compliance.

(b) **Investment Representations.** As a condition to the exercise of an Award, the Company may require the person exercising such Award to represent and warrant at the time of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares if, in the opinion of counsel for the Company, such a representation is required.

19. Inability to Obtain Authority. The inability of the Company to obtain authority from any regulatory body having jurisdiction, which authority is deemed by the Company's counsel to be necessary to the lawful issuance and sale of any Shares hereunder, will relieve the Company of any liability in respect of the failure to issue or sell such Shares as to which such requisite authority will not have been obtained.

20. Stockholder Approval. The Plan will be subject to approval by the stockholders of the Company within twelve (12) months after the date the Plan is adopted by the Board. Such stockholder approval will be obtained in the manner and to the degree required under Applicable Laws.

21. Notices and Agreements. Any notices, agreements or communications provided pursuant to the Plan will be given in writing, in a form provided by the Company (including documents delivered in electronic form). Unless specifically provided for in the Plan, notices, agreements or communications will be deemed effectively given upon receipt (including documents delivered in electronic form).

22. Governing Law. The Plan and all Awards hereunder shall be construed in accordance with and governed by the laws of the State of Delaware, but without regard to its conflict of law provisions.

LEXEO THERAPEUTICS, INC.

AMENDMENT TO 2021 EQUITY INCENTIVE PLAN

1. This Amendment to the Lexeo Therapeutics, Inc. 2021 Equity Incentive Plan (this “*Amendment*”) is dated August 10, 2021, and amends the 2021 Equity Incentive Plan (as amended, the “*Plan*”) pursuant to Section 17 of the Plan.

Unless otherwise expressly provided for in this Amendment, all capitalized words or phrases or other defined terms used in this Amendment will have the same meaning ascribed to them in the Plan.

2. Section 3(a) of the Plan is amended and restated in its entirety to read as follows:

“Subject to the provisions of Section 10 of the Plan, the maximum aggregate number of Shares that may be issued under the Plan shall be 28,937,950 Shares. The Shares may be authorized, but unissued, or reacquired Common Stock.”

[Signature Page Follows]

I hereby certify that the foregoing Amendment was duly approved by the Board of Directors and the Stockholders of Lexeo Therapeutics, Inc., effective as of the date set forth above.

By: /s/ R. Nolan Townsend

Name: R. Nolan Townsend

Title: Chief Executive Officer

LEXEO THERAPEUTICS, INC.

AMENDMENT TO 2021 EQUITY INCENTIVE PLAN

1. This Amendment to the Lexeo Therapeutics, Inc. 2021 Equity Incentive Plan (this “*Amendment*”) is dated November 4, 2021, and amends the 2021 Equity Incentive Plan (as amended, the “*Plan*”) pursuant to Section 17 of the Plan.

Unless otherwise expressly provided for in this Amendment, all capitalized words or phrases or other defined terms used in this Amendment will have the same meaning ascribed to them in the Plan.

2. Section 3(a) of the Plan is amended and restated in its entirety to read as follows:

“Subject to the provisions of Section 10 of the Plan, the maximum aggregate number of Shares that may be issued under the Plan shall be 32,326,544 Shares. The Shares may be authorized, but unissued, or reacquired Common Stock.”

[Signature Page Follows]

I hereby certify that the foregoing Amendment was duly approved by the Board of Directors and the Stockholders of Lexeo Therapeutics, Inc., effective as of the date set forth above.

By: /s/ R. Nolan Townsend

Name: R. Nolan Townsend

Title: Chief Executive Officer

LEXEO THERAPEUTICS, INC.
2021 EQUITY INCENTIVE PLAN
STOCK OPTION AWARD AGREEMENT

Unless otherwise defined herein, the terms defined in the Lexeo Therapeutics, Inc. 2021 Equity Incentive Plan (the “**Plan**”) will have the same defined meanings in this Stock Option Award Agreement (the “**Award Agreement**”).

NOTICE OF STOCK OPTION GRANT

Participant Name:

You have been granted an Option to purchase Common Stock of Lexeo Therapeutics, Inc. (the “**Company**”), subject to the terms and conditions of the Plan and this Award Agreement, as follows:

Grant Number	<u>CS-00</u>
Date of Grant	_____
Vesting Commencement Date	_____
Exercise Schedule	<u>The Option is immediately exercisable.</u>
Exercise Price per Share	USD \$ _____
Total Number of Shares	_____
Total Exercise Price	USD \$ _____
Type of Option:	<u> X </u> Incentive Stock Option _____ Nonstatutory Stock Option
Term/Expiration Date:	<u>10 Year Term</u>
Vesting Schedule:	<u>See Below</u>

Subject to Section 2 of this Award Agreement, this Option shall vest in accordance with the following schedule: Twenty-five percent (25%) of the Total Number of Shares shall vest on the 12-month anniversary of the _____ and 1/48 of the Total Number of Shares shall vest on the corresponding day of each month thereafter (and if there is no corresponding day, the last day of the month).

In addition, if Participant remains a continuous Service Provider in good standing through and including the date of the consummation of the Change in Control, then, effective as of, and contingent upon, the consummation of the Change in Control, 100% of this Option shall become fully vested and exercisable as of immediately prior to and contingent upon the consummation of such Change in Control.

Termination Period:

This Option, to the extent then vested, will be exercisable for three (3) months after Participant ceases to be a Service Provider, unless such termination is due to Participant's death, Disability or Cause. If Participant's relationship as a Service Provider is terminated as a result of the Service Provider's death or Disability, this Option, to the extent then vested, will be exercisable for twelve (12) months after Participant ceases to be a Service Provider. If Participant's relationship as a Service Provider is terminated for Cause, this Option (including any vested portion thereof) shall immediately terminate in its entirety upon Participant being first notified such termination for Cause and Participant will be prohibited from exercising this Option from and after the date of such termination. Notwithstanding the foregoing, in no event may this Option be exercised after the Term/Expiration Date as provided above and may be subject to earlier termination as provided in Section 10 of the Plan.

By Participant's signature and the signature of the Company's representative below, or by Participant otherwise accepting or exercising this Option, Participant and the Company agree that this Option is granted under and governed by the terms and conditions of the Plan and this Award Agreement, including the Terms and Conditions of Stock Option Grant, attached hereto as Exhibit A, all of which are made a part of this document. Participant has reviewed the Plan and this Award Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Award Agreement and fully understands all provisions of the Plan and Award Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator on any questions relating to the Plan and Award Agreement.

By Participant's signature and the signature of the Company's representative below, or by Participant otherwise accepting or exercising this Option, Participant and the Company agree that this Option is granted under and governed by the terms and conditions of the Plan and this Award Agreement, including the Terms and Conditions of Stock Option Grant, attached hereto as Exhibit A, all of which are made a part of this document. Participant has reviewed the Plan and this Award Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Award Agreement and fully understands all provisions of the Plan and Award Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator on any questions relating to the Plan and Award Agreement.

PARTICIPANT:

LEXEO THERAPEUTICS, INC.

Signature

By

Print Name

Title

EXHIBIT A

TERMS AND CONDITIONS OF STOCK OPTION GRANT

1. Grant of Option. The Company hereby grants to Participant named in the Notice of Stock Option Grant attached to this Award Agreement (the "**Participant**") an option (the "**Option**") to purchase the number of Shares set forth in the Notice of Stock Option Grant, at the exercise price per Share set forth in the Notice of Stock Option Grant (the "**Exercise Price**"), subject to all of the terms and conditions set forth in the Notice of Stock Option Grant and in this Award Agreement and the Plan, which is incorporated herein by reference. Subject to Section 17 of the Plan, if there is a conflict between the terms and conditions of the Plan and the terms and conditions of this Award Agreement, the terms and conditions of the Plan will prevail.

If designated in the Notice of Stock Option Grant as an Incentive Stock Option ("**ISO**"), this Option is intended to qualify as an ISO to the maximum extent permitted under Section 422 of the U.S. Internal Revenue Code of 1986, as amended (the "**Code**"). However, if this Option is intended to be an ISO, to the extent that it exceeds the USD \$100,000 rule of Code Section 422(d) it will be treated as a Nonstatutory Stock Option ("**NSO**"). Further, if for any reason this Option (or portion thereof) will not qualify as an ISO, then, to the extent of such non-qualification, such Option (or portion thereof) shall be regarded as an NSO granted under the Plan. In no event will the Administrator, the Company or any Parent or Subsidiary or any of their respective employees or directors have any liability to Participant (or any other person) due to the failure of the Option to qualify for any reason as an ISO.

2. Vesting Schedule. Except as provided in Section 3, the Option awarded by this Award Agreement will vest in accordance with the vesting provisions set forth in the Notice of Stock Option Grant. Options scheduled to vest on a certain date or upon the occurrence of a certain condition will not vest in accordance with any of the provisions of this Award Agreement, unless Participant will have been continuously a Service Provider from the Date of Grant until the date such vesting occurs. Service Provider status for purposes of this Award will end on the day that Participant is no longer actively providing services as an Employee, Director, or Independent Contractor and will not be extended by any notice period or "garden leave" that may be required contractually or under any Applicable Laws. Notwithstanding the foregoing, the Administrator (or any delegate) shall have the sole and absolute discretion to determine when Participant is no longer providing active service for purposes of Service Provider status and participation in the Plan.

3. Exercise of Option.

(a) **Right to Exercise.** This Option may be exercised only within the term set forth in the Notice of Stock Option Grant and may be exercised during such term only in accordance with the Plan and the terms of this Award Agreement.

(b) **Method of Exercise.** This Option is exercisable by delivery of an exercise notice in the form of Early Exercise Notice and Restricted Stock Purchase Agreement attached hereto as **Exhibit B** or, to the extent Participant exercises the Option with respect to vested shares only, the form of the Exercise Notice attached hereto as **Exhibit C** (collectively, the "**Exercise Notice**") or in a manner and pursuant to such procedures as the Administrator may determine, which will state the election to exercise the Option, the number of Shares in respect of which the Option is being exercised (the "**Exercised Shares**"), and such other representations and agreements as may be required by the Company pursuant to the provisions of the Plan. The Exercise Notice will be completed by Participant and delivered to the Company. The Exercise Notice will be accompanied by payment of the aggregate Exercise Price as to all Exercised Shares together with any Tax-Related Items (as defined below) required to be withheld, paid or provided pursuant to any Applicable Laws. This Option will be deemed to be exercised upon receipt by the Company of such fully executed Exercise Notice accompanied by such aggregate Exercise Price and any other requirements or restrictions that may be imposed by the Company to comply with Applicable Laws or facilitate administration of the Plan. Notwithstanding the above, Participant understands that the Applicable Laws of the country in which Participant is residing or working at the time of grant, vesting, and/or exercise of this Option (including any rules or regulations governing securities, foreign exchange, tax, labor or other matters) may restrict or prevent exercise of this Option, and neither the Company nor any Parent or Subsidiary assumes any liability in relation to this Option in such case.

4. Method of Payment. Payment of the aggregate Exercise Price will be by any of the following, or a combination thereof, at the election of Participant unless otherwise specified by the Company in its sole discretion:

- (a) cash (U.S. dollars); or
- (b) check (denominated in U.S. dollars); or
- (c) consideration received by the Company under a formal cashless exercise program adopted by the Company in connection with the Plan.

Participant understands and agrees that, unless otherwise permitted by the Company, any cross-border remittance made to exercise this Option or transfer proceeds received upon the sale of Shares must be made through a locally authorized financial institution or registered foreign exchange agency and may require Participant to provide such entity with certain information regarding the transaction.

5. Tax Obligations.

(a) Withholding Taxes. Regardless of any action the Company or Participant's employer (the "**Employer**") takes with respect to any or all applicable national, local, or other tax or social contribution, withholding, required deductions, or other payments, if any, that arise upon the grant, vesting, or exercise of this Option, the holding or subsequent sale of Shares, and the receipt of dividends, if any, or otherwise in connection with this Option or the Shares ("**Tax-Related Items**"), Participant acknowledges and agrees that the ultimate liability for all Tax-Related Items legally due by Participant is and remains Participant's responsibility and may exceed any amount actually withheld by the Company or the Employer. Participant further acknowledges and agrees that Participant is solely responsible for filing all relevant documentation that may be required in relation to this Option or any Tax-Related Items (other than filings or documentation that is the specific obligation of the Company or a Parent, Subsidiary, or Employer pursuant to Applicable Laws) such as but not limited to personal income tax returns or reporting statements in relation to the grant, vesting or exercise of this Option, the holding of Shares or any bank or brokerage account, the subsequent sale of Shares, and the receipt of any dividends. Participant further acknowledges that the Company and the Employer (a) make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the Option, including the grant, vesting, or exercise of the Option, the subsequent sale of Shares acquired under the Plan and the receipt of dividends, if any; and (b) does not commit to and is under no obligation to structure the terms of the Option or any aspect of the Option to reduce or eliminate Participant's liability for Tax-Related Items, or achieve any particular tax result. Participant also understands that Applicable Laws may require varying Share or Option valuation methods for purposes of calculating Tax-Related Items, and the Company assumes no responsibility or liability in relation to any such valuation or for any calculation or reporting of income or Tax-Related Items that may be required of Participant under Applicable Laws. Further, if Participant has become subject to tax in more than one jurisdiction between the Date of Grant and the date of any relevant taxable event, Participant acknowledges that the Company and/or the Employer (or former employer, as applicable) may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

(b) Satisfaction of Tax-Related Items. As a condition to the grant, vesting and exercise of this Option and as set forth in Section 11 of the Plan, Participant hereby agrees to make adequate provision for the satisfaction of (and will indemnify the Company and any Parent or Subsidiary for) any Tax-Related Items. No payment will be made to Participant (or his or her estate or beneficiary) related to an Option, and no Shares will be issued pursuant to an Option, unless and until satisfactory arrangements (as determined by the Company) have been made by Participant with respect to the payment of any Tax-Related Items obligations of the Company and/or any Parent, Subsidiary, or Employer with respect to the grant, vesting or exercise of the Option. In this regard, Participant authorizes the Company and/or any Parent, Subsidiary, or Employer, or their respective agents, at their discretion, to satisfy the obligations with regard to all Tax-Related Items by one or a combination of the following:

- (i) withholding from Participant's wages or other cash compensation paid to Participant by the Company or the Employer;

or

(ii) withholding from proceeds of the sale of Shares acquired upon exercise of the Option, either through a voluntary sale or through a mandatory sale arranged by the Company (on Participant's behalf pursuant to this authorization); or

(iii) withholding in Shares to be issued upon exercise of the Option.

Notwithstanding the foregoing, if Participant is subject to Section 16 of the Exchange Act, Participant may direct the Company to withhold Shares to be issued upon exercise of the Option to satisfy Participant's obligations with regard to all Tax-Related Items and any such disposition of Shares to the Company shall be exempt from Section 16(b) of the Exchange Act pursuant to Rule 16b-3(e).

If the obligation for Tax-Related Items is satisfied by withholding Shares, Participant is deemed to have been issued the full number of Shares purchased for tax purposes, notwithstanding that a number of Shares is held back solely for the purpose of paying the Tax-Related Items due as a result of Participant's participation in the Plan. Participant shall pay to the Company or a Parent, Subsidiary, or Employer any amount of Tax-Related Items that the Company may be required to withhold, pay or otherwise provide for as a result of Participant's participation in the Plan that cannot be satisfied by one or more of the means previously described in this Section 5. Participant acknowledges and agrees that the Company may refuse to honor the exercise and refuse to issue or deliver the Shares or the proceeds of the sale of Shares if Participant fails to comply with his or her obligations in connection with the Tax-Related Items.

(c) Notice of Disqualifying Disposition of ISO Shares. If the Option granted to Participant herein is an ISO, and if Participant sells or otherwise disposes of any of the Shares acquired pursuant to the ISO on or before the later of (i) the date two (2) years after the Date of Grant, or (ii) the date one (1) year after the date of exercise, Participant will immediately notify the Company in writing of such disposition.

(d) Code Section 409A (Applicable Only to Participants Subject to U.S. Taxes). Under Code Section 409A, an option that is granted with a per Share exercise price that is determined by the Internal Revenue Service (the "**IRS**") to be less than the Fair Market Value of a Share on the Date of Grant (a "**Discount Option**") may be considered "deferred compensation." A Discount Option may result in (i) income recognition by Participant prior to the exercise of the option, (ii) an additional twenty percent (20%) federal income tax, and (iii) potential penalty and interest charges. The Discount Option may also result in additional state income, penalty and interest charges to Participant. Participant acknowledges that the Company cannot and has not guaranteed that the IRS will agree that the per Share exercise price of this Option equals or exceeds the Fair Market Value of a Share on the Date of Grant in a later examination. Participant agrees that if the IRS determines that the Option was granted with a per Share exercise price that was less than the Fair Market Value of a Share on the Date of Grant, Participant will be solely responsible for Participant's costs related to such a determination.

6. Rights as Stockholder. Neither Participant nor any person claiming under or through Participant will have any of the rights or privileges of a stockholder of the Company in respect of any Shares unless and until such Shares will have been issued (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). After such issuance, Participant will have all the rights of a stockholder of the Company with respect to voting such Shares and receipt of dividends and distributions on such Shares, but prior to such issuance, Participant will not have any rights to dividends and/or distributions on such Shares.

7. No Guarantee of Continued Service or Grants. PARTICIPANT ACKNOWLEDGES AND AGREES THAT THE VESTING OF SHARES PURSUANT TO THE VESTING SCHEDULE HEREOF SHALL OCCUR ONLY BY CONTINUING AS A SERVICE PROVIDER AT THE WILL OF THE EMPLOYER OR CONTRACTING ENTITY (AS APPLICABLE) AND NOT THROUGH THE ACT OF BEING HIRED, BEING GRANTED THE OPTION OR ACQUIRING SHARES HEREUNDER. PARTICIPANT FURTHER ACKNOWLEDGES AND AGREES THAT THIS AWARD AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREUNDER AND THE VESTING SCHEDULE SET FORTH HEREIN DO NOT CONSTITUTE AN EXPRESS OR IMPLIED PROMISE OF CONTINUED ENGAGEMENT AS A SERVICE PROVIDER FOR THE VESTING PERIOD, FOR ANY PERIOD, OR AT ALL, AND WILL NOT INTERFERE IN ANY WAY WITH PARTICIPANT'S RIGHT OR THE RIGHT OF THE EMPLOYER OR THE COMPANY, PARENT, OR SUBSIDIARY TO TERMINATE PARTICIPANT'S RELATIONSHIP AS A SERVICE PROVIDER AT ANY TIME, WITH OR WITHOUT CAUSE (SUBJECT TO APPLICABLE LOCAL LAWS).

8. Nature of Grant. In accepting the Option, Participant acknowledges, understands and agrees that:

(a) the Plan is established voluntarily by the Company, it is discretionary in nature and it may be modified, amended, suspended or terminated by the Company at any time;

(b) the grant of the Option is voluntary and occasional and does not create any contractual or other right to receive future grants of Options, or benefits in lieu of Options even if Options have been granted repeatedly in the past;

(c) all decisions with respect to future awards of Options, if any, will be at the sole discretion of the Company;

(d) Participant's participation in the Plan is voluntary;

(e) the Option and the Shares subject to the Option are extraordinary items that do not constitute regular compensation for services rendered to the Company or the Employer, and that are outside the scope of Participant's employment contract, if any;

(f) the Option and the Shares subject to the Option are not intended to replace any pension rights or compensation;

(g) the Option and the Shares subject to the Option are not part of normal or expected compensation or salary for any purposes, including, but not limited to, calculating any severance, resignation, termination, redundancy, dismissal, or end of service payments, bonuses, long-service awards, pension or retirement or welfare benefits or similar payments and in no event should be considered as compensation for, or relating in any way to, past services for the Company or the Employer, subject to Applicable Laws;

(h) the future value of the underlying Shares is unknown and cannot be predicted with certainty; further, if Participant exercises the Option and obtains Shares, the value of the Shares acquired upon exercise may increase or decrease in value, even below the Exercise Price;

(i) Participant also understands that neither the Company nor any affiliate is responsible for any foreign exchange fluctuation between local currency and the United States Dollar or the selection by the Company or any affiliate in its sole discretion of an applicable foreign currency exchange rate that may affect the value of the Option (or the calculation of income or Tax-Related Items thereunder);

(j) in consideration of the grant of the Option, no claim or entitlement to compensation or damages shall arise from forfeiture of the Option resulting from termination of employment by the Employer (for any reason whatsoever and whether or not in breach of Applicable Laws, including, without limitation, applicable local labor laws), and Participant irrevocably releases the Employer from any such claim that may arise; if, notwithstanding the foregoing, any such claim is found by a court of competent jurisdiction to have arisen, Participant shall be deemed irrevocably to have waived his or her entitlement to pursue such claim; and

(k) the Option and the benefits under the Plan, if any, will not without the Administrator's consent transfer to another company in the case of a merger, take-over or transfer of liability.

9. No Advice Regarding Grant. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding Participant's participation in the Plan, or Participant's acquisition or sale of the underlying Shares. Participant is hereby advised to consult with his or her own personal tax, legal and financial advisors regarding Participant's participation in the Plan before taking any action related to the Plan.

10. Data Privacy. Participant hereby explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of Participant's Personal Data (as described below) by and among, as applicable, the Company, any Parent, Subsidiary, or affiliate, or third parties as may be selected by the Company for the exclusive purpose of implementing, administering and managing Participant's participation in the Plan. Participant understands that refusal or withdrawal of consent will affect Participant's ability to participate in the Plan; without providing consent, Participant will not be able to participate in the Plan or realize benefits (if any) from the Option. Participant understands that the Company and any Parent, Subsidiary, affiliate, or designated third parties may hold personal information about Participant, including, but not limited to, Participant's name, home address and telephone number, date of birth, social insurance number or other identification number, salary, nationality, job title, any shares of stock or directorships held in the Company or any Parent, Subsidiary, or affiliate, details of all Options or any other entitlement to Shares awarded, canceled, exercised, vested, unvested or outstanding in Participant's favor ("Personal Data"). Participant understands that Personal Data may be transferred to any Parent, Subsidiary, affiliate, or third parties assisting in the implementation, administration and management of the Plan, that these recipients may be located in the United States, Participant's country (if different than the United States), or elsewhere, and that the recipient's country may have different data privacy laws and protections than Participant's country. In particular, the Company may transfer Personal Data to the broker or stock plan administrator assisting with the Plan, to its legal counsel and tax/accounting advisor, and to the affiliate or entity that is Participant's employer and its payroll provider. Participant should also refer to any data privacy policy implemented by the Company (which will be available to Participant separately and may be updated from time to time) for more information regarding the collection, use, storage, and transfer of Participant's Personal Data.

11. Address for Notices. Any notice to be given to the Company under the terms of this Award Agreement will be addressed to the Company, in care of its Secretary at Lexeo Therapeutics, Inc., 430 East 29th Street, 14th Floor, New York, NY 10016, or at such other address as the Company may hereafter designate in writing.

12. Non-Transferability of Option. This Option may not be transferred in any manner otherwise than by will or by the laws of descent or distribution and may be exercised during the lifetime of Participant only by Participant.

13. Binding Agreement. Subject to the limitation on the transferability of this Option contained herein, this Award Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

14. Additional Conditions to Issuance of Stock. If at any time the Company will determine, in its discretion, that the listing, registration, qualification or compliance of the Shares upon or with any securities exchange or under any Applicable Laws, the tax code and related regulations or the consent or approval of any governmental regulatory authority is necessary or desirable as a condition to the grant or vesting of the Option or purchase by, or issuance of Shares to, Participant (or his or her estate) hereunder, such purchase or issuance will not occur unless and until such listing, registration, qualification, compliance, consent or approval will have been completed, effected or obtained free of any conditions not acceptable to the Company. The Company will make all reasonable efforts to meet the requirements of any Applicable Laws. Assuming such compliance, for purposes of the Tax-Related Items, the Exercised Shares will be considered transferred to Participant on the date the Option is exercised with respect to such Exercised Shares. The Company shall not be obligated to issue any Shares pursuant to this Option at any time if the issuance of Shares, or the exercise of an Option by Participant, violates or is not in compliance with any Applicable Laws.

15. Lock-Up Agreement. If so requested by the Company (or any successor thereof) or the underwriters in connection with the initial public offering of the securities of the Company (or any successor or parent thereof), or any direct listing or other transaction pursuant to which the securities of the Company will be exchanged for securities of the Company (or any successor or parent thereof) registered under the Securities Act of 1933, as amended, including, without limitation, through a transaction with a publicly-listed blank check company registered under the Securities Act, Participant shall not sell, make any short sale of, loan, grant any option for the purchase of, or otherwise dispose of any securities of the Company (or any successor thereof) however or whenever acquired (except for those being registered) without the prior written consent of the Company or such underwriters, as the case may be, for 180 days from the effective date of the registration statement or becoming a listed security, and Participant shall execute an agreement reflecting the foregoing as may be requested by the Company (or any successor or parent thereof) or the underwriters at the time of such offering or listing.

16. Plan Governs. This Award Agreement is subject to all terms and provisions of the Plan. If there is a conflict between one or more provisions of this Award Agreement and one or more provisions of the Plan, the provisions of the Plan will govern. Capitalized terms used and not defined in this Award Agreement will have the meaning set forth in the Plan.

17. Administrator Authority. The Administrator will have the power to interpret the Plan and this Award Agreement and to adopt such rules for the administration, interpretation and application of the Plan as are consistent therewith and to interpret or revoke any such rules (including, but not limited to, the determination regarding whether any Shares subject to the Option have vested). All actions taken, and all interpretations and determinations made, by the Administrator in good faith will be final and binding upon Participant, the Company and all other interested persons. No member of the Administrator will be personally liable for any action, determination or interpretation made in good faith with respect to the Plan or this Award Agreement.

18. Electronic Delivery and Acceptance. The Company may, in its sole discretion, decide to deliver any documents related to Participant's current or future participation in the Plan, this Option, the Shares subject to this Option, any other securities of the Company or any other Company-related documents, by electronic means. By accepting this Option, whether electronically or otherwise, Participant hereby (a) consents to receive such documents by electronic means, (b) consents to the use of electronic signatures, and (c) agrees to participate in the Plan and/or receive any such documents through an on-line or electronic system established and maintained by the Company or a third party designated by the Company, including but not limited to the use of electronic signatures or click-through electronic acceptance of terms and conditions.

19. Translation. If Participant has received this Award Agreement, including appendices, or any other document related to the Plan translated into a language other than English, and the meaning of the translated version is different than the English version, the English version will control.

20. Imposition of Other Requirements. The Company reserves the right to impose other requirements on Participant's participation in the Plan, on the Option and on any Shares acquired under the Plan, to the extent the Company determines it is necessary or advisable in order to comply with any Applicable Laws or facilitate the administration of the Plan, and to require Participant to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing. Furthermore, Participant understands that the Applicable Laws of the country in which he or she is resident at the time of grant, vesting, and/or exercise of this Option or the holding or disposition of Shares (including any rules or regulations governing securities, foreign exchange, tax, labor or other matters) may restrict or prevent exercise of this Option or may subject Participant to additional procedural or regulatory requirements he or she is solely responsible for and will have to independently fulfill in relation to this Option or the Shares. Participant also understands and agrees that if he works, resides, moves to, or otherwise is or becomes subject to Applicable Laws or company policies of another jurisdiction at any time, certain country-specific notices, disclaimers and/or terms and conditions may apply to Participant as from the Date of Grant, unless otherwise determined by the Company in its sole discretion.

21. Captions. Captions provided herein are for convenience only and are not to serve as a basis for interpretation or construction of this Award Agreement.

22. Agreement Severable. If any provision in this Award Agreement will be held invalid or unenforceable, such provision will be severable from, and such invalidity or unenforceability will not be construed to have any effect on, the remaining provisions of this Award Agreement.

23. Modifications to this Award Agreement. This Award Agreement and the Plan constitute the entire understanding of the parties on the subjects covered. Participant expressly warrants that he or she is not accepting this Award Agreement in reliance on any promises, representations, or inducements other than those contained herein. Modifications to this Award Agreement or the Plan can be made only in an express written contract executed by a duly authorized officer of the Company. Notwithstanding anything to the contrary in the Plan or this Award Agreement, the Company reserves the right to revise this Award Agreement as it deems necessary or advisable, in its sole discretion and without the consent of Participant, to comply with Code Section 409A or to otherwise avoid imposition of any additional tax or income recognition under Code Section 409A in connection to this Option.

24. Amendment, Suspension or Termination of the Plan. By accepting this Award, Participant expressly warrants that he or she has received an Option under the Plan, and has received, read and understood a description of the Plan. Participant understands that the Plan is discretionary in nature and may be amended, suspended or terminated by the Company at any time.

25. Governing Law and Venue. This Award Agreement will be governed by the laws of the State of Delaware, without giving effect to the conflict of law principles thereof. For purposes of litigating any dispute that arises under this Award Agreement, the parties hereby submit to and consent to the jurisdiction of the State of New York and agree that such litigation will be conducted in the courts of New York County, New York, or the federal courts for the United States for the Southern District of New York, and no other courts.

EXHIBIT B

LEXEO THERAPEUTICS, INC.

2021 EQUITY INCENTIVE PLAN

EARLY EXERCISE NOTICE AND RESTRICTED STOCK PURCHASE AGREEMENT

Lexeo Therapeutics, Inc.
Attention:

1. Exercise of Option. Effective as of today, , , the undersigned (“**Purchaser**”) hereby elects to purchase, , shares (the “**Shares**”) of the Common Stock of Lexeo Therapeutics, Inc. (the “**Company**”) under and pursuant to the 2021 Equity Incentive Plan (the “**Plan**”) and the Stock Option Award Agreement dated , (the “**Award Agreement**”). The purchase price for the Shares will be USD \$, as required by the Award Agreement. Of these Shares, Purchaser has elected to purchase _____ Shares which have become vested as of the date hereof under the Vesting Schedule set forth in the Notice of Stock Option Grant (the “**Vested Shares**”) and _____ Shares which have not yet vested under such Vesting Schedule (the “**Unvested Shares**”).

2. Delivery of Payment. Purchaser herewith delivers to the Company, or otherwise makes adequate arrangements satisfactory to the Company, the full purchase price of the Shares and any Tax-Related Items (as defined in the Agreement) to be paid in connection with the exercise of the Option.

3. Representations of Purchaser. Purchaser acknowledges that Purchaser has received, read and understood the Plan and the Award Agreement and agrees to abide by and be bound by their terms and conditions.

4. Rights as Stockholder. Until the issuance (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company) of the Shares, no right to vote or receive dividends or any other rights as a stockholder will exist with respect to the Shares subject to the Option, notwithstanding the exercise of the Option. The Shares so acquired will be issued to Purchaser as soon as practicable after exercise of the Option. No adjustment will be made for a dividend or other right for which the record date is prior to the date of issuance, except as provided in Section 10 of the Plan.

5. Tax Consultation. Purchaser understands that Purchaser may suffer adverse tax consequences as a result of Purchaser’s purchase or disposition of the Shares. Purchaser represents that Purchaser has consulted with any tax consultants Purchaser deems advisable in connection with the purchase or disposition of the Shares and that Purchaser is not relying on the Company for any tax advice.

6. Limitations on Transfer. Purchaser acknowledges and agrees that the Shares purchased under this Agreement are subject to Section 9 of the Plan, the terms and conditions that apply to the Company’s Common Stock, as set forth in the Company’s Bylaws, as may be in effect at the time of any proposed transfer (the “**Bylaw Provisions**”), and any other limitation or restriction on transfer created by Applicable Laws. In addition to the foregoing limitations on transfer, Purchaser shall not assign, encumber or dispose of any interest in the Shares while the Shares are subject to the Company’s Repurchase Option (as defined below). After any Shares have been released from such Repurchase Option, Purchaser shall not assign, encumber or dispose of any interest in the Shares except to the extent permitted by, and in compliance with, Section 9 of the Plan, the Bylaw Provisions and, Applicable Laws, and the provisions below.

(a) Repurchase Option.

(i) In the event of the voluntary or involuntary termination of Purchaser's continuous Service with the Company for any reason (including, without limitation, resignation, death or Disability), with or without Cause, the Company shall upon the date of such termination (the "Termination Date") have an irrevocable, exclusive option (the "Repurchase Option") for a period of 3 months from such date to repurchase all or any portion of the Unvested Shares (as defined below) held by Purchaser as of the Termination Date at the original purchase price per Share (adjusted for any stock splits, stock dividends and the like) specified in Section 1. As used herein, "Unvested Shares" means Shares that have not yet been released from the Repurchase Option.

(ii) Unless the Company notifies Purchaser within 3 months from the Termination Date that it does not intend to exercise its Repurchase Option with respect to some or all of the Unvested Shares, the Repurchase Option shall be deemed automatically exercised by the Company as of the end of such 3-month period following the Termination Date, provided that the Company may notify Purchaser that it is exercising its Repurchase Option as of a date prior to the end of such 3-month period. Unless Purchaser is otherwise notified by the Company pursuant to the preceding sentence that the Company does not intend to exercise its Repurchase Option as to some or all of the Unvested Shares to which it applies at the time of termination, execution of this Agreement by Purchaser constitutes written notice to Purchaser of the Company's intention to exercise its Repurchase Option with respect to all Unvested Shares to which such Repurchase Option applies. The Company, at its choice, may satisfy its payment obligation to Purchaser with respect to exercise of the Repurchase Option by either (1) delivering a check to Purchaser in the amount of the purchase price for the Unvested Shares being repurchased, or (2) in the event Purchaser is indebted to the Company, canceling an amount of such indebtedness equal to the purchase price for the Unvested Shares being repurchased, or (3) by a combination of (1) and (2) so that the combined payment and cancellation of indebtedness equals such purchase price. In the event of any deemed automatic exercise of the Repurchase Option pursuant to this Section 6(a)(ii) in which Purchaser is indebted to the Company, such indebtedness equal to the purchase price of the Unvested Shares being repurchased shall be deemed automatically canceled as of the end of such 3-month period following the Termination Date unless the Company otherwise satisfies its payment obligations. As a result of any repurchase of Unvested Shares pursuant to this Section 6, the Company shall become the legal and beneficial owner of the Unvested Shares being repurchased and shall have all rights and interest therein or related thereto, and the Company shall have the right to transfer to its own name the number of Unvested Shares being repurchased by the Company, without further action by Purchaser.

(iii) One hundred percent (100%) of the Shares shall initially be subject to the Repurchase Option. The Unvested Shares shall be released from the Repurchase Option in accordance with the Vesting Schedule set forth in the Notice of Stock Option Grant until all Shares are released from the Repurchase Option; provided, however, that such scheduled releases from the Repurchase Option shall immediately cease as of the Termination Date. Fractional shares shall be rounded down to the nearest whole share.

(b) Transfer Restrictions; Right of First Refusal. Before any Shares held by Purchaser or any transferee of Purchaser (either being sometimes referred to herein as the "Holder") may be sold or otherwise transferred (including transfer by gift or operation of law), the Company shall first, to the extent the Company's approval is required by the Plan or any applicable Bylaw Provisions, have the right to approve such sale or transfer, in full or in part, and shall then have the right to purchase all or any part of the Shares proposed to be sold or transferred, in each case, in its sole and absolute discretion (the "Right of First Refusal"). If the Holder would like to sell or transfer any Shares, the Holder must provide the Company or its assignee(s) with a Notice (as defined below) requesting approval to sell or transfer the Shares and offering the Company or its assignee(s) a Right of First Refusal on the same terms and conditions set forth in this Section 6(b). The Company may either (i) exercise its Right of First Refusal in full or in part and purchase such Shares pursuant to this Section 6(b), (ii) decline to exercise its Right of First Refusal in full or in part and permit the transfer of such Shares to the Proposed Transferee (as defined below) in full or in part or (iii) decline to exercise its Right of First Refusal in full or in part and, to the extent the Company's approval is required by the Plan or any applicable Bylaw Provisions, decline the request to sell or transfer the Shares in full or in part.

(i) Notice of Proposed Transfer. The Holder of the Shares shall deliver to the Company a written notice (the “Notice”) stating: (1) the Holder’s intention to sell or otherwise transfer such Shares; (2) the name of each proposed purchaser or other transferee (“Proposed Transferee”); (3) the number of Shares to be sold or transferred to each Proposed Transferee; (4) the terms and conditions of each proposed sale or transfer, including (without limitation) the purchase price for such Shares (the “Purchase Price”); and (5) the Holder’s offer to the Company or its assignee(s) to purchase the Shares at the Purchase Price and upon the same terms (or terms that are no less favorable to the Company).

(ii) Exercise of Right of First Refusal. At any time within 30 days after receipt of the Notice, the Company and/or its assignee(s) shall deliver a written notice to the Holder indicating whether the Company and/or its assignee(s) elect to permit or reject the proposed sale or transfer, in full or in part, and/or elect to accept or decline the offer to purchase any or all of the Shares proposed to be sold or transferred to any one or more of the Proposed Transferees, at the Purchase Price, provided that if the Purchase Price consists of no legal consideration (as, for example, in the case of a transfer by gift), the purchase price will be the fair market value of the Shares as determined in good faith by the Company. If the Purchase Price includes consideration other than cash, the cash equivalent value of the non-cash consideration shall be determined by the Company in good faith.

(iii) Payment. Payment of the Purchase Price shall be made, at the election of the Company or its assignee(s), in cash (by check), by cancellation of all or a portion of any outstanding indebtedness, or by any combination thereof within 60 days after receipt of the Notice or in the manner and at the times set forth in the Notice.

(iv) Holder’s Right to Transfer. If any of the Shares proposed in the Notice to be sold or transferred to a given Proposed Transferee are both (1) not purchased by the Company and/or its assignee(s) as provided in this Section 6(b) and (2) approved by the Company to be sold or transferred, then the Holder may sell or otherwise transfer any such Shares to the applicable Proposed Transferee at the Purchase Price or at a higher price, provided that such sale or other transfer is consummated within 120 days after the date of the Notice; provided that (A) any such sale or other transfer is also effected in accordance with the Bylaw Provisions, the transfer restrictions set forth in the Plan and any Applicable Laws and (B) the Proposed Transferee agrees in writing that the Plan, the Bylaw Provisions and the provisions of the Award Agreement and this Agreement, including this Section 6 shall continue to apply to the Shares in the hands of such Proposed Transferee. The Company, in consultation with its legal counsel, may require the Holder to provide an opinion of counsel evidencing compliance with Applicable Laws. If the Shares described in the Notice are not transferred to the Proposed Transferee within such period, or if the Holder proposes to change the price or other terms to make them more favorable to the Proposed Transferee, a new Notice shall be given to the Company, and the Company and/or its assignees shall again have the right to approve such transfer and be offered the Right of First Refusal.

(v) Exception for Certain Family Transfers. Anything to the contrary contained in this Section 6 notwithstanding, the transfer of any or all of the Shares during Holder’s lifetime or on Holder’s death by will or intestacy to Holder’s Immediate Family or a trust for the benefit of Holder or Holder’s Immediate Family shall be exempt from the provisions of this Section 6(b). “Immediate Family” as used herein shall mean lineal descendant or antecedent, father, mother, brother or sister (or their descendants), stepchild (or their antecedents or descendants), aunt or uncle (or their antecedents or descendants), brother-in-law or sister-in-law (or their antecedents or descendants) and shall include adoptive relationships, or any person sharing Holder’s household (other than a tenant or an employee). In such case, the transferee or other recipient shall receive and hold the Shares so transferred subject to the provisions of the Plan, the Bylaw Provisions and the provisions of the Award Agreement and this Agreement, including this Section 6, and there shall be no further transfer of such Shares except in accordance with the terms of this Section 6, the Plan, and the Bylaw Provisions.

(c) Company's Right to Purchase upon Involuntary Transfer. In the event of any transfer by operation of law or other involuntary transfer (including death or divorce, but excluding a transfer to Immediate Family as set forth in Section 6(b)(v) above) of all or a portion of the Shares by the record holder thereof, the Company shall have an option to purchase any or all of the Shares transferred at the Fair Market Value of the Shares on the date of transfer (as determined by the Company in its sole discretion). Upon such a transfer, the Holder shall promptly notify the Secretary of the Company of such transfer and if requested by the Company. The right to purchase such Shares shall be provided to the Company for a period of 30 days following receipt by the Company of written notice from the Holder.

(d) Assignment. The right of the Company to purchase any part of the Shares may be assigned in whole or in part to any holder or holders of capital stock of the Company or other persons or organizations.

(e) Restrictions Binding on Transferees. All transferees of Shares or any interest therein will receive and hold such Shares or interest subject to the Plan, the Bylaw Provisions, the provisions of the Award Agreement and this Agreement and, including, insofar as applicable, the Repurchase Option. In the event of any purchase by the Company hereunder where the Shares or interest are held by a transferee, the transferee shall be obligated, if requested by the Company, to transfer the Shares or interest to the Purchaser for consideration equal to the amount to be paid by the Company hereunder. In the event the Repurchase Option is deemed exercised by the Company pursuant to Section 6(a)(ii) hereof, the Company may deem any transferee to have transferred the Shares or interest to Purchaser prior to their purchase by the Company, and payment of the purchase price by the Company to such transferee shall be deemed to satisfy Purchaser's obligation to pay such transferee for such Shares or interest, and also to satisfy the Company's obligation to pay Purchaser for such Shares or interest. Any sale or transfer of the Shares shall be void unless the provisions of this Agreement are satisfied.

(f) Termination of Rights. The transfer restrictions set forth in Section 6(b) above, the Right of First Refusal granted the Company by Section 6(b) above and the right to repurchase the Shares in the event of an involuntary transfer granted the Company by Section 6(c) above shall terminate upon (i) the first sale of Common Stock of the Company to the general public pursuant to a registration statement filed with and declared effective by the Securities and Exchange Commission under the Securities Act of 1933, as amended (the "Securities Act") (other than a registration statement relating solely to the issuance of Common Stock pursuant to a business combination or an employee incentive or benefit plan) or (ii) any transfer or conversion of Shares made pursuant to a statutory merger or statutory consolidation of the Company with or into another corporation or corporations if the common stock of the surviving corporation or any direct or indirect parent corporation thereof is registered under the Exchange Act. Upon termination of such transfer restrictions, the Company will remove any stop-transfer notices referenced in Section 8(b) below and related to the restrictions in this Section 6 and a new stock certificate or, in the case of uncertificated securities, notice of issuance, for the Shares not repurchased shall be issued, on request, without the legend referred to in Section 8(a) below and delivered to Holder.

(g) Lock-Up Agreement. The lock-up provisions set forth in Section 15 of the Award Agreement shall apply to the Shares issued upon exercise of the Option hereunder and Purchaser reaffirms Purchaser's obligations set forth therein.

7. Investment and Taxation Representations. In connection with the purchase of the Shares, Purchaser represents to the Company the following:

(a) Purchaser is aware of the Company's business affairs and financial condition and has acquired sufficient information about the Company to reach an informed and knowledgeable decision to acquire the Shares. Purchaser is purchasing the Shares for investment for Purchaser's own account only and not with a view to, or for resale in connection with, any "distribution" thereof within the meaning of the Securities Act or under any applicable provision of state law. Purchaser does not have any present intention to transfer the Shares to any other person or entity.

(b) Purchaser understands that the Shares have not been registered under the Securities Act by reason of a specific exemption therefrom, which exemption depends upon, among other things, the bona fide nature of Purchaser's investment intent as expressed herein.

(c) Purchaser further acknowledges and understands that the securities must be held indefinitely unless they are subsequently registered under the Securities Act or an exemption from such registration is available. Purchaser further acknowledges and understands that the Company is under no obligation to register the securities.

(d) Purchaser is familiar with the provisions of Rule 144, promulgated under the Securities Act, which, in substance, permits limited public resale of “restricted securities” acquired, directly or indirectly, from the issuer of the securities (or from an affiliate of such issuer), in a non-public offering subject to the satisfaction of certain conditions. Purchaser understands that the Company provides no assurances as to whether he or she will be able to resell any or all of the Shares pursuant to Rule 144, which rule requires, among other things, that the Company be subject to the reporting requirements of the Exchange Act, that resales of securities take place only after the holder of the Shares has held the Shares for certain specified time periods, and under certain circumstances, that resales of securities be limited in volume and take place only pursuant to brokered transactions. Notwithstanding this Section 7(d), Purchaser acknowledges and agrees to the restrictions set forth in Section 7(e) below.

(e) Purchaser further understands that in the event all of the applicable requirements of Rule 144 are not satisfied, registration under the Securities Act, compliance with Regulation A, or some other registration exemption will be required; and that, notwithstanding the fact that Rule 144 is not exclusive, the Staff of the Securities and Exchange Commission has expressed its opinion that persons proposing to sell private placement securities other than in a registered offering and otherwise than pursuant to Rule 144 will have a substantial burden of proof in establishing that an exemption from registration is available for such offers or sales, and that such persons and their respective brokers who participate in such transactions do so at their own risk.

(f) Purchaser represents that Purchaser is not subject to any of the “Bad Actor” disqualifications described in Rule 506(d)(1)(i) to (viii) under the Securities Act. Purchaser also agrees to notify the Company if Purchaser becomes subject to such disqualifications after the date hereof.

(g) Purchaser understands that Purchaser may suffer adverse tax consequences as a result of Purchaser’s purchase or disposition of the Shares. Purchaser represents that Purchaser has consulted any tax consultants Purchaser deems advisable in connection with the purchase or disposition of the Shares and that Purchaser is not relying on the Company for any tax advice.

8. Restrictive Legends and Stop-Transfer Orders.

(a) Legends. Any stock certificate or, in the case of uncertificated securities, any notice of issuance, for the Shares shall bear the following legends (as well as any legends required by the Company or applicable state and federal corporate and securities laws):

- “THE SECURITIES REFERENCED HEREIN HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AND HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF. NO SUCH SALE OR DISTRIBUTION MAY BE EFFECTED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL IN A FORM SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933.”
- “THE SECURITIES REFERENCED HEREIN MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF AN AGREEMENT BETWEEN THE COMPANY AND THE STOCKHOLDER, A COPY OF WHICH IS ON FILE WITH AND MAY BE OBTAINED FROM THE SECRETARY OF THE COMPANY AT NO CHARGE.”

- “THE TRANSFER OF THE SECURITIES REFERENCED HEREIN IS SUBJECT TO CERTAIN TRANSFER RESTRICTIONS SET FORTH IN THE COMPANY’S STOCK PLAN, A COPY OF WHICH MAY BE OBTAINED UPON WRITTEN REQUEST TO THE COMPANY AT ITS PRINCIPAL PLACE OF BUSINESS. THE COMPANY SHALL NOT REGISTER OR OTHERWISE RECOGNIZE OR GIVE EFFECT TO ANY PURPORTED TRANSFER OF SECURITIES THAT DOES NOT COMPLY WITH SUCH TRANSFER RESTRICTIONS.”

(b) Stop-Transfer Notices. Purchaser agrees that, in order to ensure compliance with the restrictions referred to herein, the Company may issue appropriate “stop transfer” instructions to its transfer agent, if any, and that, if the Company transfers its own securities, it may make appropriate notations to the same effect in its own records.

(c) Refusal to Transfer. The Company shall not be required (i) to transfer on its books any Shares that have been sold or otherwise transferred in violation of any of the provisions of this Agreement or (ii) to treat as owner of such Shares or to accord the right to vote or pay dividends to any purchaser or other transferee to whom such Shares shall have been so transferred.

9. Escrow of Unvested Shares. For purposes of facilitating the enforcement of the provisions of Section 6(a) above, Purchaser agrees to deliver a Stock Power in the form attached to this Agreement as Annex I executed by Purchaser and by Purchaser’s spouse (if required for transfer), in blank, and such stock certificate(s), if any, to the Secretary of the Company, or the Secretary’s designee, to hold such Shares (and such stock certificate(s), if any) and Stock Power in escrow and to take all such actions and to effectuate all such transfers and/or releases as are required in accordance with the terms of this Agreement. Purchaser hereby acknowledges that the Secretary of the Company, or the Secretary’s designee, is so appointed as the escrow holder with the foregoing authorities as a material inducement to make this Agreement and that said appointment is coupled with an interest and is accordingly irrevocable. Purchaser agrees that said escrow holder shall not be liable to any party hereof (or to any other party). The escrow holder may rely upon any letter, notice or other document executed by any signature purported to be genuine and may resign at any time. Purchaser agrees that if the Secretary of the Company, or the Secretary’s designee, resigns as escrow holder for any or no reason, the Board shall have the power to appoint a successor to serve as escrow holder pursuant to the terms of this Agreement.

10. Section 83(b) Election.

(a) Purchaser understands that Section 83(a) of the Code taxes as ordinary income for a Nonstatutory Stock Option and as alternative minimum taxable income for an Incentive Stock Option the difference between the amount paid for the Shares and the Fair Market Value of the Shares as of the date any restrictions on the Shares lapse. In this context, “restriction” means the right of the Company to buy back the Shares pursuant to the Repurchase Option set forth in Section 6(a) of this Agreement. Purchaser understands that Purchaser may elect to be taxed at the time the Shares are purchased, rather than when and as the Repurchase Option expires, by filing an election under Section 83(b) (an “83(b) Election”) of the Code with the Internal Revenue Service within 30 days from the date of purchase. Even if the Fair Market Value of the Shares at the time of the execution of this Agreement equals the amount paid for the Shares, the election must be made to avoid income and alternative minimum tax treatment under Section 83(a) in the future. Purchaser understands that failure to file such an election in a timely manner may result in adverse tax consequences for Purchaser. Purchaser further understands that an additional copy of such election form should be filed with his or her federal income tax return for the calendar year in which the date of this Agreement falls. Purchaser acknowledges that the foregoing is only a summary of the effect of United States federal income taxation with respect to purchase of the Shares hereunder, does not purport to be complete, and is not intended or written to be used, and cannot be used, for the purposes of avoiding taxpayer penalties. Purchaser further acknowledges that the Company has directed Purchaser to seek independent advice regarding the applicable provisions of the Code, the income tax laws of any municipality, state or foreign country in which Purchaser may reside, and the tax consequences of Purchaser’s death, and Purchaser has consulted, and has been fully advised by, Purchaser’s own tax advisor regarding such tax laws and tax consequences or has knowingly chosen not to consult such a tax advisor. Purchaser further acknowledges that neither the Company nor any subsidiary or representative of the Company has made any warranty or representation to Purchaser with respect to the tax consequences of Purchaser’s purchase of the Shares or of the making or failure to make an 83(b) Election. PURCHASER (AND NOT THE COMPANY, ITS AGENTS OR ANY OTHER PERSON) SHALL BE SOLELY RESPONSIBLE FOR APPROPRIATELY FILING SUCH FORM WITH THE IRS, EVEN IF PURCHASER REQUESTS THE COMPANY, ITS AGENTS OR ANY OTHER PERSON MAKE THIS FILING ON PURCHASER’S BEHALF.

(b) Purchaser agrees that he or she will execute and deliver to the Company with this executed Agreement a copy of the Acknowledgment and Statement of Decision Regarding Section 83(b) Election (the “Acknowledgment”) attached hereto as Annex II. Purchaser further agrees that he or she will execute and submit with the Acknowledgment a copy of the 83(b) Election attached hereto as Annex III (for tax purposes in connection with the early exercise of an option) if Purchaser has indicated in the Acknowledgment his or her decision to make such an election.

11. Waiver of Statutory Information Rights. Purchaser acknowledges and understands that, but for the waiver made herein, Purchaser would be entitled, upon written demand under oath stating the purpose thereof, to inspect for any proper purpose, and to make copies and extracts from, the Company’s stock ledger, a list of its stockholders, and its other books and records, and the books and records of subsidiaries of the Company, if any, under the circumstances and in the manner provided in Section 220 of the Delaware General Corporation Law (any and all such rights, and any and all such other rights of Purchaser as may be provided for in Section 220, the “Inspection Rights”). In light of the foregoing, until the first sale of Common Stock of the Company to the general public pursuant to a registration statement filed with and declared effective by the Securities and Exchange Commission under the Securities Act of 1933, as amended, Purchaser hereby unconditionally and irrevocably waives the Inspection Rights, whether such Inspection Rights would be exercised or pursued directly or indirectly pursuant to Section 220 or otherwise, and covenants and agrees never to directly or indirectly commence, voluntarily aid in any way, prosecute, assign, transfer, or cause to be commenced any claim, action, cause of action, or other proceeding to pursue or exercise the Inspection Rights. The foregoing waiver applies to the Inspection Rights of Purchaser in Purchaser’s capacity as a stockholder and shall not affect any rights of a director, in his or her capacity as such, under Section 220. The foregoing waiver shall not apply to any contractual inspection rights of Purchaser under any written agreement with the Company.

12. Entire Agreement; Governing Law. The Plan and Award Agreement are incorporated herein by reference. This Early Exercise Notice and Restricted Stock Purchase Agreement, the Plan and the Award Agreement constitute the entire agreement of the parties with respect to the subject matter hereof and supersede in their entirety all prior undertakings and agreements of the Company and Purchaser with respect to the subject matter hereof, and may not be modified adversely to the Purchaser's interest except by means of a writing signed by the Company and Purchaser. This agreement is governed by the internal substantive laws, but not the choice of law rules, of the State of Delaware.

Submitted by:

Accepted by:

PURCHASER:

LEXEO THERAPEUTICS, INC.

Signature

By

Print Name

Title

Date Received

ANNEX 1

STOCK POWER

FOR VALUE RECEIVED, the undersigned ("Holder"), hereby sells, assigns and transfers unto _____ ("Transferee" _____ shares of the Common Stock of Lexeo Therapeutics, Inc., a Delaware corporation (the "Company"), standing in Holder's name on the Company's books as Certificate No. ____ whether held in certificated or uncertificated form, and does hereby irrevocably constitute and appoint _____ to transfer said stock on the books of the Company with full power of substitution in the premises.

HOLDER:

SPOUSE OF HOLDER (IF APPLICABLE)

Signature

Signature

Print Name

Print Name

Date:

Date:

This Stock Power may only be used as authorized by the Early Exercise Notice and Restricted Stock Purchase Agreement between the Holder and the Company, dated _____ and the exhibits thereto.

Instructions: Please do not fill in any blanks other than the signature line. The purpose of this Stock Power is to enable the Company to exercise its repurchase option set forth in the Agreement without requiring additional signatures on the part of Holder.

IF YOU WISH TO MAKE A SECTION 83(B) ELECTION, THE FILING OF SUCH ELECTION IS YOUR RESPONSIBILITY.

THE FORM FOR MAKING THIS SECTION 83(B) ELECTION IS ATTACHED TO THIS AGREEMENT.

YOU MUST FILE THIS FORM WITHIN 30 DAYS OF PURCHASING THE SHARES.

YOU (AND NOT THE COMPANY, ANY OF ITS AGENTS OR ANY OTHER PERSON) SHALL BE SOLELY RESPONSIBLE FOR FILING SUCH FORM WITH THE IRS, EVEN IF YOU REQUEST THE COMPANY, ITS AGENTS OR ANY OTHER PERSON TO MAKE THIS FILING ON YOUR BEHALF AND EVEN IF THE COMPANY, ANY OF ITS AGENTS OR ANY OTHER PERSON HAS PREVIOUSLY MADE THIS FILING ON YOUR BEHALF.

The election should be filed by mailing a signed election form by certified mail, return receipt requested to the IRS Service Center where you file your tax returns. See www.irs.gov.

ANNEX II

ACKNOWLEDGMENT AND STATEMENT OF DECISION

REGARDING SECTION 83(b) ELECTION

The undersigned has entered into a stock purchase agreement with Lexeo Therapeutics, Inc., a Delaware corporation (the “Company”), pursuant to which the undersigned is purchasing _____ shares of Common Stock of the Company (the “Shares”). In connection with the purchase of the Shares, the undersigned hereby represents as follows:

1. The undersigned has carefully reviewed the stock purchase agreement pursuant to which the undersigned is purchasing the Shares.

2. The undersigned either [check and complete as applicable]:

(a) _____ has consulted, and has been fully advised by, the undersigned’s own tax advisor, _____, whose business address is _____, regarding the federal, state and local tax consequences of purchasing the Shares, and particularly regarding the advisability of making elections pursuant to Section 83(b) of the Internal Revenue Code of 1986, as amended (the “Code”) and pursuant to the corresponding provisions, if any, of applicable state law; or

(b) _____ has knowingly chosen not to consult such a tax advisor.

3. The undersigned hereby states that the undersigned has decided [check as applicable]:

(a) _____ to make an election pursuant to Section 83(b) of the Code, and is submitting to the Company, together with the undersigned’s executed stock purchase agreement, an executed form entitled “Election Under Section 83(b) of the Internal Revenue Code of 1986;” or

(b) _____ not to make an election pursuant to Section 83(b) of the Code.

4. Neither the Company nor any subsidiary or representative of the Company has made any warranty or representation to the undersigned with respect to the tax consequences of the undersigned’s purchase of the Shares or of the making or failure to make an election pursuant to Section 83(b) of the Code or the corresponding provisions, if any, of applicable state law.

Dated: _____

PURCHASER:

(PRINT NAME)

(Signature)

Spouse of Purchaser (if applicable)

ANNEX III

ELECTION UNDER SECTION 83(B)

OF THE INTERNAL REVENUE CODE OF 1986

The undersigned taxpayer hereby elects, pursuant to Section 83(b) of the Internal Revenue Code, to include in taxpayer's gross income or alternative minimum taxable income, as applicable, for the current taxable year, the amount of any income that may be taxable to taxpayer in connection with taxpayer's receipt of the property described below:

1. The name, address, taxpayer identification number and taxable year of the undersigned are as follows:

NAME OF TAXPAYER:

NAME OF SPOUSE:

ADDRESS:

United States

IDENTIFICATION NO. OF TAXPAYER:

IDENTIFICATION NO. OF SPOUSE:

TAXABLE YEAR:

2. The property with respect to which the election is made is described as follows: _____ shares of the Common Stock of Lexeon Therapeutics, Inc., a Delaware corporation (the "Company").

3. The date on which the property was transferred is: _____

4. The property is subject to the following restrictions: Repurchase option at cost in favor of the Company upon termination of taxpayer's employment or consulting relationship.

5. The fair market value at the time of transfer, determined without regard to any restriction other than a restriction which by its terms will never lapse, of such property is: USD \$ _____.

6. The amount (if any) paid for such property: USD \$ _____.

The undersigned has submitted a copy of this statement to the person for whom the services were performed in connection with the undersigned's receipt of the above-described property. The transferee of such property is the person performing the services in connection with the transfer of said property.

The undersigned understands that the foregoing election may not be revoked except with the consent of the Commissioner.

Dated: _____

PURCHASER:

(Signature)

Spouse of Purchaser (if applicable)

EXHIBIT C

LEXEO THERAPEUTICS, INC.

2021 EQUITY INCENTIVE PLAN

EXERCISE NOTICE

Lexeo Therapeutics, Inc.

Attention:

1. Exercise of Option. Effective as of today, _____, _____, the undersigned (“**Purchaser**”) hereby elects to purchase, _____, shares (the “**Shares**”) of the Common Stock of Lexeo Therapeutics, Inc. (the “**Company**”) under and pursuant to the 2021 Equity Incentive Plan (the “**Plan**”) and the Stock Option Award Agreement dated _____, _____ (the “**Award Agreement**”). The purchase price for the Shares will be USD \$ _____, as required by the Award Agreement.

2. Delivery of Payment. Purchaser herewith delivers to the Company, or otherwise makes adequate arrangements satisfactory to the Company, the full purchase price of the Shares and any Tax-Related Items (as defined in the Agreement) to be paid in connection with the exercise of the Option.

3. Representations of Purchaser. Purchaser acknowledges that Purchaser has received, read and understood the Plan and the Award Agreement and agrees to abide by and be bound by their terms and conditions.

4. Rights as Stockholder. Until the issuance (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company) of the Shares, no right to vote or receive dividends or any other rights as a stockholder will exist with respect to the Shares subject to the Option, notwithstanding the exercise of the Option. The Shares so acquired will be issued to Purchaser as soon as practicable after exercise of the Option. No adjustment will be made for a dividend or other right for which the record date is prior to the date of issuance, except as provided in Section 10 of the Plan.

5. Tax Consultation. Purchaser understands that Purchaser may suffer adverse tax consequences as a result of Purchaser’s purchase or disposition of the Shares. Purchaser represents that Purchaser has consulted with any tax consultants Purchaser deems advisable in connection with the purchase or disposition of the Shares and that Purchaser is not relying on the Company for any tax advice.

6. Limitations on Transfer. Purchaser acknowledges and agrees that the Shares purchased under this Agreement are subject to Section 9 of the Plan, the terms and conditions that apply to the Company’s Common Stock, as set forth in the Company’s Bylaws, as may be in effect at the time of any proposed transfer (the “Bylaw Provisions”), and any other limitation or restriction on transfer created by Applicable Laws. Purchaser shall not assign, encumber or dispose of any interest in the Shares except to the extent permitted by, and in compliance with, Section 9 of the Plan, the Bylaw Provisions and, Applicable Laws, and the provisions below.

(a) Transfer Restrictions; Right of First Refusal. Before any Shares held by Purchaser or any transferee of Purchaser (either being sometimes referred to herein as the “Holder”) may be sold or otherwise transferred (including transfer by gift or operation of law), the Company shall first, to the extent the Company’s approval is required by the Plan or any applicable Bylaw Provisions, have the right to approve such sale or transfer, in full or in part, and shall then have the right to purchase all or any part of the Shares proposed to be sold or transferred, in each case, in its sole and absolute discretion (the “Right of First Refusal”). If the Holder would like to sell or transfer any Shares, the Holder must provide the Company or its assignee(s) with a Notice (as defined below) requesting approval to sell or transfer the Shares and offering the Company or its assignee(s) a Right of First Refusal on the same terms and conditions set forth in this Section 6(a). The Company may either (i) exercise its Right of First Refusal in full or in part and purchase such Shares pursuant to this Section 6(a), (ii) decline to exercise its Right of First Refusal in full or in part and permit the transfer of such Shares to the Proposed Transferee (as defined below) in full or in part or (iii) decline to exercise its Right of First Refusal in full or in part and, to the extent the Company’s approval is required by the Plan or any applicable Bylaw Provisions, decline the request to sell or transfer the Shares in full or in part.

(i) Notice of Proposed Transfer. The Holder of the Shares shall deliver to the Company a written notice (the “Notice”) stating: (1) the Holder’s intention to sell or otherwise transfer such Shares; (2) the name of each proposed purchaser or other transferee (“Proposed Transferee”); (3) the number of Shares to be sold or transferred to each Proposed Transferee; (4) the terms and conditions of each proposed sale or transfer, including (without limitation) the purchase price for such Shares (the “Purchase Price”); and (5) the Holder’s offer to the Company or its assignee(s) to purchase the Shares at the Purchase Price and upon the same terms (or terms that are no less favorable to the Company).

(ii) Exercise of Right of First Refusal. At any time within 30 days after receipt of the Notice, the Company and/or its assignee(s) shall deliver a written notice to the Holder indicating whether the Company and/or its assignee(s) elect to permit or reject the proposed sale or transfer, in full or in part, and/or elect to accept or decline the offer to purchase any or all of the Shares proposed to be sold or transferred to any one or more of the Proposed Transferees, at the Purchase Price, provided that if the Purchase Price consists of no legal consideration (as, for example, in the case of a transfer by gift), the purchase price will be the fair market value of the Shares as determined in good faith by the Company. If the Purchase Price includes consideration other than cash, the cash equivalent value of the non-cash consideration shall be determined by the Company in good faith.

(iii) Payment. Payment of the Purchase Price shall be made, at the election of the Company or its assignee(s), in cash (by check), by cancellation of all or a portion of any outstanding indebtedness, or by any combination thereof within 60 days after receipt of the Notice or in the manner and at the times set forth in the Notice.

(iv) Holder’s Right to Transfer. If any of the Shares proposed in the Notice to be sold or transferred to a given Proposed Transferee are both (1) not purchased by the Company and/or its assignee(s) as provided in this Section 6(a) and (2) approved by the Company to be sold or transferred, then the Holder may sell or otherwise transfer any such Shares to the applicable Proposed Transferee at the Purchase Price or at a higher price, provided that such sale or other transfer is consummated within 120 days after the date of the Notice; provided that (A) any such sale or other transfer is also effected in accordance with the Bylaw Provisions, the transfer restrictions set forth in the Plan and any Applicable Laws and (B) the Proposed Transferee agrees in writing that the Plan, the Bylaw Provisions and the provisions of the Award Agreement and this Agreement, including this Section 6 shall continue to apply to the Shares in the hands of such Proposed Transferee. The Company, in consultation with its legal counsel, may require the Holder to provide an opinion of counsel evidencing compliance with Applicable Laws. If the Shares described in the Notice are not transferred to the Proposed Transferee within such period, or if the Holder proposes to change the price or other terms to make them more favorable to the Proposed Transferee, a new Notice shall be given to the Company, and the Company and/or its assignees shall again have the right to approve such transfer and be offered the Right of First Refusal.

(v) Exception for Certain Family Transfers. Anything to the contrary contained in this Section 6 notwithstanding, the transfer of any or all of the Shares during Holder's lifetime or on Holder's death by will or intestacy to Holder's Immediate Family or a trust for the benefit of Holder or Holder's Immediate Family shall be exempt from the provisions of this Section 6(a). "Immediate Family" as used herein shall mean lineal descendant or antecedent, father, mother, brother or sister (or their descendants), stepchild (or their antecedents or descendants), aunt or uncle (or their antecedents or descendants), brother-in-law or sister-in-law (or their antecedents or descendants) and shall include adoptive relationships, or any person sharing Holder's household (other than a tenant or an employee). In such case, the transferee or other recipient shall receive and hold the Shares so transferred subject to the provisions of the Plan, the Bylaw Provisions and the provisions of the Award Agreement and this Agreement, including this Section 6, and there shall be no further transfer of such Shares except in accordance with the terms of this Section 6, the Plan, and the Bylaw Provisions.

(b) Company's Right to Purchase upon Involuntary Transfer. In the event of any transfer by operation of law or other involuntary transfer (including death or divorce, but excluding a transfer to Immediate Family as set forth in Section 6(a)(v) above) of all or a portion of the Shares by the record holder thereof, the Company shall have an option to purchase any or all of the Shares transferred at the Fair Market Value of the Shares on the date of transfer (as determined by the Company in its sole discretion). Upon such a transfer, the Holder shall promptly notify the Secretary of the Company of such transfer and if requested by the Company. The right to purchase such Shares shall be provided to the Company for a period of 30 days following receipt by the Company of written notice from the Holder.

(c) Assignment. The right of the Company to purchase any part of the Shares may be assigned in whole or in part to any holder or holders of capital stock of the Company or other persons or organizations.

(d) Restrictions Binding on Transferees. All transferees of Shares or any interest therein will receive and hold such Shares or interest subject to the Plan, the Bylaw Provisions, the provisions of the Award Agreement and this Agreement. Any sale or transfer of the Shares shall be void unless the provisions of this Agreement are satisfied.

(e) Termination of Rights. The transfer restrictions set forth in Section 6(a) above, the Right of First Refusal granted the Company by Section 6(a) above and the right to repurchase the Shares in the event of an involuntary transfer granted the Company by Section 6(b) above shall terminate upon (i) the first sale of Common Stock of the Company to the general public pursuant to a registration statement filed with and declared effective by the Securities and Exchange Commission under the Securities Act of 1933, as amended (the "Securities Act") (other than a registration statement relating solely to the issuance of Common Stock pursuant to a business combination or an employee incentive or benefit plan) or (ii) any transfer or conversion of Shares made pursuant to a statutory merger or statutory consolidation of the Company with or into another corporation or corporations if the common stock of the surviving corporation or any direct or indirect parent corporation thereof is registered under the Exchange Act. Upon termination of such transfer restrictions, the Company will remove any stop-transfer notices referenced in Section 8(b) below and related to the restrictions in this Section 6 and a new stock certificate or, in the case of uncertificated securities, notice of issuance, for the Shares not repurchased shall be issued, on request, without the legend referred to in Section 8(a) below and delivered to Holder.

(f) Lock-Up Agreement. The lock-up provisions set forth in Section 15 of the Award Agreement shall apply to the Shares issued upon exercise of the Option hereunder and Purchaser reaffirms Purchaser's obligations set forth therein.

7. Investment and Taxation Representations. In connection with the purchase of the Shares, Purchaser represents to the Company the following:

(a) Purchaser is aware of the Company's business affairs and financial condition and has acquired sufficient information about the Company to reach an informed and knowledgeable decision to acquire the Shares. Purchaser is purchasing the Shares for investment for Purchaser's own account only and not with a view to, or for resale in connection with, any "distribution" thereof within the meaning of the Securities Act or under any applicable provision of state law. Purchaser does not have any present intention to transfer the Shares to any other person or entity.

(b) Purchaser understands that the Shares have not been registered under the Securities Act by reason of a specific exemption therefrom, which exemption depends upon, among other things, the bona fide nature of Purchaser's investment intent as expressed herein.

(c) Purchaser further acknowledges and understands that the securities must be held indefinitely unless they are subsequently registered under the Securities Act or an exemption from such registration is available. Purchaser further acknowledges and understands that the Company is under no obligation to register the securities.

(d) Purchaser is familiar with the provisions of Rule 144, promulgated under the Securities Act, which, in substance, permits limited public resale of "restricted securities" acquired, directly or indirectly, from the issuer of the securities (or from an affiliate of such issuer), in a non-public offering subject to the satisfaction of certain conditions. Purchaser understands that the Company provides no assurances as to whether he or she will be able to resell any or all of the Shares pursuant to Rule 144, which rule requires, among other things, that the Company be subject to the reporting requirements of the Exchange Act, that resales of securities take place only after the holder of the Shares has held the Shares for certain specified time periods, and under certain circumstances, that resales of securities be limited in volume and take place only pursuant to brokered transactions. Notwithstanding this Section 7(d), Purchaser acknowledges and agrees to the restrictions set forth in Section 7(e) below.

(e) Purchaser further understands that in the event all of the applicable requirements of Rule 144 are not satisfied, registration under the Securities Act, compliance with Regulation A, or some other registration exemption will be required; and that, notwithstanding the fact that Rule 144 is not exclusive, the Staff of the Securities and Exchange Commission has expressed its opinion that persons proposing to sell private placement securities other than in a registered offering and otherwise than pursuant to Rule 144 will have a substantial burden of proof in establishing that an exemption from registration is available for such offers or sales, and that such persons and their respective brokers who participate in such transactions do so at their own risk.

(f) Purchaser represents that Purchaser is not subject to any of the "Bad Actor" disqualifications described in Rule 506(d)(1)(i) to (viii) under the Securities Act. Purchaser also agrees to notify the Company if Purchaser becomes subject to such disqualifications after the date hereof.

(g) Purchaser understands that Purchaser may suffer adverse tax consequences as a result of Purchaser's purchase or disposition of the Shares. Purchaser represents that Purchaser has consulted any tax consultants Purchaser deems advisable in connection with the purchase or disposition of the Shares and that Purchaser is not relying on the Company for any tax advice.

8. Restrictive Legends and Stop-Transfer Orders.

(a) Legends. Any stock certificate or, in the case of uncertificated securities, any notice of issuance, for the Shares shall bear the following legends (as well as any legends required by the Company or applicable state and federal corporate and securities laws):

- “THE SECURITIES REFERENCED HEREIN HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AND HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF. NO SUCH SALE OR DISTRIBUTION MAY BE EFFECTED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL IN A FORM SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933.”
- “THE SECURITIES REFERENCED HEREIN MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF AN AGREEMENT BETWEEN THE COMPANY AND THE STOCKHOLDER, A COPY OF WHICH IS ON FILE WITH AND MAY BE OBTAINED FROM THE SECRETARY OF THE COMPANY AT NO CHARGE.”
- ”THE TRANSFER OF THE SECURITIES REFERENCED HEREIN IS SUBJECT TO CERTAIN TRANSFER RESTRICTIONS SET FORTH IN THE COMPANY’S STOCK PLAN, A COPY OF WHICH MAY BE OBTAINED UPON WRITTEN REQUEST TO THE COMPANY AT ITS PRINCIPAL PLACE OF BUSINESS. THE COMPANY SHALL NOT REGISTER OR OTHERWISE RECOGNIZE OR GIVE EFFECT TO ANY PURPORTED TRANSFER OF SECURITIES THAT DOES NOT COMPLY WITH SUCH TRANSFER RESTRICTIONS.”

(b) Stop-Transfer Notices. Purchaser agrees that, in order to ensure compliance with the restrictions referred to herein, the Company may issue appropriate “stop transfer” instructions to its transfer agent, if any, and that, if the Company transfers its own securities, it may make appropriate notations to the same effect in its own records.

(c) Refusal to Transfer. The Company shall not be required (i) to transfer on its books any Shares that have been sold or otherwise transferred in violation of any of the provisions of this Agreement or (ii) to treat as owner of such Shares or to accord the right to vote or pay dividends to any purchaser or other transferee to whom such Shares shall have been so transferred.

9. Waiver of Statutory Information Rights. Purchaser acknowledges and understands that, but for the waiver made herein, Purchaser would be entitled, upon written demand under oath stating the purpose thereof, to inspect for any proper purpose, and to make copies and extracts from, the Company’s stock ledger, a list of its stockholders, and its other books and records, and the books and records of subsidiaries of the Company, if any, under the circumstances and in the manner provided in Section 220 of the Delaware General Corporation Law (any and all such rights, and any and all such other rights of Purchaser as may be provided for in Section 220, the “Inspection Rights”). In light of the foregoing, until the first sale of Common Stock of the Company to the general public pursuant to a registration statement filed with and declared effective by the Securities and Exchange Commission under the Securities Act of 1933, as amended, Purchaser hereby unconditionally and irrevocably waives the Inspection Rights, whether such Inspection Rights would be exercised or pursued directly or indirectly pursuant to Section 220 or otherwise, and covenants and agrees never to directly or indirectly commence, voluntarily aid in any way, prosecute, assign, transfer, or cause to be commenced any claim, action, cause of action, or other proceeding to pursue or exercise the Inspection Rights. The foregoing waiver applies to the Inspection Rights of Purchaser in Purchaser’s capacity as a stockholder and shall not affect any rights of a director, in his or her capacity as such, under Section 220. The foregoing waiver shall not apply to any contractual inspection rights of Purchaser under any written agreement with the Company.

10. Entire Agreement; Governing Law. The Plan and Award Agreement are incorporated herein by reference. This Exercise Notice, the Plan and the Award Agreement constitute the entire agreement of the parties with respect to the subject matter hereof and supersede in their entirety all prior undertakings and agreements of the Company and Purchaser with respect to the subject matter hereof, and may not be modified adversely to the Purchaser’s interest except by means of a writing signed by the Company and Purchaser. This agreement is governed by the internal substantive laws, but not the choice of law rules, of the State of Delaware.

Submitted by:

Accepted by:

PURCHASER:

LEXEO THERAPEUTICS, INC.

Signature

By

Print Name

Title

Date Received

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EMPLOYMENT AGREEMENT
for
JOSE MANUEL OTERO, PH.D.

This Employment Agreement (the “**Agreement**”) is made between Lexeo Therapeutics, Inc. (the “**Company**”) and Jose Manuel Otero, Ph.D. (the “**Executive**”) (collectively, the “**Parties**”).

WHEREAS, the Company desires for Executive to provide services to the Company, and wishes to provide Executive with certain compensation and benefits in return for such employment services; and

WHEREAS, Executive wishes to be employed by the Company and to provide personal services to the Company in return for certain compensation and benefits;

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

1. Employment by the Company.

Position. Beginning May 20, 2024, Executive shall serve as the Company’s Chief Technical Officer. During the term of Executive’s employment with the Company, Executive will devote Executive’s best efforts and substantially all of Executive’s business time and attention to the business of the Company, except for approved time off permitted by the Company’s general employment policies.

1.1 Duties and Location. Executive shall perform such duties incident to the position(s) held by Executive, including without limitation such duties and responsibilities as may be assigned to Executive by the Chief Executive Officer (“CEO”), to whom Executive will report. Executive shall work in the Company’s New York City office as needed and requested by the Company, and Executive will be permitted to work remotely from his home office in Connecticut when not in the New York City office. The Company reserves the right, at the Board’s discretion, to reasonably require Executive to perform Executive’s duties at places other than Executive’s primary office location from time to time, and to require reasonable business travel. The Company may modify Executive’s job title and duties as it deems necessary and appropriate in light of the Company’s needs and interests from time to time.

1.2 Policies and Procedures. The employment relationship between the Parties shall be governed by the general employment policies and practices of the Company, except that when the terms of this Agreement differ from or are in conflict with the Company’s general employment policies or practices, this Agreement shall control.

1.3 Indemnification. The Executive shall be provided indemnification coverage under the Company’s D&O liability insurance policies to the same extent as directors and other executive officers of the Company.

2. Compensation.

2.1 Salary. For services to be rendered hereunder, Executive shall receive a base salary at the rate of **Four Hundred Thirty-Five Thousand Dollars (\$435,000)** per year (the “**Base Salary**”), subject to standard payroll deductions and withholdings and payable in accordance with the Company’s regular payroll schedule. The Base Salary is subject to periodic review and modification by the CEO and the Board (or the Compensation Committee of the Board), from time to time, at their sole discretion.

Annual Cash Bonus. Executive will be eligible for an annual discretionary cash bonus of up to **Forty Percent (40%)** of Executive’s Base Salary (the “**Annual Bonus**”). Whether Executive receives an Annual Bonus for any given year, and the amount of any such Annual Bonus, will be determined by the CEO and the Board (or the Compensation Committee of the Board) in their sole discretion based upon the Company’s performance and Executive’s achievement of individual objectives and milestones to be determined on an annual basis. Any Annual Bonus that is awarded will be paid within the first ninety (90) days of the calendar year following the applicable bonus year. Executive will not be eligible for, and will not earn, any Annual Bonus if Executive’s employment terminates for any reason, or if Executive or the Company has given notice of the termination of Executive’s employment, before the payment date, except as expressly provided for in Section 5.5 herein.

2.2 Equity Awards. Subject to the approval of the Company’s Compensation Committee of the Board of Directors (the “Committee”), you will be granted a mix of equity awards as follows:

- An option to purchase 187,500 shares of the Company’s Common Stock (the “Option”). The Option will vest and become exercisable over 4 years at the rate of 25% of the total number of Option shares on the 1-year anniversary of your start date of employment with the Company and 1/48th of the total number of Option shares on each monthly anniversary thereafter, subject to your continuous service with the Company through each vesting date. The exercise price per share of the Option will be equal to the fair market value per share of the Company’s Common Stock on the date the Option is granted, as determined by the Board in good faith. There is no guarantee that the Internal Revenue Service will agree with this value.
- 31,250 restricted stock units of the Company’s Common Stock (the “RSUs”). The RSUs will vest over a period of approximately 4 years. RSUs for the Company will generally vest on specific dates each quarter for the entire Company. The vesting start date of your RSUs will be the next Company RSU vesting date that occurs after your start date. The RSUs will vest as to 25% of the total number of RSUs on the 1- year anniversary of your RSU vesting start date and 1/16th of the total number of RSU shares on each quarterly date 3-months thereafter, subject to your continuous service with the Company through each vesting date.

3. Standard Company Benefits. Executive shall be entitled to participate in all employee benefit programs for which Executive is eligible under the terms and conditions of the benefit plans that may be in effect from time to time and provided by the Company to its employees, subject to the eligibility criteria, rules, plan provisions and regulations applicable to such plans, except to the extent that participation in such plans or programs would result in duplication of benefits provided hereunder. The Company reserves the right to cancel or change the benefit plans or programs it offers to its employees at any time, in its sole discretion.

4. Expenses. The Company will reimburse Executive for reasonable travel, entertainment or other expenses incurred by Executive in furtherance or in connection with the performance of Executive’s duties hereunder, subject to, and in accordance with, the Company’s expense reimbursement policy as in effect from time to time.

5. Termination of Employment; Severance

5.1 At-Will Employment. Executive's employment relationship is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without cause or advance notice.

5.2 Termination Based on Death or Disability. In the event of the Executive's death, the Executive's employment with the Company shall terminate automatically. The Company, in its discretion, shall have the right to terminate the Executive's employment because of the Executive's Disability during the Employment Period, subject to applicable law. For purposes of this Agreement, "Disability" means that the Executive has been unable, for 60 consecutive days, or for any period aggregating 90 business days in any consecutive 180 day period, as the case may be, to perform a substantial portion of the Executive's duties under this Agreement, as a result of physical or mental impairment, illness or injury, as determined by a medical doctor reasonably selected by the Company and approved by the Executive, such approval not to be unreasonably withheld, delayed or conditioned. Such determination shall be deemed to be conclusive for all purposes of this Section 5.2. In connection with the foregoing, the Executive shall cooperate with such medical doctor, including without limitation, by submitting to such medical tests and examinations as may be requested by the medical doctor. A termination of the Executive's employment by the Company for Disability shall be communicated to the Executive by written notice upon the expiration of the applicable period and shall be effective on the 30th day after receipt of such notice by the Executive (the "Disability Effective Date"), unless the Executive returns to satisfactory full-time performance of the Executive's previous duties before the Disability Effective Date. In the event the Executive's employment is terminated due to death or Disability, the Company shall have no further obligations to the Executive hereunder, except the Company shall pay to the Executive (or, in the event of death, to the Executive's estate) any (i) Base Salary earned or payable but unpaid to the Executive through the Date of Termination, (ii) reimbursable business expenses incurred but unpaid through the Date of Termination (subject to Company's applicable expense policies, including submission of all required documentation), and (iii) any other amounts or benefits required by applicable law.

5.3 Termination Without Cause; Resignation for Good Reason.

(i) The Company may terminate Executive's employment with the Company at any time without Cause (as defined below). Further, Executive may resign at any time for Good Reason (as defined below).

(ii) In the event Executive's employment with the Company is terminated by the Company without Cause, or Executive resigns for Good Reason, then provided such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "**Separation from Service**"), and provided that Executive remains in compliance with the terms of this Agreement, the Company shall provide Executive with the following severance benefits:

(a) The Company shall pay Executive, as severance, twelve (12) months of Executive's base salary in effect as of the date of Executive's employment termination, subject to standard payroll deductions and withholdings (the "**Severance**"). The Severance will be paid in a single lump sum on or about the Company's first regular payroll date following the 60th day after Executive's Separation from Service.

(b) Provided Executive timely elects continued coverage under COBRA, the Company shall pay Executive's COBRA premiums to continue Executive's coverage (including coverage for eligible dependents, if applicable) ("**COBRA Premiums**") through the period (the "**COBRA Premium Period**") starting on Executive's Separation from Service and ending on the earliest to occur of: (i) twelve (12) months following Executive's Separation from Service; (ii) the date Executive becomes eligible for group health insurance coverage through a new employer; or (iii) the date Executive ceases to be eligible for COBRA continuation coverage for any reason, including plan termination. In the event Executive becomes covered under another employer's group health plan or otherwise ceases to be eligible for COBRA during the COBRA Premium Period, Executive must immediately notify the Company of such event. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Premiums without a substantial risk of violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company instead shall pay to Executive, on the first day of each calendar month, a fully taxable cash payment equal to the applicable COBRA premiums for that month (including premiums for Executive and Executive's eligible dependents who have elected and remain enrolled in such COBRA coverage), subject to applicable tax withholdings (such amount, the "**Special Cash Payment**"), for the remainder of the COBRA Premium Period. Executive may, but is not obligated to, use such Special Cash Payments toward the cost of COBRA premiums.

5.4 Termination for Cause; Resignation Without Good Reason; Death or Disability.

(i) The Company may terminate Executive's employment with the Company at any time for Cause. Further, Executive may resign at any time without Good Reason. Executive's employment with the Company may also be terminated due to Executive's death or disability.

(ii) If Executive resigns without Good Reason, or the Company terminates Executive's employment for Cause, or upon Executive's death or disability, then (i) Executive will no longer vest in the Option and any other stock options held by the Executive, (ii) all payments of compensation by the Company to Executive hereunder will terminate immediately (except as to amounts already earned), and (c) Executive will not be entitled to any severance benefits, including (without limitation) the Severance, COBRA Premiums, Special Cash Payments, unless required by law.

5.5 Termination in Connection with Change in Control. If the Company terminates Executive's employment no more than three (3) months prior to a Change in Control (as defined herein) or within twelve (12) months after a Change in Control, Executive shall be entitled to receive the following severance benefits:

(i) The Company shall pay Executive, as severance, twelve (12) months of Executive's base salary in effect as of the date of Executive's employment termination, subject to standard payroll deductions and withholdings (the "**CIC Severance**"). The CIC Severance will be paid in a single lump sum on or about the Company's first regular payroll date following the 60th day after Executive's Separation from Service.

(ii) Provided Executive timely elects continued coverage under COBRA, the Company shall pay Executive's COBRA premiums to continue Executive's coverage (including coverage for eligible dependents, if applicable) ("**CIC COBRA Premiums**") through the period (the "**CIC COBRA Premium Period**") starting on Executive's Separation from Service and ending on the earliest to occur of: (i) twelve (12) months following Executive's Separation from Service; (ii) the date Executive becomes eligible for group health insurance coverage through a new employer; or (iii) the date Executive ceases to be eligible for COBRA continuation coverage for any reason, including plan termination. In the event Executive becomes covered under another employer's group health plan or otherwise ceases to be eligible for COBRA during the CIC COBRA Premium Period, Executive must immediately notify the Company of such event. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the CIC COBRA Premiums without a substantial risk of violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company instead shall pay to Executive, on the first day of each calendar month, a fully taxable cash payment equal to the applicable COBRA premiums for that month (including premiums for Executive and Executive's eligible dependents who have elected and remain enrolled in such COBRA coverage), subject to applicable tax withholdings (such amount, the "**CIC Special Cash Payment**"), for the remainder of the CIC COBRA Premium Period. Executive may, but is not obligated to, use such CIC Special Cash Payments toward the cost of COBRA premiums.

(iii) The Company shall pay Executive, as further severance, a lump sum amount equal to her full bonus target for the calendar year in which the Change in Control occurs (the "**CIC Bonus Payment**"), to be paid no later than thirty (30) days following Executive's Separation from Service.

(iv) The Company shall accelerate the vesting of any shares, options, or other equity grants then unvested and outstanding as of the Executive's Separation from Service, such that Executive will thereafter be 100% vested in any shares, options, or other equity grants awarded by the Company to Executive during Executive's employment with the Company (the "**Vesting Acceleration**").

6. Conditions to Receipt of Severance, COBRA Premiums, and Special Cash Payments. The receipt of the Severance, CIC Severance, COBRA Premiums, CIC COBRA Premiums, Special Cash Payments, CIC Special Cash Payments, CIC Bonus Payment, and Vesting Acceleration (collectively, the "Severance Benefits") will be subject to Executive signing and not revoking a separation agreement and release of claims in a form satisfactory to the Company (the "Separation Agreement") within a time period specified by the Company, in its sole discretion. No Severance Benefits will be paid or provided until the Separation Agreement becomes effective. Executive shall also resign from all positions and terminate any relationships as an employee, advisor, officer or director with the Company and any of its affiliates, each effective on the date of termination.

7. Section 409A. It is intended that all of the severance benefits and other payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon Separation from Service set forth herein and/or under any other agreement with the Company are deemed to be "deferred compensation", then to the extent delayed commencement of any portion of such payments is required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided to Executive prior to the earliest of (i) the expiration of the six-month period measured from the date of Executive's Separation from Service with the Company, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Paragraph shall be paid in a lump sum to Executive, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred.

8. Definitions.

(i) Cause. For purposes of this Agreement, "Cause" for termination will mean: (a) Executive's conviction for, or entry of a guilty plea or plea of nolo contendere for, any felony or crime involving dishonesty; (b) Executive's participation in any fraud against the Company; (c) material breach of Executive's duties to the Company; (d) persistent unsatisfactory performance of Executive's job duties after written notice from the Board and a reasonable opportunity to cure (if deemed curable); (e) Executive's intentional damage to any property of the Company; (f) Executive's misconduct, or other violation of Company policy that causes harm; (g) Executive's breach of any written agreement with the Company; and (h) conduct by Executive which in the good faith and reasonable determination of the Board demonstrates gross unfitness to serve, including but not limited to conduct involving moral turpitude, corruption, dishonesty, or other conduct that harms the Company's reputation or prospects.

(ii) Good Reason. For purposes of this Agreement, Executive shall have "Good Reason" for resignation from employment with the Company if any of the following actions are taken by the Company without Executive's prior written consent: (a) a material reduction in Executive's base salary, which the parties agree is a reduction of at least 10% of Executive's base salary (unless pursuant to a salary reduction program applicable generally to the Company's similarly situated executive employees); (b) a material reduction in Executive's duties (including responsibilities and/or authorities), *provided, however*, that a change in job position shall not be deemed a "material reduction" in and of itself unless Executive's new duties are materially reduced from the prior duties; or (c) relocation of Executive's principal place of employment to a place that increases Executive's one-way commute by more than sixty (60) miles as compared to Executive's then-current principal place of employment immediately prior to such relocation. In order to resign for Good Reason, Executive must provide written notice to the Board within 30 days after the first occurrence of the event giving rise to Good Reason setting forth the basis for Executive's resignation, allow the Company at least 30 days from receipt of such written notice to cure such event, and if such event is not reasonably cured within such period, Executive must resign from all positions Executive then holds with the Company not later than 90 days after the expiration of the cure period.

(iii) Change in Control. For purposes of this Agreement, "Change in Control" shall have the meaning set forth in the Lexeo Therapeutics, Inc. 2023 Equity Incentive Plan.

9. Proprietary Information Obligations.

9.1 Confidential Information Agreement. As a condition of employment, Executive shall execute and abide by the Company's standard form of Employee Confidential Information And Inventions Assignment Agreement (the "Confidentiality Agreement").

9.2 Third-Party Agreements and Information. Executive represents and warrants that Executive's employment by the Company does not conflict with any prior employment or consulting agreement or other agreement with any third party, and that Executive will perform Executive's duties to the Company without violating any such agreement. Executive represents and warrants that Executive does not possess confidential information arising out of prior employment, consulting, or other third party relationships, that would be used in connection with Executive's employment by the Company, except as expressly authorized by that third party. During Executive's employment by the Company, Executive will use in the performance of Executive's duties only information which is generally known and used by persons with training and experience comparable to Executive's own, common knowledge in the industry, otherwise legally in the public domain, or obtained or developed by the Company or by Executive in the course of Executive's work for the Company. Executive expressly acknowledges that she will not use any confidential or proprietary information of a third-party in connection with the performance of his duties to the Company.

10. Outside Activities During Employment.

10.1 Non-Company Business. Except with the prior written consent of the Board, Executive will not during the term of Executive's employment with the Company undertake or engage in any other employment, occupation or business enterprise, other than ones in which Executive is a passive investor. In any event, Executive may: (i) engage in civic and not-for-profit activities; (ii) engage in activities in connection with personal investments; (iii) serve, following receiving consent from the Board (which shall not unreasonably be withheld), on board of directors positions for up to two (2) organizations, and (iv) serve as an advisor, or as a member of an advisory board, following receiving consent from the Board (which shall not unreasonably be withheld), on up to two (2) organizations; so long as such activities do not materially interfere with the performance of Executive's duties hereunder.

10.2 No Adverse Interests. Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise. This does not prohibit the Executive from purchasing any publicly listed securities or funds which hold publicly listed securities.

11. Dispute Resolution. To ensure the timely and economical resolution of disputes that may arise in connection with Executive's employment with the Company, Executive and the Company agree that any and all disputes, claims, or causes of action arising from or relating to the enforcement, breach, performance, negotiation, execution, or interpretation of this Agreement, the Confidential Information Agreement, or Executive's employment, or the termination of Executive's employment, including but not limited to all statutory claims, with the exception of discrimination and harassment claims, will be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16 (the "FAA"), and to the fullest extent permitted by law, by final, binding and confidential arbitration by a single arbitrator conducted in New York, New York by Judicial Arbitration and Mediation Services Inc. ("JAMS") under the then applicable JAMS rules appropriate to the relief being sought (the applicable rules are available at the following web addresses: (i) <https://www.jamsadr.com/rules-employment-arbitration/> and (ii) <https://www.jamsadr.com/rules-comprehensive-arbitration/>); provided, however, this arbitration provision not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, claims involving allegations of sexual harassment and discrimination, to the extent such claims are not permitted by applicable law(s) to be submitted to mandatory arbitration and the applicable law(s) are not preempted by the FAA or otherwise invalid (collectively, the "Excluded Claims"). A hard copy of the rules will be provided to Executive upon request. A hard copy of the rules will be provided to Executive upon request. **By agreeing to this arbitration procedure, both Executive and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding.** In addition, all claims, disputes, or causes of action under this section, whether by Executive or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The Arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding.

To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. The Company acknowledges that Executive will have the right to be represented by legal counsel at any arbitration proceeding. Questions of whether a claim is subject to arbitration under this Agreement) shall be decided by a federal court in the State of New York. However, procedural questions which grow out of the dispute and bear on the final disposition are matters for the arbitrator. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; (b) issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award; and (c) be authorized to award any or all remedies that Executive or the Company would be entitled to seek in a court of law. Executive and the Company shall equally share all JAMS' arbitration fees. To the extent JAMS does not collect or Executive otherwise does not pay to JAMS an equal share of all JAMS' arbitration fees for any reason, and the Company pays JAMS Executive's share, Executive acknowledges and agrees that the Company shall be entitled to recover from Executive half of the JAMS arbitration fees invoiced to the parties (less any amounts Executive paid to JAMS) in a federal or state court of competent jurisdiction. Except as modified in the Confidential Information Agreement, each party is responsible for its own attorneys' fees. Nothing in this Agreement is intended to prevent either Executive or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction. To the extent a New York federal court determines that any applicable law prohibits mandatory arbitration of Excluded Claims, if Executive intends to bring multiple claims, including one or more Excluded Claims, the Excluded Claim(s) may be publicly filed with a court, while any other claims will remain subject to mandatory arbitration.

12. Section 280G Matters.

12.1 If any payment or benefit Executive will or may receive from the Company or otherwise (a “**280G Payment**”) would (i) constitute a “parachute payment” within the meaning of Section 280G of the Code, and (ii) but for this Section, be subject to the excise tax imposed by Section 4999 of the Code (the “**Excise Tax**”), then any such 280G Payment provided pursuant to this Agreement (a “**Payment**”) shall be equal to the Reduced Amount. The “**Reduced Amount**” shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax, or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state, and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive’s receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the “**Reduction Method**”) that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the “**Pro Rata Reduction Method**”).

12.2 Notwithstanding any provision of this Section 12 to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Executive as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are “deferred compensation” within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

12.3 The Company shall appoint a nationally-recognized accounting, consulting or law firm to make the determinations required by this Section 12. The Company shall bear all expenses with respect to the determinations by such firm required to be made hereunder.

12.4 If Executive receives a Payment for which the Reduced Amount was determined pursuant to clause (x) of and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, Executive agrees to promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) of Section 12(i)) so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) of Section 12(i), Executive shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

13. General Provisions.

13.1 Notices. Any notices provided must be in writing and will be deemed effective upon the earlier of personal delivery (including personal delivery by fax) or the next day after sending by overnight carrier, to the Company at its primary office location and to Executive at the address as listed on the Company payroll.

13.2 Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction to the extent possible in keeping with the intent of the parties.

13.3 Waiver. Any waiver of any breach of any provisions of this Agreement must be in writing to be effective, and it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

13.4 Complete Agreement. This Agreement, together with the Confidentiality Agreement, constitutes the entire agreement between Executive and the Company with regard to this subject matter and is the complete, final, and exclusive embodiment of the Parties' agreement with regard to this subject matter. This Agreement is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. It is entered into without reliance on any promise or representation other than those expressly contained herein, and it cannot be modified or amended except in a writing signed by a duly authorized officer of the Company.

13.5 Amendments and Waivers. This Agreement cannot be changed, modified or amended, and no provision or requirement hereof may be waived, without the consent in writing of the Executive and the Company. The failure of a party at any time or times to require performance of any provision hereof shall in no manner affect the right of such party at a later time to enforce the same. No waiver by a party of the breach of any term or covenant contained in this Agreement, 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 breach, or a waiver of the breach of any other term or covenant in this Agreement.

13.6 Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement.

13.7 Headings. The headings of the paragraphs hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

13.8 Successors and Assigns. This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors, assigns, heirs, executors and administrators, except that Executive may not assign any of his duties hereunder and he may not assign any of his rights hereunder without the written consent of the Company, which shall not be withheld unreasonably.

13.9 Tax Withholding and Indemnification. All payments and awards contemplated or made pursuant to this Agreement will be subject to withholdings of applicable taxes in compliance with all relevant laws and regulations of all appropriate government authorities. Executive acknowledges and agrees that the Company has neither made any assurances nor any guarantees concerning the tax treatment of any payments or awards contemplated by or made pursuant to this Agreement. Executive has had the opportunity to retain a tax and financial advisor and fully understands the tax and economic consequences of all payments and awards made pursuant to the Agreement.

13.10 Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of New York.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the day and year written below.

LEXEO THERAPEUTICS, INC.

By: /s/ R. Nolan Townsend

R. Nolan Townsend
Chief Executive Officer

Date: 4/10/2024

JOSE MANUEL OTERO, PH.D.

/s/ Jose Manuel Otero

Chief Technical Officer

Date: 4/10/2024

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

Execution Version

THIRD LICENSE AGREEMENT

BETWEEN

LEXEO THERAPEUTICS, INC.

AND

CORNELL UNIVERSITY

FOR

DOCKET NO. D-9332, D-10224, D-11139

CTL CONTRACT NO. [*]**

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THIRD LICENSE AGREEMENT

This Third License Agreement (this “**Agreement**”) is made by and between Lexeo Therapeutics, Inc., a Delaware corporation, having an office at 345 Park Avenue South, 6th Floor, New York, NY 10010 (“**LICENSEE**”), and Cornell University, a New York education corporation (“**Cornell**”), as represented by its Cornell Center for Technology Licensing (“**CTL**”) at 395 Pine Tree Road, Suite 310, Ithaca, NY 14850. Cornell and LICENSEE each may be referred to herein as a “**Party**” and together as the “**Parties**.”

This Agreement is effective on the date of the last signature hereto (the “**Effective Date**”).

RECITALS

WHEREAS, Dr. Ronald G. Crystal and collaborators at Cornell (“**Cornell Inventors**” collectively and “**Dr Crystal**” for Dr. Ronald G. Crystal specifically) and collaborators at INSERM invented a gene therapy for the cardiac manifestations of Friedreich’s ataxia (the “**Initial Invention**”) (CTL Docket D-6197), concerning which INSERM and Cornell entered into an inter-institutional agreement (Cornell contract [***]) for the Initial Invention and associated know-how that existed at that time (“**Initial Know-How**”), which agreement preserved Cornell’s freedom to use and develop the Initial Invention and Initial Know-How.

WHEREAS, INSERM patented the Initial Invention and in 2014 licensed those patent rights and the Initial Know-How to AAVLife, which subsequently changed its name to Annapurna Therapeutics and later merged into Adverum Biotechnologies Inc (“**Adverum**”).

WHEREAS, effective May 28, 2020 Cornell and LICENSEE entered into a Second License Agreement (Cornell contract [***], the “**Second License Agreement**”) under which Cornell licensed then-existing know-how concerning the Initial Invention (“**Know-How**”, as further defined below) to LICENSEE, which agreement preserved Cornell’s freedom to use and develop the Know-How. Said Second License Agreement did not specify the Know-How.

WHEREAS, in March 2021 LICENSEE acquired rights to the Initial Invention and Initial Know-How from Adverum.

WHEREAS, Cornell Inventors applied for and obtained funding from the NHLBI under [***] (the “**Grants**”) to conduct a clinical trial using the Initial Invention, submitted that certain IND number 028029 (the “**Study IND**”), received a Study May Proceed notification from the U.S. Food and Drug Administration, and obtained approval to conduct the study under Weill Cornell IRB Protocol [***], as may be amended from time to time (the “**Study IRB**”).

WHEREAS, Cornell and LICENSEE entered into that certain Contract Services Agreement between LICENSEE and Cornell, effective February 18, 2021 (the “**2021 CSA**”), pursuant to which Cornell conducted certain animal studies on behalf of LICENSEE in the laboratory of Cornell Inventors;

WHEREAS, the 2021 CSA provided LICENSEE with ownership of all intellectual property generated through performance of these animal studies under the 2021 CSA, and LICENSEE has filed a patent application claiming certain inventions related to such studies, along with inventions made by Cornell Inventors arising from work funded by the Grants and owned by Cornell and docketed at Cornell as CTL Docket D-10224 entitled “Methods and Pharmaceutical Compositions for the Treatment and the Prevention of Cardiomyopathy Associated with Friedreich’s Ataxia” (as further defined below, the “**Patents Rights**”);

WHEREAS, Cornell is conducting a clinical trial of a gene therapy for the treatment of Friedreich’s Ataxia under the Grants and not funded or supported by LICENSEE, under the Study IND and the Study IRB (the “**Study**”), which Study has generated and will continue to generate certain data (as further defined below, the “**Data**”), docketed at Cornell as CTL Docket D-11139;

WHEREAS, Cornell desires that the Patent Rights, the Know-How, and the Data (each, as hereinafter defined) be developed and utilized to the fullest possible extent so that their benefits can be enjoyed by the general public; and LICENSEE desires to obtain certain rights and licenses with respect to the Patent Rights, the Data, and the Know-How all on the terms and conditions set forth below;

WHEREAS, LICENSEE understands that LICENSEE is paying consideration hereunder for its access to the Data and the Know-How and such rights in the Patent Rights, and not continued secrecy therein.

WHEREAS, LICENSEE and Cornell wish to amend the Second License Agreement to remove the Know-How from it, and to include the Know-How in this Agreement.

NOW, THEREFORE, the Parties agree:

ARTICLE 1. DEFINITIONS

The terms, as defined herein, shall have the same meanings in both their singular and plural forms.

- 1.1 “**Affiliate**” means, with respect to LICENSEE, any corporation or other person or business in which LICENSEE owns or controls, directly or indirectly, at least fifty percent (50%) of the outstanding stock, units of membership, or other voting rights entitled to elect directors or officers, or in which LICENSEE is owned or controlled directly or indirectly by any corporation or other person or business or group of persons which owns at least fifty percent (50%) of the outstanding stock, units of membership, or other voting rights entitled to elect directors or officers; but in any country where the local law does not permit foreign equity participation of at least fifty percent (50%), then an “Affiliate” includes any company in which LICENSEE owns or controls or is owned or controlled by, directly or indirectly, the maximum percentage of outstanding stock, units of membership, or voting rights permitted by local law.
- 1.2 “**BLA**” means (a) in the United States, a Biologics License Application, as defined in the United States Public Health Service Act (42 U.S.C. §262), and applicable regulations promulgated thereunder by the FDA, or any equivalent application that replaces such application, (b) in the European Union, a marketing authorization, as defined in applicable regulations of the European Medicines Agency, and (c) in any other country, the relevant equivalent to the foregoing.
- 1.3 “**Commercially Reasonable Efforts**” means, with respect to any person, such efforts that are consistent with the efforts and resources used by a biopharmaceutical company of similar size and market capitalization as such person in the exercise of its commercially reasonable business practices relating to an exercise of a right or performance of an obligation under this Agreement, including the research, development, manufacture and commercialization of a pharmaceutical or biologic compound or product, as applicable, at a similar stage in its research, development or commercial life as the relevant Licensed Product, and that has commercial and market potential similar to the relevant Licensed Product, taking into account issues of intellectual property coverage, safety and efficacy, stage of development, product profile, competitiveness of the marketplace, proprietary position, regulatory exclusivity, anticipated or approved labeling, present and future market and commercial potential, the likelihood of receipt of Regulatory Approval, profitability (including pricing and reimbursement status achieved or likely to be achieved), amounts payable to licensors of patent or other intellectual property rights, alternative products and legal issues.
- 1.4 “**Completion**” means, with respect to a Phase II Clinical Trial or Phase III Clinical Trial, the earlier of (a) [***] following the database lock for such clinical trial and (b) the completion of a final study report by LICENSEE for such clinical trial.

- 1.5 “**Confidential Information**” means: (a) with respect to Cornell, (i) information disclosed by CTL to LICENSEE during the Term, which if disclosed in writing shall be marked “Confidential”, or if first disclosed otherwise by CTL, shall within [***]of such disclosure be reduced to writing by CTL and sent to LICENSEE; and (ii) Data, the Study IND included in Know-How, and the FDA correspondence related to the right of reference granted in Paragraph 2.5, in each case whether or not marked “Confidential”; and (b) with respect to LICENSEE, reports provided by LICENSEE to CTL hereunder and any other information disclosed by LICENSEE to CTL during the Term, which if disclosed in writing shall be marked “Confidential”, or if first disclosed otherwise by LICENSEE, shall within [***] of such disclosure be reduced to writing by LICENSEE and sent to CTL.
- 1.6 “**Cover**”, “**Covering**” or “**Covered**” means, with respect to a Valid Claim and a Licensed Product or Licensed Method, that the manufacture, use, offer for sale, sale or importation of the Licensed Product or the use of the Licensed Method, as applicable, would infringe, induce infringement of, or contribute to infringement of, a Valid Claim in the country in which such activity occurred, if not for the License granted hereunder. For the purposes of this definition, a Valid Claim in a pending application shall be treated as though it had issued for the period of time described in clause (b) of the definition of “Valid Claim” below.
- 1.7 “**Data**” means the data and reports from the Study set forth in Appendix B, as may be updated from time to time by amendment of this Agreement. “Data” includes subsets of the Data. Data incorporated into another dataset by LICENSEE, an Affiliate, a Sublicensee, or a Contractor (“Other Dataset”) shall still be treated as “Data”; for clarity, such incorporation does not relieve LICENSEE of its obligations concerning Data, regardless of whether said Other Dataset is considered a new work or a new dataset.
- 1.8 “**Excluded Entity**” means, as of the grant of any Sublicense or assignment permitted under this Agreement, any corporation or other business entity, government or governmental entity, or individual that: (a) is in active litigation, arbitration proceedings or other contractual dispute with Cornell; (b) is engaged in “patent troll” or other similar activities; or (c) is on any list of prohibited governments, individuals or entities enacted under United States economic sanctions or anti-boycott laws.
- 1.9 “**Field**” means human and non-human prophylactic and therapeutic uses of Licensed Products.
- 1.10 “**First Commercial Sale**” means the first commercial sale of a Licensed Product by LICENSEE or any Affiliate or Sublicensee in a country in an arms’-length transaction to a third-party following receipt of applicable Regulatory Approval of such Licensed Product in such country.
- 1.11 “**FDA**” means the United States Food and Drug Administration.
- 1.12 “**FFDCA**” means the United States Federal Food, Drug, and Cosmetic Act, as set forth at 21 U.S.C. ch. 9 §301 et seq., as may be amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).
- 1.13 “**Generic Equivalent**” means: (a) for any small molecule, any product with the same active ingredient and route of administration as a Licensed Product (including pursuant to Section 505(b)(2) of the FFDCA or any foreign equivalent with respect to such Licensed Product) that is legally marketed for the same Indication as said Licensed Product by a third-party who is not an Affiliate, Sublicensee or Distributor of LICENSEE; and (b) for any biologic, any product with a “highly similar” active ingredient(s) as such Licensed Product, as the phrase “highly similar” is used in 42 U.S.C. § 262(i)(2), and subject to the factors set forth in FDA’s Guidance for Industry, “Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product,” (February 2012), at Section VI, and any successor FDA guidance thereto, or any foreign equivalent, that is legally marketed for the same Indication as said Licensed Product by a third-party who is not an Affiliate, Sublicensee or Distributor of LICENSEE.

- 1.14 “**IND**” means (a) in the United States, an Investigational New Drug application, as defined in 21 C.F.R, Part 312, or any equivalent application that replaces such application, (b) in the European Union, a clinical trial application, as defined in applicable regulations of the European Medicines Agency, and (c) in any other country, the relevant equivalent to the foregoing.
- 1.15 “**Indication**” means any human disease, condition or syndrome, or sign or symptom of, or associated with, a human disease, condition or syndrome in a particular target patient population; it being understood that: (a) different line therapies for the same disease or condition, such as (for example) first-line treatment for a disease or condition as compared to second-line treatment for such same disease or condition, shall not be deemed to be a different Indication; and (b) all variants of a single disease or condition (e.g., variants of colon cancer or variants of prostate cancer), whether classified by severity or otherwise, shall be treated as the same Indication.
- 1.16 “**Know-How**” means the know-how contained in Cornell Docket D-9332, as described in Appendix C.
- 1.17 “**License**” means the license granted by Cornell to LICENSEE pursuant to Paragraph 2.1.
- 1.18 “**Licensed Method**” means any method that uses the Study IND included in Know-How or the right of reference granted in Paragraph 2.5, or the use, practice and performance of which is Covered by a Valid Claim.
- 1.19 “**Licensed Product**” means any composition or product: (a) that is Covered by a Valid Claim; (b) that is in clinical trials based on an IND citing the right of reference to the Study IND granted in Paragraph 2.5 or on any IND including technical information in the Study IND included in Know-How; (c) which receives Regulatory Approval based on a BLA citing the right of reference to the Study IND granted in Paragraph 2.5 or any IND including technical information in the Study IND included in Know-How; (d) that is produced by or enabled by a Licensed Method; or (e) for which the IND or the BLA includes or references the Data. For the purpose of this Agreement, LICENSEE agrees that the above definition shall be interpreted as [***].
- 1.20 “**Licensed Product Activity**” means the research, commercialization, development or manufacturing of any Licensed Product in the Field.
- 1.21 “**Major Market**” means any of the following countries or jurisdictions: [***].
- 1.22 “**Major Biopharmaceutical Company**” means: (a) a publicly traded pharmaceutical company whose market capitalization exceeds [***] at the end of the company’s most recent fiscal year preceding the effective date of the proposed Sublicense to such company by LICENSEE; or (b) a company whose products or services primarily use biotechnology methods for their production, design or delivery and whose annual sales exceed [***] for the company’s most recent fiscal year preceding the effective date of the proposed Sublicense to such company by LICENSEE as shown on the company’s financial statements that are audited by a nationally recognized accounting firm.
- 1.23 “**Net Sales**” means, with respect to a Licensed Product for any period, the total amount billed or invoiced on sales of such Licensed Product during such period by LICENSEE or any Affiliate or Sublicensee to third-parties (including wholesalers or Distributors), in bona fide arm’s-length transactions, less the following deductions, in each case related specifically to such Licensed Product and actually allowed and taken by such third-parties and not otherwise recovered by or reimbursed to LICENSEE or any Affiliate or Sublicensee:
- (a) trade, cash and quantity discounts;

(b) price reductions or rebates, retroactive or otherwise, imposed by, negotiated with or otherwise paid to governmental authorities or other payees;

(c) taxes on sales (such as sales, value added, or use taxes) to the extent added to the sale price and set forth separately as such in the total amount invoiced; provided, however, with respect to value-added taxes (“VAT”), only the first VAT LICENSEE or any Affiliate or Sublicensee withholds and pays to the government on behalf of a foreign customer for the sale of the Licensed Product may be deducted, provided that any VAT refund received by LICENSEE or any Affiliate or Sublicensee for which a deduction was previously made during the Term shall be added to the Net Sales of the period during which such VAT refund is received;

(d) amounts repaid or credited by reason of rejections, defects, return goods allowance, recalls or returns, or because of retroactive price reductions, including rebates or wholesaler charge backs;

(e) the portion of administrative fees paid during the relevant time period to group purchasing organizations, pharmaceutical benefit managers or Medicare Prescription Drug Plans relating to such Licensed Product;

(f) any invoiced amounts that are not collected and are written off by LICENSEE or any Affiliate or Sublicensee, including bad debts, provided that (i) such amount shall not exceed, for a given reporting period under Paragraph 4.1, [***], and (ii) if the debt is thereafter paid, the corresponding credit amount shall be added to the Net Sales of the period during which it is paid;

(g) that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) and reasonably allocable to sales of such Licensed Product; and

(h) freight, insurance, import/export, and other transportation charges to the extent added to the sale price and set forth separately as such in the total amount invoiced, as well as any fees for services provided by wholesalers and warehousing chains related to the distribution of such Licensed Product.

Net Sales shall not include transfers or dispositions for charitable, promotional, pre-clinical, clinical, regulatory, or governmental purposes for which, in each case, no consideration is received. Net Sales shall include the amount of fair-market value of all other consideration received by LICENSEE or any Affiliate or Sublicensee in respect of such Licensed Product, whether such consideration is in cash, payment in kind, exchange or other form. Net Sales shall not include sales between or among LICENSEE or any Affiliate or Sublicensee after which the purchaser resells the Licensed Product, which resale shall be included in Net Sales; sales between or among LICENSEE or any Affiliate or Sublicensee for end-use by the purchaser shall be included in Net Sales.

Net Sales shall be calculated in accordance with the standard internal policies and procedures of LICENSEE or any Affiliate or Sublicensee which must be in accordance with the consolidated financial statements of LICENSEE prepared in accordance with US GAAP or IFRS, as applicable. There shall be no double counting in determining the foregoing deductions from gross amounts invoiced to calculate “Net Sales” hereunder.

If any Licensed Product contains two (2) or more active pharmaceutical ingredients and is sold either as a fixed dose/unit or as separate doses/units in a single package (a “**Combination Product**”), then the Net Sales for such Combination Product in each country or jurisdiction shall be calculated as follows:

(w) If LICENSEE or any Affiliate or Sublicensee separately sells in such country or other jurisdiction, (i) a product containing, as its sole active ingredient, the sole active ingredient in the Licensed Product (the “**Licensed Compound**”) that is contained in such Combination Product (the “**Mono Product**”) and (ii) products containing, as their sole active ingredients, the other active ingredients in such Combination Product, the Net Sales attributable to such Combination Product shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction $A/(A+B)$ where: “A” is LICENSEE’s (or any Affiliate’s or Sublicensee’s, as applicable) average Net Sales price during the period to which the Net Sales calculation applies for the Mono Product in such country or other jurisdiction; and “B” is LICENSEE’s (or any Affiliate’s or Sublicensee’s, as applicable) average net sales price (determined in the same manner as “Net Sales”), during the period to which the Net Sales calculation applies in such country or other jurisdiction, for products that contain as their sole active ingredients the other active ingredients in such Combination Product.

(x) If LICENSEE or any Affiliate or Sublicensee separately sells in such country or other jurisdiction the Mono Product but does not separately sell in such country or other jurisdiction products containing, as their sole active ingredients, the other active ingredients in such Combination Product, the Net Sales attributable to such Combination Product shall be calculated by multiplying the Net Sales of such Combination Product by the fraction A/C where: “A” is LICENSEE’s (or any Affiliate’s or Sublicensee’s, as applicable) average Net Sales price, during the period to which the Net Sales calculation applies, for the Mono Product in such country or other jurisdiction; and “C” is LICENSEE’s (or any Affiliate’s or Sublicensee’s, as applicable) average Net Sales price in such country or other jurisdiction, during the period to which the Net Sales calculation applies, for such Combination Product.

(y) If no LICENSEE, Affiliate or Sublicensee separately sells in such country or other jurisdiction the Mono Product but does separately sell products containing as their sole active ingredients the other active ingredients contained in such Combination Product, the Net Sales attributable to such Combination Product shall be calculated by multiplying the Net Sales of such Combination Product by the fraction $(D-E)/D$ where: “D” is the average Net Sales price, during the period to which the Net Sales calculation applies, for such Combination Product in such country or other jurisdiction; and “E” is the average net sales price (determined in the same manner as “Net Sales”), during the period to which the Net Sales calculation applies, for products that contain as their sole active ingredients the other active ingredients in such Combination Product.

(z) If no LICENSEE, Affiliate or Sublicensee separately sells in such country or other jurisdiction both the Mono Product and the other active ingredient or ingredients in such Combination Product, the Net Sales attributable to such Combination Product shall be determined by the Parties in good faith based on the relative fair-market value of such Mono Product and such other active ingredient or ingredients.

1.24 “**Orphan Drug Product**” means a Licensed Product for a specific Indication for which the FDA has granted “Orphan-drug exclusive approval” as defined in 21 CFR Part 316 or which has been granted orphan drug exclusivity under similar regulations in any Major Market or other foreign jurisdiction.

- 1.25 “**Patent Rights**” means Cornell’s ownership interest in (a) the patent applications and patents listed in Appendix A, and applications which claim priority thereto, and continuing applications thereof including divisions, substitutions, and continuations-in-part (but only to the extent the claims thereof are enabled by disclosure of the parent application); (b) any patents issuing on said applications including reissues, reexaminations and extensions; and (c) any corresponding foreign applications or patents.
- 1.26 “**Phase I/II Clinical Trial**” means a human clinical trial of a Licensed Product intended to explore a variety of doses, dose response, and duration of effect, and to generate evidence of clinical safety and effectiveness of the Licensed Product for a particular Indication or Indications in a target patient population, or a similar clinical study prescribed by any applicable regulatory authority, from time to time, pursuant to applicable law or otherwise, including for example the trials referred to in 21 C.F.R. §312.21(b), as amended (or the non-United States equivalent thereof).
- 1.27 “**Phase III Clinical Trial**” or “**Pivotal Trial**” means a human clinical trial of a Licensed Product in any country that would satisfy the requirements of 21 C.F.R. §312.21(c), as amended (or the non-United States equivalent thereof) and is intended to (a) establish that the Licensed Product is safe and efficacious for its intended use, (b) define contraindications, warnings, precautions and adverse reactions that are associated with the Licensed Product in the dosage range to be prescribed, and (c) support Regulatory Approval for such Licensed Product.
- 1.28 “**Regulatory Approval**” means all approvals of each applicable regulatory authority necessary for the commercial marketing and sale of a Licensed Product for a particular Indication in a country.
- 1.29 “**Royalty Term**” means, on a country-by-country basis, the period of time beginning on the First Commercial Sale of a Licensed Product in a given country and expiring on a country-by-country basis, with respect to each Licensed Product, upon the later of:
- (a) the expiration or invalidation of the last to expire or be invalidated of the Valid Claims that Covers such Licensed Product in the country of sale;
 - (b) the expiration of any granted statutory period of marketing and/or data exclusivity for the Licensed Product that confers an exclusive commercialization period during which LICENSEE or any Affiliate or Sublicensee has the exclusive right to market and sell a Licensed Product in such country through such a regulatory exclusivity right; or
 - (c) the month of the First Commercial Sale of a Generic Equivalent of the Licensed Product in such country.
- 1.30 “**Sponsor Rights**” means with respect only to Cornell Docket D-10224, (a) all of the applicable provisions of any license to, or grant from, the Federal Government executed by Cornell, and (b) the overriding obligations to the Federal Government under 35 U.S.C. §§ 200-212 and all applicable governmental implementing regulations.

- 1.31 “**Sublicense**” means an agreement into which LICENSEE or other permitted Sublicensee enters with a third-party (other than a Contractor or a Distributor) for the purpose of: (a) granting certain rights; (b) granting an option to certain rights; or (c) forbearing the exercise of any rights, granted to LICENSEE under the License, after the Effective Date. “**Sublicensee**” means a third-party with whom LICENSEE or other permitted Sublicensee enters into a Sublicense. “**Contractor**” means a third-party contract research organization that is performing research on behalf of and for the sole benefit of LICENSEE or any Affiliate or Sublicensee under a contract. “**Distributor**” means any third-party appointed by LICENSEE or any Affiliate or Sublicensee to distribute, market and sell Licensed Product with or without packaging rights, in one (1) or more countries in the Territory, in circumstances where such person purchases its requirements of Licensed Product from LICENSEE or any Affiliate or Sublicensee but does not otherwise make any royalty or other comparable payment to LICENSEE or any Affiliate or Sublicensee with respect to intellectual property rights with respect to such Licensed Product.
- 1.32 “**Sublicense Fees**” means income received by LICENSEE from any Sublicensee. The following types of income received from a Sublicensee shall be excluded from Sublicense Fees: (a) royalties on sales of Licensed Products; (b) net proceeds [***] to LICENSEE, but only to the extent said [***] is at [***]; (c) [***] reimbursement for (i) any [***] by or on behalf of LICENSEE or any Affiliate, or (ii) any [***] for Licensed Products that LICENSEE [***] (including in the case of the [***] reimbursements described in this clause (c), any amounts paid to LICENSEE with respect to [***] as and to the extent that LICENSEE (X) [***] and (Y) [***]); (d) documented line-item reimbursement for amounts actually paid to Cornell by LICENSEE under this Agreement; (e) reimbursement of actual [***]; and (f) net proceeds resulting from any sale of any [***] LICENSEE to Sublicensees [***].
- 1.33 “**Term**” means, on a country-by-country basis, the period of time beginning on the Effective Date and continuing until the earliest of: (a) termination of this Agreement as set forth in Article 7; and (b) the last to expire Royalty Term.
- 1.34 “**Territory**” means worldwide.
- 1.35 “**Valid Claim**” means: (a) with respect to a claim of any issued and unexpired patent within the Patent Rights, that the validity, enforceability or patentability of such claim has not been affected by (i) irretrievable lapse, abandonment, revocation, dedication to the public or disclaimer or (ii) a holding, finding or decision of invalidity, unenforceability or non-patentability by a court, governmental agency, national or regional patent office or other appropriate body that has competent jurisdiction, such holding, finding or decision being final and unappealable or unappealed within the time allowed for appeals; or (b) a pending patent application within the Patent Rights that has been filed and prosecuted in good faith and no more than [***] have elapsed since the filing of the earliest priority application for such patent application.

ARTICLE 2. GRANTS

2.1 **License.** Subject to the limitations set forth in this Agreement, Cornell hereby grants to LICENSEE, and LICENSEE hereby accepts, (a) an exclusive license, with the right to grant Sublicenses in accordance with Paragraph 2.2 below, under the Patent Rights to make and have made, to use and have used, to sell and have sold, to offer for sale, and to import and have imported Licensed Products and to practice Licensed Methods, and (b) a non-exclusive license, with the right to grant Sublicenses in accordance with Paragraph 2.2 below to use the Data and Know-How in connection with the Licensed Product Activity, in each case ((a) and (b)), in the Field and in the Territory. LICENSEE may extend the License to its Affiliates provided that LICENSEE shall first provide to Cornell a written assurance from the Affiliate, in form and substance satisfactory to Cornell, that the Affiliate agrees to comply with all applicable terms and conditions of, and obligations to Cornell under, this Agreement.

2.2 Sublicense.

(a) **Generally.** The License includes the right of LICENSEE to grant Sublicenses under Patent Rights, the Data, and the Know-How:

(i) to Major Biopharmaceutical Companies (but in no case any Excluded Entities) through multiple tiers;

(ii) with Cornell's prior written consent, to other third-parties (other than Affiliates or Excluded Entities) but without the right to enter into further Sublicenses; and

(b) **Sublicense Requirements.** With respect to any Sublicense granted pursuant to Paragraph 2.2(a), LICENSEE (and a Sublicensee, to the extent permitted to act as a sublicensor pursuant to Paragraph 2.2.(a)) shall:

(i) not receive, or agree to receive, anything of value in lieu of cash as consideration from a third-party under a Sublicense granted pursuant to Paragraph 2.2(a) without the prior written consent of Cornell (other than grants of licenses and/or assignments of intellectual property and customary contractual commitments associated with sublicenses);

(ii) to the extent applicable, include all of the rights of and obligations due to Cornell contained in this Agreement in all material respects;

(iii) ensure that any such Sublicense shall be consistent with the terms and conditions of this Agreement in all material respects;

(iv) promptly provide Cornell with an unredacted copy of each Sublicense issued and of any amendment made to any Sublicense; and

(v) collect and guarantee payment of all payments due, directly or indirectly, to Cornell from Sublicensees and summarize and deliver all reports due, directly or indirectly, to Cornell from Sublicensees.

(c) **Fate of Sublicenses upon Termination of this Agreement.** Notwithstanding anything to the contrary, upon termination of this Agreement for any reason, Cornell shall grant to each Sublicensee license rights under the Patent Rights, Data, and Know-How with exclusivity, field, term, financial, and diligence terms equivalent to those in said Sublicense; provided, however, that in no event shall Cornell be obligated: (i) to grant rights to a Sublicensee to anything Cornell does not possess or control; (ii) to surrender rights Cornell has reserved under Paragraph 2.3 of this Agreement; or (iii) to take on any new or incremental obligation beyond Cornell's express obligations under this Agreement.

(d) **No Sublicenses to Excluded Entities.** Notwithstanding anything herein to the contrary, unless it has obtained the prior written consent of Cornell in its sole discretion, neither LICENSEE nor any other permitted Sublicensee may grant a Sublicense to any Excluded Entity.

(e) If LICENSEE grants a license to any third party with respect to its own interest in any patent application or patent within Patent Rights held by LICENSEE outside of this Agreement (e.g., if LICENSEE jointly owns the patent application or patent with Cornell), LICENSEE shall also, concurrent with such license, grant a Sublicense of the corresponding Patent Rights to said third party as part of the same agreement.

2.3 Reservation of Rights. Cornell reserves the right to:

- (a) use the Patent Rights solely for non-commercial educational and other non-commercial research purposes;
- (b) allow other nonprofit institutions to use the Patent Rights solely for non-commercial educational and non-commercial research purposes; and
- (c) use and license third-parties to use, the Know-How and Data for any purpose.

2.4 Transfer of Data and Data Obligations; Publication.

(a) **Transfer of Data.** Cornell will deliver the Data to LICENSEE [***], provided that any Data shall be shared in compliance with all applicable laws and regulations and the Study IRB.

(b) **Permitted Use.** LICENSEE, its Affiliates, and Sublicensees, may use the Data solely for research and development activities conducted by LICENSEE (which shall include use in regulatory filings and interactions conducted in accordance with Paragraph 2.4(c) if said filings or interactions are public or subject to Freedom of Information Act requests), as well as publication in accordance with Paragraph 2.4(c) and as otherwise expressly permitted in this Agreement. LICENSEE, its Affiliates, and Sublicensees shall:

- (i) not use or further disclose Data or any information contained therein other than as permitted by this Agreement or required by applicable law;
- (ii) use appropriate safeguards to prevent use or disclosure of the Data or any information contained therein other than as provided for by this Agreement;
- (iii) report promptly to Cornell any access, use or disclosure of the Data or any part of it not provided for by this Agreement of which LICENSEE becomes aware;
- (iv) ensure that any agents, including Contractors, to whom LICENSEE provides access to the Data or any part of it agrees to the same restrictions and conditions that apply to LICENSEE under this Agreement;
- (v) not use any information contained in the Data to identify the individuals whose information is contained in the Data, nor to contact them or their family members under any circumstances;
- (vi) should any subject withdraw consent, remove said subject's data from the Data immediately, upon notification from Cornell; and
- (vii) should Cornell be obligated to amend this Agreement with respect to Data due to changes in applicable law, regulation, or Cornell policy, promptly execute such an amendment with Cornell.

(c) Publication

(i) The Parties agree to use their best efforts and work together in good faith to jointly present and publish the Data (a “**Joint Publication**”). Authorship on such presentations and publications shall be determined in accordance with the recommendations of the International Journal of Medical Committee Editors (the “IJMCE Guidelines”), and Dr. Crystal shall have the option to elect first and last authorship and to determine the order of middle Cornell authors on the first presentation of the Data in a scientific conference and the first publication of a manuscript reporting the Data in a scientific journal and any subsequent Joint Publications in which the majority of the previously unreported data is from the Cornell Study. Consistent with the IJMCE Guidelines, all individuals who qualify for authorship under the IJMCE Guidelines must provide approval of the final presentation or publication.

(ii) Notwithstanding Paragraph 2.4(c)(i), Cornell may publish or present the Data separately and without the consent of LICENSEE (each a “**Cornell Publication**”). Cornell shall provide a copy of each Cornell Publication to LICENSEE for review at least [***] prior to the date of submission for publication (including abstracts) or of public disclosure. Each Party shall discuss and consider in good faith the other Party’s suggestions with respect to the publication and timing of each Cornell Publication.

(iii) LICENSEE shall not publish, present, or make publicly available the Data or summaries thereof other than through Joint Publication in accordance with Paragraph 2.4(c)(i) or following receipt of prior written consent of Cornell via CTL, which shall not be unreasonably withheld. The restrictions on Data set forth in Paragraphs 2.4(b) and 2.4(c) shall not apply to a given set of Data to the extent that said given set of Data has been published in compliance with this Paragraph 2.4(c).

2.5 Right of Reference

Cornell shall grant and hereby grants to LICENSEE a right of reference to the Study IND for purposes of INDs and BLAs for Licensed Products in the form of gene therapy products for Friedreich’s Ataxia. Accordingly, within [***], Cornell shall submit to FDA any notice or authorization necessary to make such right of reference effective. The right of reference granted herein includes and supersedes the right of reference already granted [***]. To support the right of reference:

(i) Cornell shall maintain complete and accurate records with respect to subjects participating in the Study and shall record all Data generated as a result of conducting the Study in a timely manner. Cornell shall take reasonable and customary precautions, including periodic backup of computer files, to prevent the loss or alteration of the Data. Should the FDA desire to audit the Data, Cornell shall provide the FDA full and prompt access to all Data, and will permit the FDA, during normal business hours and at mutually agreeable times, to inspect and make abstracts of the Data to verify the accuracy of the Data. For clarity, Cornell’s agreement to permit the FDA to audit the Data does not include an agreement that LICENSEE itself may audit the Data.

(ii) Cornell will retain in a safe and secure location at least one (1) copy of all printed and electronic Data for the longer of (a) [***] following completion or early termination of the Study, or (b) the period required by applicable law or regulation. In no event will Cornell dispose of any such records without first giving LICENSEE [***] prior written notice of its intent to do so and an opportunity to transfer the records to LICENSEE, at LICENSEE’s reasonable expense.

(iii) [***] Cornell will provide LICENSEE with copies of all correspondence with the FDA regarding the Study IND; provided that any such correspondence relating to a serious adverse event in the Study shall be provided to LICENSEE in de-identified form at the same time it is provided to the FDA and the IRB. All correspondence with the FDA regarding the Study IND provided under this Agreement is Confidential Information of Cornell and any subject-related information therein shall be protected the same way Data is protected under Paragraph 2.4(b).

ARTICLE 3. CONSIDERATION

3.1 **Fees and Royalties.** The Parties understand that the fees and royalties payable by LICENSEE to Cornell under this Agreement are partial consideration for the License and for the right of reference granted in Paragraph 2.5. LICENSEE shall pay Cornell:

(a) (i) a **license issue fee** of [***], and (ii) an initial **data transfer fee** of [***], each paid [***] within [***] of the Effective Date; and (iii) an annual data transfer fee of [***] paid [***] of the Effective Date until [***].

(b) **license maintenance fees** payable on each anniversary of the Effective Date according to the following schedule; provided, however, that LICENSEE’s obligation to pay this fee shall end on the date when LICENSEE is commercially selling a Licensed Product and the license maintenance fee payable shall be pro-rated for the number of months remaining in that license year.

FEE PAYABLE TO CORNELL	DATE
[***]	[***] anniversaries of the Effective Date
[***]	[***] anniversary of Effective Date
[***]	[***] anniversary of Effective Date
[***]	[***] anniversary of Effective Date and each subsequent anniversary thereafter

(c) **milestone payments** in the amounts payable according to the following schedule of events:

(i) for each Licensed Product, provided that each milestone payment identified as (A), (B) and (C) in the table shown in subparagraph 3.1(c)(i) below shall be payable only once per Licensed Product:

AMOUNT	DATE OR EVENT
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

; and (ii) one time on the first occurrence of the applicable event with respect to the first Licensed Product to achieve such milestone. The following milestone payments shall each be payable up to one (1) time only, regardless of how many Licensed Products achieve the corresponding milestone:

AMOUNT	EVENT
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(d) during the Royalty Term, on a per-Licensed Product and country-by-country basis, an **earned royalty** of:

(i) [***] on Net Sales in countries where the Licensed Product is (A) is an Orphan Drug Product and (B) is Covered by a Valid Claim; and

(ii) [***] on Net Sales in countries where the Licensed Product is (A) is an Orphan Drug Product and (B) not Covered by a Valid Claim.

(iii) in addition to the royalties in Paragraph 3.1(d)(i) and (ii), an additional [***] on Net Sales where the Licensed Product is an Orphan Drug Product if, and only if the Net Sales are by a Sublicensee.

(iv) [***] on Net Sales in countries where the Licensed Product (A) is not an Orphan Drug Product and (B) is Covered by a Valid Claim; and

(v) [***] on Net Sales in countries where the Licensed Product (A) is not an Orphan Drug Product and (B) is not Covered by a Valid Claim; and

(vi) in addition to the royalties in Paragraph 3.1(d)(iv) and (v), an additional [***] on Net Sales where the Licensed Product is not an Orphan Drug Product if, and only if the Net Sales are by a Sublicensee.

(iii) In the event LICENSEE, its Affiliate or a Sublicensee is required to pay royalties and milestones to one or more third-parties for patent rights necessary to sell any Licensed Product, and the total royalties payable by LICENSEE exceed [***] of Net Sales of such Licensed Product, then LICENSEE or a Sublicensee may deduct [***] from the earned royalties payable to Cornell for every [***] LICENSEE, its Affiliate or Sublicensee actually pays to said third-parties of the amount LICENSEE, its Affiliate or Sublicensee pays above [***] of Net Sales of such Licensed Product; provided, however, that in no event shall the amount payable to Cornell with respect to such Licensed Product be less than [***] of the amount then due under Paragraph 3.1(d) (the **“Royalty Cap Deduction”**) with respect to such Licensed Product. LICENSEE may carry over and apply any payments made by LICENSEE, its Affiliate or a Sublicensee as described in the immediately preceding sentence that are not deducted as a result of the Royalty Cap Deduction, to any subsequent royalty payments due under Paragraph 3.1(d), and shall begin applying such reduction to such royalties as soon as practicable and continue applying such reduction as soon as permitted by this paragraph thereafter in accordance with the Royalty Cap Deduction.

(e) [***] of all **Sublicense Fees**.

(f) (i) if the royalties payable by LICENSEE under Paragraphs 3.1(d)(i) and (ii), and (iii) if applicable, to Cornell in the August 31 and February 28 payments due under Paragraph 4.3(b)(ii) with respect to a single calendar year of Net Sales (**“Yearly Paid Orphan Royalties”**) are less than the amounts listed below (**“Minimum Annual Orphan Royalty”**):

YEAR OF COMMERCIAL SALE	MINIMUM ANNUAL ROYALTY
[***]	[***]
[***]	[***]
[***] and each year thereafter	[***]

; and

(ii) if the royalties payable by LICENSEE under Paragraphs 3.1(d)(iv) and (v), and (vi) if applicable, to Cornell in the August 31 and February 28 payments due under Paragraph 4.3(b)(ii) with respect to a single calendar year of Net Sales (“**Yearly Paid Non-orphan Royalties**”) are less than the amounts listed below (“**Minimum Annual Non-orphan Royalty**” and together with the Minimum Annual Orphan Royalty, the “**Minimum Annual Royalty**”):

YEAR OF COMMERCIAL SALE	MINIMUM ANNUAL ROYALTY
[***]	[***]
[***]	[***]
[***] and each year thereafter	[***]

then LICENSEE shall also pay to Cornell in said February 28 royalty payment, (A) the difference between the Minimum Annual Orphan Royalty and the Yearly Paid Orphan Royalties for Orphan Drug Products, and (B) the difference between the Minimum Annual Non-orphan Royalty and the Yearly Paid Non-orphan Royalties for Licensed Products that are not Orphan Drug Products; provided, however, that for the first and last years of commercial sales of Licensed Products, the amount of Minimum Annual Royalty payable shall be pro-rated for the number of months in the calendar year during which Licensed Products were sold.

(f) All fees and royalty payments specified in Paragraphs 3.1(a) through 3.1(f) above shall be paid by LICENSEE pursuant to Paragraph 4.3 and shall be delivered by LICENSEE to Cornell as noted in Paragraph 10.1.

3.2 This Paragraph left intentionally blank.

3.3 Due Diligence.

(a) Subject to Paragraph 3.3(b), LICENSEE, together with its Sublicensees, shall:

(i) (A) for LICENSEE or other Sublicensee that is not a Major Biopharmaceutical Company, diligently proceed with the development, manufacture and sale of Licensed Products; or (B) for any Sublicensee that is a Major Biopharmaceutical Company, use Commercially Reasonable Effort to proceed with the development, manufacture and sale of Licensed Products; and

(ii) develop a Licensed Product as follows, wherein each row in the following table is an obligation under this Paragraph 3.3(a)

MILESTONE TO BE ACHIEVED	TIME BY WHICH MILESTONE MUST BE ACHIEVED
[***]	[***]
[***]	[***]

; and

(iii) market Licensed Products in each country within the Territory within [***]of receiving Regulatory Approval to market such Licensed Products, together with all applicable pricing and reimbursement approvals, in said country; and

(iv) (A) for LICENSEE or other Sublicensee that is not a Major Biopharmaceutical Company, reasonably fulfill the market demand for Licensed Products following commencement of marketing at any time during the term of this Agreement or (B) for any Sublicensee that is a Major Biopharmaceutical Company, use Commercially Reasonable Efforts to fulfill the market demand for Licensed Products following commencement of marketing at any time during the term of this Agreement; and

(v) maintain all necessary governmental approvals and permits for the manufacture, use and sale of Licensed Products in each applicable country.

(b) If LICENSEE or its applicable Sublicensee fails to perform any of its obligations specified in Paragraphs 3.3(a)(i)-(v), then Cornell as its sole remedy shall have the right and option to terminate this Agreement as follows: (i) in the case of Paragraph 3.3(a)(ii), Cornell shall have the right to terminate this Agreement in full in accordance with the terms and conditions of this Agreement, and (ii) in the case Paragraphs 3.3(a)(i) and (iii)-(v), Cornell shall have the right to terminate this Agreement in part (but not as a whole), solely with respect to the applicable Licensed Product.

(c) If, during the Term, Cornell receives one or more bona fide written offers from a capable third-party for a license under the Patent Rights to commercialize such Licensed Product in any Major Market (“Third Party Offer”), then Cornell shall refer such offers to LICENSEE. In addition, Cornell may, having one or more Third Party Offers, exclude said country from the Territory and license such right to one or more third-parties unless LICENSEE has, within [***] from the date of such referral, (i) established or begun a product development program with respect to such Licensed Product, or (ii) executed an agreement with a Sublicensee that commits the Sublicensee to develop and commercialize such Licensed Product in such country. Notwithstanding the foregoing, this Paragraph 3.3(c) shall not apply to any Sublicensee that constitutes a Major Biopharmaceutical Company.

3.4 Collaborative Research. Licensee shall provide research support to the Cornell Inventors to further develop inventions or new works concerning [***].

ARTICLE 4. REPORTS, RECORDS AND PAYMENTS

4.1 Reports; Quarterly Meetings

(a) Development Reports. Beginning [***] after the Effective Date and ending on the date of the First Commercial Sale of a Licensed Product in the United States, LICENSEE shall report to Cornell progress covering LICENSEE's (and Affiliates' and Sublicensees') activities and efforts in the development of rights granted to LICENSEE under this Agreement for the preceding [***]. The report shall include, but not be limited to, activities and efforts to develop and test all Licensed Products, and obtain governmental approvals necessary for marketing the same, as well as business development, corporate development, and fund-raising activities (including cumulative amounts raised, and the amount of each financing round) related to development of Licensed Products. Such semi-annual reports shall be due within [***] of the reporting period and shall use the form as provided herein as Appendix F.

(b) Commercialization Reports. After the First Commercial Sale of a Licensed Product anywhere in the Territory, LICENSEE shall submit to Cornell semi-annual reports on or before each February 28 and August 31 of each year. Each report shall cover LICENSEE's (and each Affiliate's and Sublicensee's) most recently completed calendar half-year and shall show:

(i) the number of each type of Licensed Product sold;

(ii) the gross sales and Net Sales during the most recently completed calendar half-year, an explanation of all deductions under Net Sales as defined in Paragraph 1.23, and the royalties, in US dollars, payable with respect thereto;

(iii) Sublicense Fees received during the most recently completed calendar half-year and all amounts deducted under the exceptions in Paragraph 1.32 and explanations therefor, all in US dollars, and the amount payable with respect thereto;

(iv) the method used to calculate the royalties and Sublicense Fee payments;

(v) the exchange rates used; and

(vi) relevant business and corporate development efforts relating to the rights granted in this Agreement and to the diligence development efforts described herein.

LICENSEE shall provide the above information using the form as shown in Appendix G and include information on the date of the First Commercial Sale of each Licensed Product in each country. If, following the First Commercial Sale of the Licensed Product, no sales of Licensed Products have been made or no Sublicense Fees has been received by LICENSEE during any reporting period, LICENSEE shall so report.

(c) Quarterly Meetings. From and after the Effective Date, Cornell and LICENSEE's management team shall meet at least once per calendar quarter to discuss the status of the Licensed Product Activity for each Licensed Product.

4.2 Records & Audits.

(a) LICENSEE shall keep, and shall require Affiliates and Sublicensees to keep, accurate and correct records of all Licensed Products manufactured, used, and sold, and Sublicense Fees paid and received under this Agreement. Such records shall be retained by LICENSEE for at least [***] following a given reporting period.

(b) Subject to entry of commercially reasonable confidentiality agreements between the Parties and any audit firm, all records shall be available during normal business hours for inspection at the expense of Cornell by Cornell's Internal Audit Department or by a Certified Public Accountant selected by Cornell and in compliance with the other terms of this Agreement for the sole purpose of verifying reports and payments or other compliance issues. Such access need not be given to any such set of records more often than once each calendar year or more than [***] after the date of any report to be audited. Such inspector shall not disclose to Cornell any information other than information relating to the accuracy of reports and payments made under this Agreement or other compliance issues. In the event that any such inspection shows an under reporting and underpayment in excess of [***] for any period, then LICENSEE shall pay the cost of the audit as well as any additional sum that would have been payable to Cornell had the LICENSEE reported correctly, plus an interest charge at a rate of [***]. Such interest shall be calculated from the date the correct payment was due to Cornell up to the date when such payment is actually made by LICENSEE. For underpayment not in excess of [***] for any [***] period, LICENSEE shall pay the difference within [***] without inspection cost but with interest charge per the provisions of Paragraph 4.3(c).

4.3 Payments.

(a) All fees, reimbursements and royalties due to Cornell shall be paid in United States dollars and all checks shall be made payable to "Cornell University", referencing Cornell's taxpayer identification number, [***], and sent to Cornell according to Paragraph 10.1 (Correspondence). When Licensed Products are sold in currencies other than United States dollars, LICENSEE shall first determine the earned royalty in the currency of the country in which Licensed Products were sold and then convert the amount into equivalent United States funds, using the exchange rate quoted in the Wall Street Journal on the last business day of the applicable reporting period.

(b) Royalty Payments.

(i) Royalties shall accrue when Licensed Products are invoiced, or if not invoiced, when delivered.

(ii) LICENSEE shall pay earned royalties [***] on or before February 28 and August 31 of each calendar year. Each such payment shall be for earned royalties accrued within LICENSEE's most recently completed calendar half-year.

(iii) Royalties earned on Net Sales occurring in any country outside the United States shall not be reduced by LICENSEE for any taxes, fees, or other charges imposed by the government of such country on the payment of royalty income (other than as permitted in the calculation of Net Sales), except that all payments required to be made by LICENSEE in fulfillment of Cornell's tax liability in any particular country may be credited against earned royalties or fees due Cornell for that country and LICENSEE shall promptly provide Cornell with written documentation evidencing each such payment. LICENSEE shall pay all bank charges resulting from the transfer of such royalty payments.

(iv) In the event that either Party engages in (A) any assignment of any of its rights under this Agreement or (B) any corporate migration, redomestication, redomiciliation, reincorporation, or any other transaction or legal scheme which results in the imposition of or increase in any withholding tax on payments pursuant to this Agreement (any such Party which engages in the conduct described above in subclauses (A) or (B), the “**Engaging Party**”), the Engaging Party (or the resulting successor of any such transaction) agrees to pay additional amounts to the other Party sufficient for such other Party to be in the same net after-tax position in which the other Party would have been if the Engaging Party would not have undertaken such (X) assignment of any of its rights under this Agreement or (Y) corporate migration, redomestication, redomiciliation, reincorporation, or any other transaction or legal scheme.

(v) If at any time legal restrictions prevent the prompt remittance of part or all royalties by LICENSEE with respect to any country where a Licensed Product is sold or a Sublicense is granted pursuant to this Agreement, LICENSEE shall convert the amount owed to Cornell into US currency and shall pay Cornell directly from its US sources of fund for as long as the legal restrictions apply.

(vi) In the event that any patent or patent claim within Patent Rights is held invalid in a final decision by a patent office from which no appeal or additional patent prosecution has been or can be taken, or by a court of competent jurisdiction and last resort and from which no appeal has or can be taken, all obligation to pay royalties based solely on that patent or claim or any claim patentably indistinct therefrom shall cease as of the date of such final decision. LICENSEE shall not, however, be relieved from paying any royalties that accrued before the date of such final decision, that are based on another patent or claim not involved in such final decision, or that are based on the use of the Data.

(c) **Late Payments.** In the event royalty, reimbursement and/or fee payments are not received by Cornell when due, LICENSEE shall pay to Cornell interest charges at a rate of [***]. Such interest shall be calculated from the date payment was due until actually received by Cornell.

ARTICLE 5. PATENT MATTERS

5.1 Patent Prosecution and Maintenance.

(a) LICENSEE may file and lead prosecution of United States and, if available, foreign patents, and patent applications within Patent Rights using counsel of its choice. LICENSEE shall provide written notice to Cornell when LICENSEE initiates drafting of any new patent applications within the Patent Rights listing Cornell employees as inventors, so that Cornell can determine to whom its employees should assign. LICENSEE shall provide Cornell with copies of all prosecution filings and patent office correspondence within Patent Rights, and Cornell shall keep this documentation confidential. LICENSEE shall seek and reasonably consider Cornell’s advice and input, via CTL, on all material patent prosecution matters with respect to the Patent Rights. Patent counsel prosecuting and maintaining patent applications and patents within Patent Rights shall take instructions only from LICENSEE and (subject to Paragraph 5.4) all patents and patent applications in the Joint Patent Rights shall be assigned to LICENSEE and to Cornell.

(b) Should LICENSEE decide to finally terminate, abandon, or allow any patent or patent application within Patent Rights in any jurisdiction to lapse, such that prosecution or maintenance of said application or patent within Patent Rights would be closed or lost in said jurisdiction then, at least [***] prior to any such termination, abandonment, or lapse, LICENSEE shall offer to Cornell the right to continue prosecution or maintenance at Cornell’s sole expense, and should Cornell elect to do so, LICENSEE shall timely cooperate with Cornell’s counsel to provide Cornell with control of said application or patent and LICENSEE shall assign its rights in any such application or patent to Cornell and LICENSEE shall have no further rights therein;

(c) LICENSEE shall apply for an extension of the term of any patent in the Patent Rights if appropriate under the Drug Price Competition and Patent Term Restoration Act of 1984 and/or European, Japanese and other foreign counterparts of this law, and Cornell shall reasonably cooperate at LICENSEE's expense. LICENSEE shall prepare all documents for such application, and Cornell shall execute such documents and to take any other additional action as LICENSEE reasonably requests in connection therewith.

5.2 Patent Infringement.

(a) In the event that Cornell (to the extent of the actual knowledge of the licensing professional at CTL responsible for the administration of this Agreement) or LICENSEE learns of infringement of potential commercial significance of any patent in the Patent Rights, the knowledgeable Party will provide the other Party with written notice of such infringement, which notice shall include any evidence of such infringement available to such Party. Within [***] after receipt of such notice, the Parties shall meet to discuss how to proceed with respect to such infringement. Each Party shall consider in good faith the input from the other Party, including without limitation to what extent an infringement action may be detrimental to the overall patent protection for Licensed Products.

(b) During the period in which, and in the jurisdiction where, LICENSEE has exclusive rights under this Agreement, neither Cornell nor LICENSEE will notify a third-party (including the infringer) of infringement or put such third-party on notice of the existence of any Patent Rights prior to the meeting required by Paragraph 5.2(a). Cornell shall have the right to terminate this Agreement immediately without the obligation to provide [***] notice as set forth in Paragraph 7.1 if LICENSEE notifies a third-party of infringement or puts such third-party on notice of the existence of any patent or patent application in the Patent Rights with respect to such infringement in breach of this Paragraph 5.2(b).

(c) Following the meeting required by Paragraph 5.2(a), LICENSEE and the Sublicensees shall have the initial right to take legal action against such third-party for the infringement of any patent in the Patent Rights in the Field and within the Territory. LICENSEE shall keep Cornell promptly informed regarding the status of any such suit or action and shall provide Cornell with copies of all material documents (*e.g.*, complaints, answers, counterclaims, material motions, orders of the court, memoranda of law and legal briefs, interrogatory responses, depositions, material pre-trial filings, expert reports, affidavits filed in court, transcripts of hearings and trial testimony, trial exhibits and notices of appeal) filed in, or otherwise relating to, such suit or action. If LICENSEE or any Sublicensee elect to bring suit, Cornell may join that suit at its own expense. If required under applicable law in order for LICENSEE or its Sublicensees to initiate or maintain such suit, Cornell shall join as a party to the suit, at LICENSEE's sole cost and expense. If, in a suit initiated by LICENSEE or its Sublicensees, Cornell is required to be or is otherwise involuntarily joined, LICENSEE will pay any costs incurred by Cornell arising out of such suit, including but not limited to, any reasonable legal fees of counsel that Cornell selects and retains to represent Cornell in the suit.

(d) If LICENSEE (and any Sublicensees involved) do not take prompt legal action following the meeting required by Paragraph 5.2(a), or give notice to Cornell that they have elected not to pursue legal action and their reasoning for that decision, then Cornell may unilaterally take such legal action as Cornell deems appropriate.

(c) Any recovery or settlement received in connection with any suit concerning a patent in the Patent Rights (i) first, will be shared by Cornell and LICENSEE equally until the actual out-of-pocket litigation costs of one of the Parties are fully recovered; (ii) next, shall be provided to the party that has not yet fully recovered its actual out-of-pocket litigation costs until all such costs are fully recovered; and (iii) finally, with respect to any remaining amount, shall then be shared between Cornell and LICENSEE [***]. If, however, Cornell has no out of pocket costs, Cornell's share of any remaining amount shall be shared as follows: [***]. Cornell and LICENSEE agree to be bound by all determinations of patent infringement, validity, and enforceability (but no other issue) resolved by any adjudicated judgment in a suit brought in compliance with this Paragraph 5.2.

(d) Notwithstanding Paragraph 5.2(c), any agreement made by LICENSEE for purposes of settling any litigation or other dispute shall comply with the requirements of Paragraph 2.2.

(e) Each Party will cooperate with the other Party in litigation proceedings instituted hereunder but at the expense of the Party who initiated the suit (unless such suit is being jointly prosecuted by the Parties).

(f) Any litigation proceedings will be controlled by the Party bringing the suit, except that Cornell may be represented by counsel of its choice in any suit brought by LICENSEE.

5.3 Patent Marking. LICENSEE shall mark all Licensed Products made, used or sold under the terms of this Agreement, or their containers, in accordance with the applicable patent marking laws.

5.4 Ownership of Data and Know-How.

(a) Cornell shall retain ownership of the Data, the Know-How, and the Study IND.

(b) The ownership of any intellectual property generated, created or otherwise made by LICENSEE and/or each Sublicensee, respectively, shall be governed by US patent law, unless there is a subsequent written agreement between LICENSEE or any Affiliate and Cornell, in which case such subsequent written agreement shall prevail.

(c) LICENSEE shall make no use of each of the Patent Rights, Data, and the Know-How outside the scope of this Agreement and the License.

ARTICLE 6. GOVERNMENTAL MATTERS

6.1 Governmental Approval or Registration. If this Agreement or any associated transaction is required by the law of any nation to be either approved or registered with any governmental agency, LICENSEE shall assume all legal obligations to do so. LICENSEE shall notify Cornell if it becomes aware that this Agreement is subject to a United States or foreign government reporting or approval requirement. LICENSEE shall make all necessary filings and pay all costs including fees, penalties, and all other out-of-pocket costs associated with such reporting or approval process.

6.2 Export Control Laws. LICENSEE shall observe all applicable United States and foreign laws with respect to the transfer of Licensed Products and related technical data to foreign countries, including, without limitation, the International Traffic in Arms Regulations and the Export Administration Regulations.

6.3 U.S. Government Rights. The parties acknowledge that the Federal Government retains rights in Cornell docket D-10224. The License for Cornell Docket D-10224 is expressly subject to all applicable Federal Government rights, including, but not limited to, any applicable requirement that products that are based on Cornell docket D-10224 and are sold in the United States, must be substantially manufactured in the United States (unless a valid waiver is obtained from the United States National Institutes of Health or other applicable authority).

ARTICLE 7. TERMINATION AND EXPIRATION OF THE AGREEMENT

7.1 Termination by Cornell.

(a) If LICENSEE fails to perform or violates any term of this Agreement in any material respect, then Cornell may give written notice of default (“**Notice of Default**”) to LICENSEE. If LICENSEE fails to cure the default in all material respects within [***] of the Notice of Default, Cornell may terminate this Agreement and the License by a second written notice (“**Notice of Termination**”) to LICENSEE. If a Notice of Termination is sent to LICENSEE, this Agreement shall automatically terminate on the effective date of that notice in accordance with the terms and conditions of this Agreement. Termination shall not relieve LICENSEE of its obligation to pay any fees owed at the time of termination and shall not impair any accrued right of Cornell.

(b) Cornell shall have the right to terminate this Agreement immediately, without the obligation to provide written notices as set forth in Paragraph 7.1(a), if LICENSEE files a claim including in any way the assertion that any claim, patent, or patent application in the Patent Rights is invalid or unenforceable where the filing is by LICENSEE, a third-party on behalf of LICENSEE, or a third-party at the written urging of LICENSEE.

(c) Cornell may terminate this Agreement pursuant to Paragraph 3.3(b).

7.2 Termination by LICENSEE.

(a) LICENSEE shall have the right at any time and for any reason to terminate this Agreement, in whole or in part with respect to the right of reference, the Data, the Know-How, or any Patent Rights hereunder, upon a [***] written notice to Cornell. Said notice shall state LICENSEE’s reason for terminating this Agreement.

(b) Any termination under Paragraph 7.2(a) shall not relieve LICENSEE of any obligation or liability accrued under this Agreement prior to termination or rescind any payment made to Cornell or action by LICENSEE prior to the time termination becomes effective. Termination shall not affect in any manner any rights of Cornell arising under this Agreement prior to termination.

7.3 Survival on Termination. The following Paragraphs and Articles shall survive the termination of this Agreement:

- (a) Article 4 (REPORTS, RECORDS AND PAYMENTS);
- (b) Paragraph 7.3 (Survival on Termination);
- (c) Paragraph 7.4 (Disposition of Data and Know-How and Licensed Products on Hand);
- (d) Paragraph 8.2 (Indemnification);
- (e) Article 9 (USE OF NAMES AND TRADEMARKS); and
- (f) Paragraph 10.2 (Secrecy).

7.4 Disposition of Data and Know-How and Licensed Products on Hand.

(a) **Expiration.** Upon the expiration of the Royalty Term for a given Licensed Product in a given country, LICENSEE will retain a non-exclusive, royalty-free license to use the Data and Know-How, including to continue selling said Licensed Product in said country; LICENSEE’s obligations to Cornell in Paragraph 8.2 and Article 9 remain in effect for as long as LICENSEE is using the Data or Know-How and must be transferred with any transfer of the Data or Know-How to a third-party. This Paragraph 7.4(a) and the grant and obligations in this Paragraph 7.4(a) survive expiration of this Agreement. This Paragraph 7.4(a) does not apply if this Agreement is terminated under Paragraphs 7.1 or 7.2.

(b) **Termination.** Upon termination of this Agreement in whole or in part under Paragraphs 7.1 or 7.2, LICENSEE may dispose of all previously made or partially made Licensed Product within a period of [***] of the effective date of such termination provided that the sale of such Licensed Product by LICENSEE, Affiliates, or Sublicensees shall be subject to the terms of this Agreement, including but not limited to the rendering of reports and the payment of royalties required under this Agreement. Upon termination of this Agreement, at Cornell's election, LICENSEE will destroy or return to Cornell all Data and Know-How and notify Cornell in writing that said Data and Know-How has been returned or destroyed. LICENSEE shall no longer have rights to use the Know-How or Data or right of reference upon termination.

ARTICLE 8. LIMITED WARRANTY, INDEMNIFICATION AND INSURANCE

8.1 Limited Warranty.

(a) Cornell warrants that, without conducting any investigation or any inquiry, it has the lawful right to grant the License, and that, as of the Effective Date, CTL has not received written notice from any third-party of any pending or threatened legal action or suit asserting that the use of the Patent Rights, Data, or Know-How as contemplated hereunder for the development and commercialization of any Licensed Product would infringe or misappropriate the patent rights or intellectual property rights of any third-party.

(b) The License is provided "AS IS" and without WARRANTY OF MERCHANTABILITY or WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE or any other warranty, express or implied. Cornell makes no representation or warranty that the Licensed Product, Licensed Method, or the use of the Patent Rights, Data, or Know-How will not infringe any other patent or other proprietary rights.

(c) In no event shall Cornell be liable for any incidental, special or consequential damages resulting from exercise of the License or the use of the Patent Rights, any Licensed Product, any Licensed Method, the Data, or the Know-How.

(d) Nothing in this Agreement shall be construed as:

- (i) a warranty or representation by Cornell as to the validity or scope of any patent or patent application in the Patent Rights;
- (ii) a warranty or representation that anything made, used, sold or otherwise disposed of under any license granted in this Agreement is or shall be free from infringement of patents of third parties;
- (iii) an obligation to bring or prosecute actions or suits against third-parties for patent infringement except as provided in Paragraph 5.2 hereof;
- (iv) conferring by implication, estoppel or otherwise any license or rights under any patents of Cornell other than those in the Patent Rights as defined in this Agreement, regardless of whether those patents are dominant or subordinate to those in the Patent Rights;
- (v) an obligation to furnish any know-how not provided in the Data, Know-How, or in the patents and patent application in the Patent Rights; or
- (vi) an obligation to update the Know-How or Data beyond what is explicitly described in Appendices B and C.

8.2 Indemnification. LICENSEE shall indemnify, hold harmless and defend: Cornell and its trustees, officers, employees, and agents, the sponsors of the research that led to the Invention; and the Inventors of the patents and patent applications in Patent Rights and their employers (collectively, the “**Indemnified Parties**”) against any and all claims, or suits (each, a “**Claim**”), and associated losses, damage, costs, fees, and expenses (collectively, “**Liabilities**”), in each case resulting from or arising out of this Agreement or any Sublicense. This indemnification shall include, but not be limited to, any product liability Claims. LICENSEE shall control any litigation or potential litigation involving the defense of any Claim, including the selection of counsel, with input from Cornell. In the event that a conflict of interest arises between LICENSEE’s interest and Cornell’s interest, Cornell reserves the right to protect its interest in defending against any Claim by selecting its own counsel, with any attorneys’ fees and litigation expenses paid for by LICENSEE, pursuant to this Paragraph 8.2. LICENSEE will not settle or compromise any Claim giving rise to Liabilities in any manner that imposes any restrictions or obligations on Cornell or grants any rights to the Patent Rights (other than permitted Sublicenses) without Cornell’s prior written consent. If LICENSEE fails or declines to assume the defense of any Claim or fails to reimburse an Indemnified Party for any liabilities within [***] after notice of such Claim from Cornell, then Cornell may assume the defense of such Claim for the account and at the risk of LICENSEE. The indemnification rights of the Indemnified Parties under this Paragraph 8.2 are in addition to all other rights that an Indemnified Party may have at law, in equity or otherwise.

8.3 Insurance.

(a) LICENSEE, at its sole cost and expense, shall insure its activities in connection with the work under this Agreement and obtain, keep in force and maintain insurance or an equivalent program of self-insurance as follows:

(i) Prior to the first “in human” test of a Licensed Product: comprehensive or commercial general liability insurance (contractual liability included) with limits of at least: (A) each occurrence, [***]; (B) products/completed operations aggregate, [***]; (C) personal and advertising injury, [***]; (D) general aggregate (commercial form only), [***]; and (E) professional liability, [***] per occurrence and [***] in the aggregate; and

(ii) Commencing upon the first “in human” test of a Licensed Product: comprehensive or commercial general liability insurance (contractual liability included) with limits of at least: (A) each occurrence, [***]; (B) products/completed operations aggregate, [***]; (C) personal and advertising injury, [***]; (D) general aggregate (commercial form only), [***]; and (E) professional liability, [***] per occurrence and [***] in the aggregate; and

(iii) The coverage and limits referred to above shall not in any way limit the liability of LICENSEE.

(b) LICENSEE shall, within [***] of Effective Date and annually thereafter on anniversary of Effective Date during the Term, furnish Cornell with certificates of insurance showing compliance with all requirements. Such certificates shall: (i) provide for [***] advance written notice to Cornell of any modification; (ii) indicate that Cornell has been endorsed as an additionally insured party under the coverage referred to above; and (iii) include a provision that the coverage shall be primary and shall not participate with nor shall be excess over any valid and collectable insurance or program of self-insurance carried or maintained by Cornell.

(c) Cornell shall notify LICENSEE in writing of any claim or suit brought against Cornell in respect of which Cornell intends to invoke the provisions of this Article 8. LICENSEE shall keep Cornell informed on a current basis of its defense of any claims under this Article 8.

8.4 Representations, Warranties and Acknowledgements by LICENSEE.

(a) LICENSEE warrants that, to the extent it receives and uses any Data or technical information generated at Cornell and related to a Licensed Product (“**Cornell Technology**”), it will only receive and use the Cornell Technology that is documented in this Agreement, a subsequent amendment to this Agreement, a subsequent license agreement with Cornell, a master services agreement with Cornell, or a research collaboration agreement with Cornell.

(b) LICENSEE acknowledges that Inventors do not have the authority to grant LICENSEE the right to possess or use Cornell Technology. LICENSEE acknowledges that any use or possession of Cornell Technology by LICENSEE arising from any transfers outside of those permitted and documented in a license or research collaboration agreement with Cornell would constitute misappropriation of said Cornell Technology.

(c) LICENSEE acknowledges that Cornell Inventors are bound by Cornell Policy 1.4, “Conflicts of Interest and Commitment (Excluding Financial Conflict of Interest Related to Research)” and Cornell Policy 1.7 “Financial Conflict of Interest Related to Research” and agrees that it will cooperate in Cornell’s efforts to manage Cornell Inventors’ compliance with such policies, including providing reports and information to the bodies managing said policies upon their request.

ARTICLE 9. USE OF NAMES AND TRADEMARKS

9.1 **Use of Names and Trademarks.** Nothing contained in this Agreement confers any right to use in advertising, publicity, or other promotional activities any name, trade name, trademark, or other designation of either party hereto (including contraction, abbreviation or simulation of any of the foregoing). Unless required by law, the use by LICENSEE of the name, “Cornell University,” “Weill Cornell Medicine” or “Weill Cornell Medical College”, “Department of Genetic Medicine”, or the names of any inventor, employee, student or faculty member of Cornell is prohibited, without the express written consent of Cornell.

9.2 **Disclosure to Cornell Inventors.** Cornell may disclose to Cornell Inventors the terms and conditions of this Agreement upon their request. If such disclosure is made, Cornell shall request Cornell Inventors not disclose such terms and conditions to others.

9.3 **Disclosure to Third-Parties.** Cornell may acknowledge the existence of this Agreement and the extent of the grant in Article 2 to third-parties, but Cornell shall not disclose the financial terms of this Agreement to third-parties, except where Cornell is required by law or the order of a court of competent jurisdiction to do so.

9.4 **Press Releases or Required Disclosures.** LICENSEE may acknowledge or make press releases regarding the existence of this Agreement, the extent of the grants, including the right of reference, in Article 2, but LICENSEE shall not disclose the financial terms of this Agreement except where LICENSEE is required by law or by the order of a court of competent jurisdiction to do so. To the extent LICENSEE makes any forward-looking statement in its press releases mentioning Cornell, LICENSEE shall receive prior consent of Cornell, which shall not be unreasonably withheld. LICENSEE may disclose the existence and terms of this Agreement in governmental or regulatory filings to the extent required by law. For clarity, any publication or presentation of Data or summaries thereof remains subject to Paragraph 2.4(c).

ARTICLE 10. MISCELLANEOUS PROVISIONS

10.1 **Correspondence.** Any notice, invoice or payment required to be given to either party under this Agreement shall be deemed to have been properly given and effective:

- (a) on the date of delivery if delivered in person, via ACH or via Fed Wire;
- (b) one (1) day after the successful transmission in pdf file format if sent by electronic mail using the Internet; or
- (c) five (5) days after mailing if mailed by first-class or certified mail, postage paid, to the respective addresses given below, or to such other address as is designated by written notice given to the other party.

If sent to LICENSEE:

Reports and Notices Contact:

[***]

If sent to Cornell:

For all correspondence *except payments* -

[***]

For all payments -

If sent by mail:

[***]

If remitted by electronic payments via ACH or Fed Wire:

Receiving bank name:	[***]
Bank account no.:	[***]
Bank routing (ABA) no.:	[***]
SWIFT code:	[***]
Bank account name:	[***]
Bank ACH format code:	[***]
Bank address:	[***]
Additional information:	[***]

An email copy of the wire transfer transaction receipt will be sent to Director for Finance and Operations at [***]. LICENSEE is responsible for all bank charges of wire transfer of funds for payments. The bank charges will not be deducted from total amount due to Cornell.

10.2 **Secrecy.**

- (a) For the purposes of this Paragraph 10.2, “Cornell” as the receiving Party shall be limited to CTL, Cornell’s Office of University Counsel, and Cornell’s Division of Financial Affairs.
- (b) Each receiving Party shall:

- (i) use the Confidential Information for the sole purpose of performing or verifying performance under the terms of this Agreement;
- (ii) safeguard Confidential Information against disclosure to others with the same degree of care as it exercises with its own data of a similar nature;
- (iii) not disclose Confidential Information to others (except to its Affiliates, Contractors, Sublicensees, directors, employees, agents or consultants, as well as prospective investors, who are bound by a like obligation of confidentiality) without the express written permission of the disclosing Party, except that no Party shall be prevented from using or disclosing any of the Confidential Information that:

- (A) the receiving Party can demonstrate by written records was previously known to it;
- (B) is now, or becomes in the future, public knowledge other than through acts or omissions of the receiving Party;
- (C) is lawfully obtained by the receiving Party from sources independent of the disclosing Party; or
- (D) is required to be disclosed by law or a court of competent jurisdiction.

(c) The secrecy obligations with respect to Confidential Information shall continue for a period ending [***] from the termination or expiration date of this Agreement, except for LICENSEE's confidentiality obligations with regard to Data, the Study IND included in Know-How, and the FDA correspondence related to the right of reference granted in Paragraph 2.5, which shall continue [***], unless excepted under Paragraph 10.2(b)(iii).

10.3 Assignability. LICENSEE, including each Affiliate of LICENSEE, will not grant a security interest, in the License or this Agreement during the Term. This Agreement may be assigned by Cornell (so long as Cornell remains obligated for all obligations under this Agreement as if such assignment had not occurred), but is personal to LICENSEE and assignable by LICENSEE only with the prior written consent of Cornell, which consent shall not be unreasonably refused or delayed. Notwithstanding the foregoing, LICENSEE may, without Cornell's prior written consent, (i) assign this Agreement, in whole or in part, to any Affiliate at any time (so long as LICENSEE remains obligated for all obligations under this Agreement as if such assignment had not occurred) and (ii) during the Term to a third-party, in each case only if all the following conditions are met:

- (a) if applicable, the assignment occurs in connection with a merger, acquisition, consolidation or other business combination or sale or other disposition of all or substantially all of LICENSEE's business or assets relating to the subject matter hereof; and
- (b) LICENSEE is in good standing with respect to this Agreement; and
- (c) if assignee is an Affiliate, every Affiliate is in good standing in all material respects with respect to every agreement that such Affiliate has with Cornell; and
- (d) assignee (including each affiliate of assignee) is not an Excluded Entity; and
- (e) assignee has sufficient resources to fulfill all of LICENSEE's obligations under this Agreement; and
- (f) prior to the assignment, assignee provides Cornell written confirmation that assignee shall assume all of LICENSEE's interests, rights, duties, liabilities and obligations under this Agreement, and agrees to comply with all terms and conditions of this Agreement as if assignee were an original party to this Agreement.

10.4 No Waiver. No waiver by either Party of any breach or default of any covenant or agreement set forth in this Agreement shall be deemed a waiver as to any subsequent and/or similar breach or default.

10.5 **Governing Laws.** THIS AGREEMENT SHALL BE INTERPRETED AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK without regard to any conflicts of law provision that would result in the application of the laws of any state other than the State of New York, but the scope and validity of any patent or patent application shall be governed by the applicable laws of the country of the patent or patent application.

10.6 **Disputes.**

(a) The Parties will use reasonable efforts to resolve amicably any disputes that may relate to or arise under this Agreement. If the Parties are unable to resolve within [***] after one Party notifies the other Party in writing of the existence and nature of such dispute, then the Parties hereby submit to the exclusive jurisdiction of and venue in the state and federal courts located in the Southern District of New York with respect to any and all disputes concerning the subject of, or arising out of, this Agreement.

(b) Notwithstanding the foregoing, should the Parties disagree about the fair-market value of non-cash consideration used in calculating Net Sales or the value of the fraction used to calculate Net Sales for a Combination Product (Paragraph 1.23), of the fair-market value of equity in LICENSEE purchased by a Sublicensee as consideration for its Sublicense (Paragraph 1.32(f)), or of the fair-market value of non-cash consideration received from a Sublicensee as consideration for its Sublicense (Paragraph 2.2(b)(i)), the Parties shall resolve the dispute using the baseball arbitration process defined in Appendix E.

10.7 **Joint Drafting.** The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement.

10.8 **Force Majeure.** A Party may be excused from any performance required herein if such performance is rendered impossible or unfeasible due to any catastrophe or other major event beyond its reasonable control, including, without limitation, war, riot, quarantines, and insurrection; laws, proclamations, edicts, ordinances, or regulations; strikes, lockouts, or other serious labor disputes; and floods, fires, epidemics, explosions, or other natural disasters. When such events have abated, the non-performing Party's obligations herein shall resume.

10.9 **Headings.** The headings of the several paragraphs are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

10.10 [***] the document in Appendix D, which is being executed concomitantly with this Agreement.

10.11 **Entire Agreement.** This Agreement, including the Appendices hereto, embodies the entire understanding of the Parties and supersedes all previous communications, representations or understandings, either oral or written, between the Parties relating to the subject matter hereof.

10.12 **Amendments.** No amendment or modification of this Agreement shall be valid or binding on the Parties unless made in writing and signed on behalf of each Party.

10.13 **Severability.** In the event that any of the provisions contained in this Agreement is held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Agreement, and this Agreement shall be construed as if the invalid, illegal, or unenforceable provisions had never been contained in it.

IN WITNESS WHEREOF, both Cornell and LICENSEE have executed this Agreement, in duplicate originals, by their respective and duly authorized officers on the day and year written.

-- Signatures on following page --

LEXEO THERAPEUTICS, INC

CORNELL UNIVERSITY

By: /s/ R. Nolan Townsend
(Signature of an authorized officer)

Name: R. Nolan Townsend

Title: Chief Executive Officer

Date: 4/21/2024

By: /s/ Lisa Placanica
(Signature of an authorized officer)

Name: Lisa Placanica

Title: Senior Managing Director

Date: 4/21/2024

I, the undersigned, hereby confirm that I have read the Agreement, that its contents are acceptable to me and that I will act in accordance with its terms, including the provisions of Paragraph 2.4.

 /s/ Ronald G. Crystal
Dr. Ronald G. Crystal

 4/21/2024
Date

Appendix A: Patent Rights

[***]

Appendix A

Appendix B: Data and Reports

[**]

Appendix C: Know-How in Docket D-9332

[**]

Appendix D: Amendment to Second License Agreement

[**]

Appendix E: Baseball Arbitration

[**]

Appendix F: Development Report

[***]

Appendix G: Commercialization Report

[**]

CERTIFICATION

I, R. Nolan Townsend certify that:

1. I have reviewed this Form 10-Q of Lexeo 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. I am 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;
 - (c) 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
 - (d) 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. 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.

Dated: August 12, 2024

/s/ R. Nolan Townsend

By: R. Nolan Townsend
Chief Executive Officer (Principal Executive
Officer and Principal Financial Officer)

CERTIFICATION

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), R. Nolan Townsend, Chief Executive Officer, Principal Executive Officer and Principal Financial Officer of Lexeo Therapeutics, Inc. (the “Company”), hereby certifies that, to the best of his knowledge:

1. The Company’s Quarterly Report on Form 10-Q for the period ended June 30, 2024, to which this Certification is attached as Exhibit 32.1 (the “Periodic Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 12, 2024

/s/ R. Nolan Townsend

R. Nolan Townsend

Chief Executive Officer (Principal Executive
Officer and 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 Lexeo Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.
