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: 001-39273

Lyra Therapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**84-1700838**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
480 Arsenal Way Watertown, MA	**02472**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 393-4600

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(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value per share	LYRA	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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of August 1, 2024, the registrant had 65,456,735 shares of common stock, $0.001 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical fact contained in this Quarterly Report on Form 10-Q are forward-looking statements, including but not limited, to statements regarding:

- our restructuring initiatives and our ability to continue as a going concern;
- our estimates and statements regarding our future revenue, future results of operations, and financial position;
- the sufficiency of our cash and cash equivalents to fund our operations;
- plans to develop, manufacture, and commercialize LYR-210;
- the timing of our ongoing or planned clinical trials for LYR-210, and any future product candidates;
- the timing of and our ability to obtain and maintain regulatory approvals for LYR-210, and any future product candidates;
- the clinical utility of LYR-210;
- our commercialization, marketing, and manufacturing capabilities and strategy;
- our expectations about the willingness of healthcare professionals to use LYR-210, and any future product candidates;
- our expectations regarding the development and commercialization of LYR-210 pursuant to the terms of the LianBio License Agreement (as defined below);
- our intellectual property position;
- our competitive position and developments and projections relating to our competitors or our industry;
- the impact of laws and regulations;
- risks associated with the COVID-19 pandemic ("COVID-19") and related macroeconomic factors, which may adversely impact our business and clinical trials;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act, or the JOBS Act;
- our business strategy;
- our projected research and development costs; and
- the plans and objectives of management for future operations.

These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the 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,” “contemplate,” “believe,” “estimate,” “predict,” “potential,” “would” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words or expressions. The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of known and unknown risks, uncertainties, and assumptions, including those described under the sections in this Quarterly Report on Form 10-Q entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Quarterly Report on Form 10-Q. 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. 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.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

Unless the context requires otherwise, we use the terms “Lyra,” “the Company,” “we,” “us,” “our” and similar designations in this Quarterly Report on Form 10-Q to refer to Lyra Therapeutics, Inc. and its wholly owned subsidiary, Lyra Therapeutics Securities Corporation.

SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part II, Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include the following:

- any potential financial or strategic option we pursue in order to maximize shareholder value may not result in the identification of a suitable transaction, or if one is identified and pursued, may not be completed on attractive terms, or at all;

- we are attempting to sublease or assign our three leaseholds, which represent significant operating costs, and there can be no assurance that we will accomplish this effort on favorable terms, or at all, which would adversely affect our business, results of operations and financial condition;

- we have incurred significant losses since inception and expect to incur significant additional losses for the foreseeable future;

- our recurring losses from operations raise substantial doubt regarding our ability to continue as a going concern;

- we will need significant additional funding in order to complete development of and obtain regulatory approval for our product candidates and commercialize our products, if approved. The failure of our ENLIGHTEN 1 Phase 3 trial to meet its primary endpoint has made it more difficult for the Company to raise capital. If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts, and/or discontinue operations;

- following the failure of our ENLIGHTEN 1 Phase 3 trial evaluating LYR-210 for the treatment of chronic rhinosinusitis (CRS) to meet its primary endpoint, which was announced in May 2024, there is significant uncertainty about the Company’s ability to complete development of LYR-210 and our ability to obtain regulatory approval for LYR-210 is at least significantly delayed and may not be possible;

- our common stock may be delisted from The Nasdaq Global Market if we cannot regain compliance with Nasdaq’s continued listing requirements, which could harm our business, the trading price of our common stock, our ability to raise additional capital and the liquidity of the market for our common stock;

- in connection with a cost reduction initiative following the failure of our ENLIGHTEN 1 Phase 3 trial to meet its primary endpoint, we implemented a reduction in force impacting approximately 87 employees, which was effected during May and June 2024, and this loss of key personnel significantly and adversely affects our ability to manufacture our product candidates, among other activities;

- we are no longer engaged in the manufacturing of our product candidates in-house;

- our business is highly dependent on the success of our most advanced product candidate, LYR-210, which requires on-going clinical testing before we can seek regulatory approval and potentially launch our product. If LYR-210 does not receive regulatory approval or is not successfully commercialized, or is significantly delayed in doing so, our business will be harmed;

- clinical trials required for our lead product candidate and any future product candidates are expensive and time-consuming, their outcome is uncertain, and if our clinical trials do not meet safety or efficacy endpoints in these evaluations, or if we experience significant delays in these trials, our ability to commercialize our product candidates and our financial position will be impaired;

- any failure by a third party to conduct our pre-clinical or clinical trials according to good clinical practices and in a timely manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize our product candidates;

- even if LYR-210 receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success;

•we are party to a collaboration, and may enter into other collaborations, that place the development and commercialization of our product candidates outside our control, require us to relinquish important rights or may otherwise be on terms unfavorable to us, and if our collaborations are not successful, our product candidates may not reach their full market potential;

•managing our obligations under our license and other strategic agreements may divert management time and our limited resources, causing delays or disruptions to our business;

•our operating activities may be restricted by certain covenants in our license and strategic agreements, which could limit our development and commercial opportunities;

•failure to obtain marketing approval in international jurisdictions would prevent our products from being marketed in such jurisdictions;

•developments by competitors may render our products or technologies obsolete or non-competitive or may reduce the size of our markets;

•the successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and pricing policies;

•failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue;

•if we are unable to obtain, maintain, or adequately protect our intellectual property rights, we may not be able to compete effectively in our market;

•the impact of international terrorism, political unrest and wars on our business; and

•the impact of other events such as the COVID-19 pandemic may adversely impact our business and operations, including our clinical trials.

Table of Contents

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

LYRA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands, except share data)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 31,905	$ 22,353
Short-term investments	35,593	80,400
Prepaid expenses and other current assets	1,937	2,068
Total current assets	69,435	104,821
Property and equipment, net	1,665	2,043
Operating lease right-of-use assets	21,490	33,233
Restricted cash	1,992	1,392
Other assets	—	1,111
Total assets	$ 94,582	$ 142,600
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,971	$ 3,131
Restructuring liability	3,127	—
Accrued expenses and other current liabilities	6,095	9,374
Operating lease liabilities	4,269	5,434
Deferred revenue	814	1,658
Total current liabilities	19,276	19,597
Operating lease liabilities, net of current portion	32,479	21,447
Deferred revenue, net of current portion	11,850	12,136
Total liabilities	63,605	53,180
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at June 30, 2024 and December 31, 2023; no shares issued and outstanding at June 30, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at June 30, 2024 and December 31, 2023; 65,455,735 and 57,214,550 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	65	57
Additional paid-in capital	412,854	400,685
Accumulated other comprehensive income (loss), net of tax	(4)	33
Accumulated deficit	(381,938)	(311,355)
Total stockholders' equity	30,977	89,420
Total liabilities and stockholders' equity	$ 94,582	$ 142,600

See accompanying notes to unaudited condensed consolidated financial statements.

LYRA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Collaboration revenue	$ 598	$ 458	$ 1,130	$ 868
Operating expenses:				
Research and development	13,264	10,799	31,502	23,395
General and administrative	5,139	4,570	10,957	9,697
Impairment of property and equipment	1,883	1,592	1,883	1,592
Impairment of right-of-use assets	22,836	—	22,836	—
Restructuring and other related charges	6,450	—	6,450	—
Total operating expenses	49,572	16,961	73,628	34,684
Loss from operations	(48,974)	(16,503)	(72,498)	(33,816)
Other income:				
Interest income	855	897	1,941	1,969
Total other income	855	897	1,941	1,969
Loss before income tax expense	(48,119)	(15,606)	(70,557)	(31,847)
Income tax expense	(12)	(12)	(26)	(26)
Net loss	(48,131)	(15,618)	(70,583)	(31,873)
Other comprehensive loss:				
Unrealized holding loss on short-term investments, net of tax	(29)	(15)	(37)	(37)
Comprehensive loss	$ (48,160)	$ (15,633)	$ (70,620)	$ (31,910)
Net loss per share attributable to common stockholders— basic and diluted	$ (0.74)	$ (0.36)	$ (1.09)	$ (0.79)
Weighted-average common shares outstanding— basic and diluted	65,459,678	43,676,387	64,739,520	40,273,472

See accompanying notes to unaudited condensed consolidated financial statements.

LYRA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)
(in thousands, except share amounts)

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Loss, net of tax	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2022	31,827,659	$ 32	$ 329,387	$ 10	$ (248,675)	$ 80,754
Exercise of common stock options	2,115	—	4	—	—	4
Issuance of common stock upon RSU vesting	7,041	—	—	—	—	—
Unrealized loss on available-for-sale securities	—	—	—	(22)	—	(22)
Stock-based compensation	—	—	1,610	—	—	1,610
Net loss	—	—	—	—	(16,255)	(16,255)
Balance at March 31, 2023	31,836,815	$ 32	$ 331,001	$ (12)	$ (264,930)	$ 66,091
Issuance of common stock and pre-funded warrants, net of issuance costs of $3,332	17,652,962	$ 18	$ 46,650	—	—	$ 46,668
Exercise of common stock options	55,262	—	97	—	—	97
Unrealized loss on available-for-sale securities	—	—	—	(15)	—	(15)
Stock-based compensation	—	—	1,354	—	—	1,354
Net loss	—	—	—	—	(15,618)	(15,618)
Balance at June 30, 2023	49,545,039	$ 50	$ 379,102	$ (27)	$ (280,548)	$ 98,577

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Loss, net of tax	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2023	57,214,550	$ 57	$ 400,685	$ 33	$ (311,355)	$ 89,420
Exercise of common stock options	918	—	3	—	—	3
Shares issued under ATM, net of issuance costs of $150	1,041,666	1	4,849	—	—	4,850
Exercise of pre-funded warrants	1,255,500	1	1	—	—	2
Exercise of common stock warrants	1,424,272	2	3,806	—	—	3,808
Issuance of common stock upon RSU vesting	27,869	—	—	—	—	—
Unrealized loss on available-for-sale securities	—	—	—	(8)	—	(8)
Stock-based compensation	—	—	1,881	—	—	1,881
Net loss	—	—	—	—	(22,452)	(22,452)
Balance at March 31, 2024	60,964,775	$ 61	$ 411,225	$ 25	$ (333,807)	$ 77,504
Exercise of pre-funded warrants	4,490,876	$ 4	$ 4	—	—	$ 8
Exercise of common stock options	84	—	—	—	—	—
Unrealized loss on available-for-sale securities	—	—	—	(29)	—	(29)
Stock-based compensation	—	—	1,625	—	—	1,625
Net loss	—	—	—	—	(48,131)	(48,131)
Balance at June 30, 2024	65,455,735	$ 65	$ 412,854	$ (4)	$ (381,938)	$ 30,977

See accompanying notes to unaudited condensed consolidated financial statements.

LYRA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Six Months Ended June 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (70,583)	$ (31,873)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,286	2,964
Depreciation expense	281	261
Impairment of property and equipment	1,883	1,592
Write-off of deferred financing costs	140	—
Impairment of right-of-use assets	22,836	—
Net amortization of premium on short-term investments	(1,608)	(1,352)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	131	1,135
Operating lease right-of-use assets	227	803
Other assets	1,111	(2,527)
Accounts payable	1,818	3,189
Accrued expenses and other current liabilities	(2,502)	(2,928)
Restructuring Liability	3,127	—
Operating lease liabilities	(1,453)	(528)
Deferred revenue	(1,130)	(868)
Net cash used in operating activities	(42,436)	(30,132)
Cash flows from investing activities:		
Purchases of property and equipment	(2,345)	(116)
Purchases of short-term investments	(35,141)	(29,930)
Maturity of short-term investments	81,519	34,800
Net cash provided by investing activities	44,033	4,754
Cash flows from financing activities:		
Proceeds from sale of common stock, purchase warrants and pre-funded warrants, net of issuance costs	8,819	50,000
Payment of deferred offering costs	(267)	(2,912)
Proceeds from exercise of stock options	3	101
Net cash provided by financing activities	8,555	47,189
Net increase in cash, cash equivalents and restricted cash	10,152	21,811
Cash, cash equivalents and restricted cash, beginning of period	23,745	33,942
Cash, cash equivalents and restricted cash, end of period	$ 33,897	$ 55,753
Supplemental disclosure of non-cash financing and investing activities:		
Property and equipment purchases included in accounts payable	$ 64	$ 54
Other assets included in accounts payable and other current liabilities	$ —	$ 505
Right of Use Asset in Exchange for Lease Liability	$ 13,667	$ —
Prepaid expenses for right-of-use asset included in operating lease liabilities	$ 440	$ —
Deferred offering costs included in accounts payable and accrued expenses	$ 23	$ 420

See accompanying notes to unaudited condensed consolidated financial statements.

LYRA THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Organization, Restructuring, Going Concern and Basis of Presentation

Lyra Therapeutics, Inc. (the "Company") is a clinical-stage biotechnology company focused on the development and commercialization of therapies for the localized treatment of patients with chronic rhinosinusitis, or CRS. The Company's proprietary technology is designed to consistently deliver medicines directly to the affected tissue for sustained periods with a single administration. The Company's product candidates, LYR-210 and LYR-220, are bioabsorbable nasal implants designed to be administered in a simple, in-office procedure and intended to deliver six months of continuous anti-inflammatory drug therapy to the sinonasal passages for the treatment of CRS. The Company was incorporated as a Delaware corporation on November 21, 2005 and is located in Watertown, Massachusetts. On July 16, 2018, the Company formerly changed its name from 480 Biomedical, Inc. to Lyra Therapeutics, Inc.

The Company is subject to risks common to companies in the therapeutics and pharmaceutical industry, including but not limited to, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval for any drug product candidate that it may identify and develop, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development by competitors of technological innovations, reliance on third party manufacturers, ability to transition from pilot-scale manufacturing to large-scale production of products and the need to obtain adequate additional financing to fund the development of its product candidates.

Restructuring

On May 16, 2024, the Company reported that topline results from the Company's Phase 3 ENLIGHTEN 1 trial evaluating LYR-210, a bioabsorbable sinonasal implant (7500µg mometasone furoate), as a six-month treatment of chronic rhinosinusitis (CRS). ENLIGHTEN 1 did not meet its primary endpoint of demonstrating statistically significant improvement compared to sham control in the composite score of the three cardinal symptoms (3CS) of CRS (nasal obstruction, nasal discharge, facial pain/pressure) at 24 weeks. ENLIGHTEN 1 is one of two Phase 3 clinical trials evaluating LYR-210. ENLIGHTEN 2, the second pivotal Phase 3 trial of LYR-210 in CRS, is ongoing, with enrollment expected to be completed in the second half of 2024 and topline results expected in the first half of 2025.

In connection with the ENLIGHTEN 1 trial failing to meet its primary endpoint, on May 16, 2024, the Board of Directors of the Company (the "Board of Directors") approved a reduction in the Company's workforce impacting 87 employees, which occurred during May and June 2024. In connection with the reduction in force, the Company stopped manufacturing and commercialization efforts for LYR-210, as well as development efforts for LYR-220 in an effort to reduce operating expenses. Furthermore, the Company is currently in the process of marketing all three of its leased properties for sub-leasing arrangements.

The Company has recorded a restructuring charge in the amount of $6.5 million primarily related to severance and retention costs as further discussed in Note 4. The Company has also recorded an impairment charge for the write-down of property and equipment of $1.9 million and right-of-use assets in the amount of $22.8 million as further discussed in Notes 5 and 6.

Going Concern

The failure of the Company's Phase 3 ENLIGHTEN 1 trial to meet its primary endpoint, which resulted in the Company's restructuring during the second quarter of 2024, provides significant uncertainty regarding the Company's ability to meet its business plans and conduct its future operations. The Company has incurred recurring net operating losses every year since inception and has an accumulated deficit of approximately $381.9 million at June 30, 2024. The Company expects to continue to generate operating losses for the foreseeable future. At June 30, 2024, the Company had approximately $31.9 million of cash and cash equivalents and $35.6 million of short-term investments. These conditions raise substantial doubt about the Company's ability to continue as a going concern for one year from the date these condensed consolidated financial statements are issued.

From inception through June 30, 2024, the Company has raised an aggregate of $424.8 million to fund its operations, of which $162.1 million were gross proceeds from sales of redeemable convertible preferred stock, $96.3 million were net proceeds from the April 2022 financing, $46.5 million were net proceeds from the May 2023 Financing (as defined below), $57.3 million were net proceeds from the Company's initial public offering, $23.9 million were net proceeds related to the Company's Controlled Equity Offering Agreement (the "Original Sales Agreement") dated September 1, 2023, $16.8 million were gross proceeds from government contracts, $17.0 million were gross proceeds from the LianBio License Agreement, and $3.8 million were gross proceeds from the exercise of common stock warrants.

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") assuming the Company will continue as a going concern and contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

The Company is currently considering various operational and strategic options in light of the failure of the ENLIGHTEN 1 trial to meet its primary endpoint, including additional clinical trials, the sale of assets, or a strategic business combination. The Board of Directors has not decided on a specific plan other than to reduce operating expenses in order to manage its cash position. The Company is attempting to sublease all of its leased locations, and, may also seek to negotiate an early termination of its leases with its landlords. The Company may be unable to sublease its locations on favorable terms or at all. In addition, the Company may not be able to obtain an early termination of its leases with its landlords on favorable terms or at all.

The Company will continue to evaluate its headcount of employees and may further reduce its workforce, which will result in additional severance and retention costs, which may impact the Company's ability to meet objectives. If the Company decides to pursue any form of growth strategy in the future, it will need additional financing to support its continuing operations. Until the Company can generate significant revenue from product sales, if ever, it plans to finance its operations through a combination of equity or debt financings, collaboration agreements, strategic alliances and licensing arrangements. The Company may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all. The inability to obtain funding as and when needed would have a negative impact on the Company's financial condition and ability to pursue its business strategies. If the Company is unable to obtain funding when needed, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. The Company will need to generate significant revenue to achieve profitability, and it may never do so.

Basis of Presentation

The accompanying interim condensed consolidated financial statements and related disclosures are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and the instructions to Form 10-Q and Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company's audited consolidated financial statements and related notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the Securities and Exchange Commission on March 22, 2024. Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standard Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). In management's opinion, these unaudited condensed consolidated financial statements include all normal and recurring adjustments necessary for a fair presentation of the Company's condensed consolidated financial statements for the periods presented.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2023, included in the Company's Annual Report on Form 10-K filed with the SEC on March 22, 2024. Since the date of those financial statements, there have been no changes to its significant accounting policies except as noted below.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. For the three and six months ended June 30, 2024, other comprehensive loss consisted of unrealized losses, net of taxes from its short-term investments.

Restricted Cash

The Company had restricted cash of approximately $2.0 million as of June 30, 2024 and approximately $1.4 million as of December 31, 2023. These balances were held as of June 30, 2024 at one of the Company's financial institutions to secure the Company's letters of credit for its facility leases.

The Company's statements of cash flows include restricted cash with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on such statements. A reconciliation of the cash, cash equivalents, and

restricted cash reported within the balance sheet that sum to the total of the same amounts shown in the statement of cash flows is as follows:

	June 30, 2024	December 31, 2023
Cash and cash equivalents	$ 31,905	$ 22,353
Restricted cash	1,992	1,392
Total	$ 33,897	$ 23,745

Net Loss per Share

The Company has reported losses since inception and has computed basic net loss per share attributable to common stockholders by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. The Company has included pre-funded warrants in its computation of basic net loss per share based on the nominal exercise price.

The Company applies the two-class method to calculate its basic and diluted net loss per share, as the Company has issued shares that meet the definition of participating securities. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. The Company's participating securities contractually entitle the holders of such shares to participate in dividends, but do not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. Additionally, in periods in which the Company reports a net loss, diluted net loss per share is the same as basic net loss per share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

The following table sets forth the potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because to include them would be anti-dilutive (in common stock equivalent shares):

	Three and Six Months Ended June 30,	
	2024	2023
Stock options	7,045,833	5,871,813
Common stock warrants	8,606,303	10,030,575
Restricted stock units	867,472	243,703
Total	16,519,608	16,146,091

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the Company's consolidated financial position, results of operations or cash flows.

Effective January 1, 2024, the Company, as required, adopted ASU No. 2023-07, Segment Reporting (Topic 280) ("ASU 2023-07") Improvements to Reportable Segment Disclosure for its annual financial statements and notes thereto for the year ending December 31, 2024 to be included in its 2024 Annual Report on Form 10-K. The Company is not required to adopt the standard for interim periods until the first quarter of 2025.

This standard requires disclosure of significant segment expenses that are regularly provided to the Chief Operating Decision Maker, "CODM", and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items to reconcile to segment profit or loss and the title and position of the entity's CODM.

The Company will include the required disclosure information in the notes to the financial statements for the year ending December 31, 2024 included in its 2024 Annual Report on Form 10-K and is required to apply ASU No. 2023-07 on a retrospective basis. The adoption of ASU No. 2023-07 will include expanded disclosure for its 2024 financial statements, but the Company does not expect that there will be a material impact to the financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which is intended to provide enhancements to annual income tax disclosures. In particular, the standard will require more detailed information in the income tax rate reconciliation, as well as the disclosure of income taxes paid disaggregated by jurisdiction, among other enhancements. The standard is effective for years beginning after December 15, 2024 and early adoption is permitted. The Company is currently evaluating the impact of the standard on the presentation of its consolidated financial statements and footnotes.

Effective January 1, 2023, the Company adopted Accounting Standards Update (ASU) No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments (ASU 2016-13). ASU 2016-13 requires that credit losses be reported as an allowance using an expected losses model, representing the entity's current estimate of credit losses expected to be incurred. For available-for-sale debt securities with unrealized losses, this standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. The adoption of ASU 2016-13 did not have a material impact on its consolidated financial statements.

3. Fair Value Measurements

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

		Fair Value Measurements at Reporting Date Using		
	June 30, 2024	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents				
Money market funds	$ 8,624	$ 8,624		
Total cash equivalents	$ 8,624	$ 8,624	$ —	$ —
Short-term investments:				
U.S. treasury bills	35,593		35,593	
Total Short-term investments	$ 35,593	$ —	$ 35,593	$ —

		Fair Value Measurements at Reporting Date Using		
	December 31, 2023	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$ 11,167	$ 11,167	$ —	$ —
U.S. treasury bills	8,980	—	8,980	—
Total cash equivalents	$ 20,147	$ 11,167	$ 8,980	$ —
Short-term investments:				
U.S. treasury bills	76,918	—	76,918	—
U.S. Government Agency and foreign national bank securities	3,482	—	3,482	—
Total Short-term investments	$ 80,400	$ —	$ 80,400	$ —

As of June 30, 2024, the Company's cash equivalents were invested in money market funds, which were valued based on Level 1 inputs. As of June 30, 2024, the Company's short-term investments consisted of U.S. treasury bills which were valued based on Level 2 inputs. As of December 31, 2023, the Company's cash equivalents were invested in money market funds and U.S. treasury bills, which were valued based on Level 1 and Level 2 inputs, respectively. As of December 31, 2023, the Company's short-term investments consisted of U.S. treasury bills which were valued based on Level 2 inputs and U.S. Government Agency Securities and foreign national bank securities, which were valued based on Level 2 inputs. In determining the fair value of its investments at each

date presented above, the Company relied on quoted prices for similar securities in active markets or using other inputs that are observable or can be corroborated by observable market data for Level 2 investments. All available-for-sale securities have contractual maturities of less than one year. The Company did not have any financial assets or liabilities during any of the periods presented in the accompanying consolidated financial statements that required Level 3 inputs.

The carrying values of the Company's accounts payable, accrued expenses and deferred revenue approximate their fair values due to the short-term nature of these liabilities and as such these are considered Level 1 in the fair value hierarchy.

4. Restructuring and Other Related Charges

In connection with the ENLIGHTEN 1 trial failing to meet its primary endpoint, on May 16, 2024, the Board of Directors approved a reduction in the Company's workforce, impacting 87 employees, which occurred during May and June 2024. The Company incurred costs related to employee termination benefits and other costs associated with the restructuring mainly during the second quarter of 2024, with the remainder of the costs to be incurred through May 1, 2025. These amounts are recorded as restructuring and other related charges within our consolidated statements of operations and comprehensive loss as they are incurred. For the three and six months ended June 30, 2024, restructuring and other related charges were $6.5 million, which consisted of $4.7 million of severance costs, $0.8 million of accrued retention costs, and $1.0 million of other costs.

Restructuring liability activities during the three and six months ended June 30, 2024:

	January 1, 2024	Accruals	Cash Payments	June 30, 2024
2024 Restructuring Plan				
Severance Costs	$ —	$ 4,706,249	$ (2,783,091)	$ 1,923,158
Retention Costs	—	823,821	—	823,821
Other Costs	—	920,399	(540,225)	380,174
Total	$ —	$ 6,450,469	$ (3,323,316)	$ 3,127,153

5. Property and Equipment and Related Impairment

Property and equipment consist of the following (in thousands) as of June 30, 2024 and December 31, 2023:

	June 30, 2024	December 31, 2023
Property and equipment:		
Laboratory equipment	$ 4,169	$ 2,736
Computer software and equipment	160	105
Office furniture and fixtures	934	662
Leasehold improvements	485	461
Total	$ 5,748	$ 3,964
Less: Accumulated depreciation	(2,200)	(1,921)
Less: Impairment	(1,883)	—
Property and equipment, net	$ 1,665	$ 2,043

During the second quarter of 2024 and as a result of the Company's Phase 3 ENLIGHTEN 1 trial failing to meet its primary endpoint, the Company performed a recoverability test for its property and equipment. The Company concluded that the undiscounted cash flows associated with its property and equipment was less than the carrying value of the property and equipment. The Company compared the fair value of the property and equipment to the carrying value and recorded an impairment charge in the amount of $1.9 million which is included as an impairment of property and equipment in the accompanying consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2024. The Company determined fair market value of the equipment based on a third-party appraisal of the equipment through use of publicly available used equipment quotes. The equipment was valued as of May 15, 2024.

6. Impairment of Right-of-Use Assets

In connection with the Company's Phase 3 ENLIGHTEN 1 trial failing to meet its primary endpoint, in May 2024, the Company engaged a commercial real estate broker to market the Company's three leased properties for sublease arrangements. As of the June 30, 2024 financial statements, the Company has not sublet any of its leased properties. Based upon these impairment indicators, the Company has performed a recoverability test over its right-of-use asset and concluded the right-of-use assets are impaired. As a result, the Company has recorded an impairment charge in the amount of $22.8 million, which is included as an impairment of right-of-use asset in the accompanying consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2024. The right-of-use asset was valued as of May 15, 2024.

The Company has engaged a valuation specialist to perform a fair value determination of the right-of-use assets using a discounted cash flow methodology, which included the following range of assumptions:

Discount Rate	9.5-10.5%
Term (years)	2.96-9.13
Expected Sublease Rent Increases	3.0%

7. Preferred and Common Stock

The Company has 10,000,000 shares of undesignated preferred stock, par value $0.001 per share. There were no shares issued or outstanding as of June 30, 2024 or June 30, 2023.

The holders of common stock are entitled to one vote for each share held. Common stockholders are not entitled to receive dividends, unless declared by the Board of Directors.

The Company currently has an effective shelf registration statement on Form S-3 (No. 333-278163) filed with the SEC on March 22, 2024 ("Form S-3"), under which it may offer from time to time in one or more offerings any combination of common and preferred stock, debt securities, warrants and units of up to $300.0 million in the aggregate.

September 2023 Financing

On September 1, 2023, the Company entered into a Controlled Equity Offering Sales Agreement (the "Original Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor") pursuant to which the Company may offer and sell, from time to time through Cantor, shares of the Company's common stock for aggregate gross proceeds of up to $50.0 million. The offering and sale of up to $50.0 million of the common shares has been registered under the Securities Act of 1933, as amended (the "Securities Act"), pursuant to the Company's Registration Statement on Form S-3 (File No. 333-256020) (the "Registration Statement"), which was originally filed with the SEC on May 11, 2021, and declared effective by the SEC on May 20, 2021, the base prospectus contained within the Registration Statement, and a prospectus supplement relating to the shares that was filed with the SEC on September 1, 2023.

Pursuant to the Original Sales Agreement, Cantor may sell the shares in sales deemed to be "at the market offerings" as defined in Rule 415(a)(4) promulgated under the Securities Act. The Company has no obligation to sell any of the shares under the Original Sales Agreement and may at any time suspend or terminate the offering of the shares pursuant to the Original Sales Agreement upon notice to Cantor and subject to other conditions. Cantor will act as sales agent and will use commercially reasonable efforts to sell on the Company's behalf all of the shares requested to be sold by the Company, on mutually agreed terms between Cantor and the Company.

The Original Sales Agreement contains customary representations, warranties and agreements by the Company, and indemnification obligations of the Company and Cantor and other obligations of the parties. Under the terms of the Original Sales Agreement, the Company has agreed to pay Cantor a commission equal to 3.0% of the aggregate gross proceeds from any shares sold through it pursuant to the Original Sales Agreement. In addition, the Company has agreed to reimburse certain expenses incurred by Cantor in connection with the Original Sales Agreement. On February 14, 2024, the Company issued 1,041,666 shares under the Company's ATM agreement with net proceeds of $4.8 million.

On March 22, 2024, the Company amended and restated the Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co. ("Cantor") pursuant to which the Company may offer and sell, from time to time through Cantor, shares of the Company's common stock for aggregate gross proceeds of up to $75.0 million. The offering and sale of up to $75.0 million of the common shares has been registered under the Securities Act of 1933, as amended (the "Securities Act"), pursuant to the Company's

Registration Statement on Form S-3 (File No. 333-278163) (the "Registration Statement"), which was originally filed with the Securities and Exchange Commission on March 22, 2024, the base prospectus contained within the Registration Statement, and a prospectus supplement relating to the shares that was filed with the SEC on March 22, 2024 (the "Prospectus Supplement").

May 2023 Financing

On May 25, 2023, the Company entered into the Purchase Agreement, with the purchasers, pursuant to which the Company agreed to sell securities to the Investors in a private placement (the “Private Placement”). The Purchase Agreement provided for the sale and issuance by the Company of:

17,652,962 shares of the Company’s common stock and accompanying warrants to purchase up to 8,826,481 shares of the Company’s common stock (Purchase Warrants), with an exercise price of $2.67 per share, for aggregate gross proceeds of $44.0 million. Each Purchase Warrant became exercisable on November 30, 2023, and expires on November 30, 2028. Additionally, the Company issued Pre-Funded Warrants to purchase 2,408,188 shares of the Company’s common stock (Pre-Funded Warrants), with an exercise price of $0.001 per share, and accompanying purchase warrants to purchase up to 1,204,094 shares of the Company’s common stock (Purchase Warrants), with an exercise price of $2.673 per share, for aggregate gross proceeds of $6.0 million. In total 10,030,575 Purchase Warrants were issued and 2,408,188 Pre-Funded Warrants were issued. The Pre-Funded Warrants are immediately exercisable and expire on May 31, 2028. The closing of the Private Placement occurred on May 31, 2023.

The Company received an aggregate of $50.0 million in gross proceeds, or $46.5 million after deducting issuance costs. The Company has allocated the net proceeds among the common stock, the Purchase Warrants and the Pre-Funded Warrants using the relative fair value method for each of the above transactions. The Company has allocated $30.5 million to the shares of common stock, $4.2 million to the Pre-Funded Warrants and $12.0 million to the Purchase Warrants.

The Company’s outstanding warrants are freestanding instruments and are classified within stockholders’ equity since the warrants are indexed to the Company’s common stock and meet the equity classification criteria.

A total of 1,424,272 Purchase Warrants were exercised related to the May 2023 financing as of June 30, 2024 at a purchase price of $2.673 per share.

April 2022 Financing

On April 13, 2022, the Company announced the closing of its private placement of common stock (or, in lieu thereof, Pre-Funded Warrants to purchase common stock), resulting in gross proceeds of approximately $100.5 million (the “April 2022 Financing”). The Company received approximately $96.3 million in net proceeds after deducting estimated offering costs of $4.2 million. Pursuant to the securities purchase agreement, (i) certain investors purchased an aggregate of 18,815,159 shares of common stock at $4.22 per share for gross proceeds to the Company of $79.4 million and (ii) certain investors purchased Pre-Funded Warrants to purchase an aggregate of 5,000,000 shares of common stock, with the exercise price of $0.001 per share for gross proceeds of $21.1 million to the Company. The warrants are exercisable on or after April 13, 2022 and expire on April 12, 2027.

The Pre-Funded Warrants were classified as a component of stockholders’ equity within additional paid-in capital and were recorded at the issuance date using a relative fair value allocation method. The Pre-Funded Warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of shares of common stock upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In addition, such Pre-Funded Warrants do not provide any guarantee of value or return. The Company valued the Pre-Funded Warrants at issuance, concluding that their sales price approximated their fair value, and allocated net proceeds from the sale proportionately to the common stock and Pre-Funded Warrants, of which $19.7 million was allocated to the Pre-Funded Warrants and recorded as a component of additional paid-in capital. All Pre-Funded Warrants issued in the April 2022 Financing were exercised as of June 30, 2024.

The Company has reserved for future issuances the following shares of common stock as of June 30, 2024:

	As of June 30, 2024
Pre-funded warrants	—
Common stock warrants	8,606,303
Stock options and restricted stock units	10,080,915
Employee stock purchase plan	724,906
Total	19,412,124

8. Common Stock Warrants

The following table represents a summary of the warrants outstanding and exercisable as of June 30, 2024, all of which are equity-classified:

	Number of Common Warrants	Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value	Expiration Date	Number of Pre-funded Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value	Expiration Date
Outstanding at December 31, 2023	10,030,575	$ 2.673	4.90	$ 25,700	November 30, 2028	5,756,349	$ 0.001	3.92	$ 30,200	April 2027-May 2028
Exercised	(1,424,272)	$ 2.673		$ 5,052		(5,756,349)	$ 0.001		$37,770	
Outstanding at June 30, 2024	8,606,303	$ 2.673	4.40	$ 30,527	November 30, 2028	—	$ —	—	$ —	—

9. Stock-Based Compensation Expense

The Company currently grants equity-based awards under its 2020 Incentive Award Plan (“2020 Plan”) and its 2022 Employment Inducement Award Plan (“Inducement Award Plan”). The Company previously granted equity-based awards under its 2005 Equity Incentive Plan (“2005 Plan”) and 2016 Equity Incentive Plan (“2016 Plan” and together with the 2020 Plan, the Inducement Award Plan and the 2005 Plan, the “Plans”). The Company also maintains the 2020 Employee Stock Purchase Plan (the “ESPP”).

A summary of the restricted stock unit activity under the Plans for the six months ended June 30, 2024 was as follows:

	Shares	Weighted-Average Grant Date Fair Value
Restricted stock units outstanding as of December 31, 2023	105,048	$ 3.20
Granted	984,929	$ 5.49
Vested	(27,869)	$ 3.29
Forfeited	(194,636)	$ 4.28
Restricted stock units outstanding as of June 30, 2024	867,472	$ 5.56

A summary of the stock option activity under the Plans for the six months ended June 30, 2024 was as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	5,709,980	$ 5.68	8.0	$ 6,334
Granted	2,605,002	4.89		
Exercised	(1,002)	3.96		
Cancelled	(1,268,147)	4.56		
Outstanding at June 30, 2024	7,045,833	$ 5.59	8.0	$ —

The fair value of each stock option granted to employees, directors and non-employees was estimated on the date of grant using the Black-Scholes option-pricing model, or a Monte Carlo simulation in the case of certain options granted to executive officers, with the following weighted-average assumptions for the three and six months ended June 30, 2024 and 2023:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Risk-free interest rate	4.4%	3.8%	4.2%	3.7%
Expected dividend yield	—%	—%	—%	—%
Expected term (in years)	5.7	6.1	6.0	6.0
Expected volatility	111.5%	82.0%	80.5%	82.9%

The weighted-average fair value of options granted to employees, directors and non-employees during the three months ended June 30, 2024 and 2023 was $1.19 and $2.24, respectively. The weighted-average fair value of options granted to employees, directors and non-employees during the six months ended June 30, 2024 and 2023 was $2.80 and $2.07, respectively.

Stock-based compensation expense included in the Company's consolidated statements of operations and comprehensive loss was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	$ (290)	$ 287	$ 413	$ 571
General and administrative	1,414	1,067	2,873	2,393
Total	$ 1,124	$ 1,354	$ 3,286	$ 2,964

For the period ended June 30, 2024, approximately $15,000 of the stock-based compensation expense was recorded as a liability. For the period ended June 30, 2023, the Company did not record any stock-based compensation expense as a liability.

Unrecognized share-based compensation related to stock-based options amounted to $7.5 million at June 30, 2024 and is expected to be recognized over a weighted average period of approximately 3.05 years. Unrecognized share-based compensation related to restricted stock units amounted to $2.6 million at June 30, 2024 and is expected to be recognized over a weighted average period of approximately 2.3 years.

In March 2024, the Company granted options to purchase 550,000 shares of common stock at an exercise price of $6.07 per share to its Chief Executive Officer ("2024 Performance Option") and granted 385,000 RSUs to its Executive Chair ("2024 PSUs"), each with performance-based vesting conditions under the 2020 Plan. Vesting of the 2024 Performance Option and the 2024 PSUs are based on the achievement of various clinical and regulatory milestones during the specified periods.

For the performance-based stock awards, the Company measures stock compensation expense based on the fair value of the award on the grant date and then once the Company determines the performance criteria is probable of achievement, recognizes such amount over the vesting term of the award, which is approximately 3.8 years. The Company determined the fair value of the

2024 Performance Option using the Black-Scholes option-pricing model using the following inputs: risk-free interest rate of 4.26%, volatility of 76.82%, expected dividend yield 0%, and expected term of 6.0 years.

The Company measured the 2024 PSUs based on the fair value of the Company's stock on the date of grant.

As of March 31, 2024, the Company has determined that 183,333 shares of common stock subject to the 2024 Performance Option and 128,333 shares of common stock underlying the 2024 PSUs are probable to vest and as of June 30, 2024 has recognized approximately $112,000 of expense, which is included in stock-based compensation expense. As of June 30, 2024, there is $1.4 million of unrecognized stock compensation expense to be recognized in connection with all of the performance-based awards that are deemed to be probable as of June 30, 2024.

As of June 30, 2024, there were 1,531,693 shares available for grant under the 2020 Plan and 635,917 shares available for grant under the Inducement Award Plan.

As of June 30, 2024, there are a total of 724,906 shares available for issuance, no awards outstanding under the 2020 ESPP and no shares have been issued under the 2020 ESPP.

10. Collaboration Agreement

Under the LianBio License Agreement, in order to evaluate the transaction price for purposes of ASC 606, the Company determined that the upfront payment of $12.0 million and the reimbursable cost of the clinical supply of LYR-210 constitute the entirety of the consideration to be included in the transaction price as of the outset of the arrangement, which was allocated to the two performance obligations as follows: $8.4 million to the Combined Performance Obligation and $3.6 million to the Development Activities Performance Obligation. In February 2022, the Company received $5.0 million upon achievement of the first of the development milestones related to dosing its first patient and the transaction price was adjusted by $5.0 million which was allocated to the two performance obligations as follows: $3.5 million to the Combined Performance Obligation and $1.5 million to the Development Activities Performance Obligation. The remaining potential milestone payments that the Company is eligible to receive were excluded from the transaction price as of June 30, 2024, as all milestone amounts were fully constrained based on the probability of achievement.

The Company and LianBio amended the LianBio License Agreement on September 26, 2022, to allow, among other things, LianBio to conduct its own Phase 3 clinical trial and adjust certain future milestones. The amendment also requires both parties to negotiate a supply agreement prior to December 31, 2023. There was a side letter executed on December 27, 2022 which extended the negotiations of a supply agreement. The amendment did not result in any change in the Company's determination of its performance obligations under the arrangement and all future milestones remain constrained from the transaction price. The Company has determined that the contract modification did not have a material impact on the allocation of the transaction price to the two performance obligations.

LianBio announced that in October 2023 its Board of Directors commenced a comprehensive strategic review of its business. The LianBio Board ultimately concluded that selling off assets and winding down operations was the best way to realize maximum shareholder value. LianBio reported that a substantial portion of the wind down activities, including fulfillment of transition service obligations under its existing agreements and gradual cessation of currently active clinical trials, will be completed by the end of 2024. LianBio announced in February 2024 that it was further reducing the size of its workforce to approximately 50 employees with plans to reduce that number further over the course of 2024. LianBio stated it will maintain a core group of employees necessary to implement an orderly wind down and support its efforts to maximize the value of its remaining business and assets including the collaboration with the Company. Due to these developments, the future of the Company's collaboration with LianBio is uncertain as LianBio continues its wind down, while seeking a third party to acquire LianBio's rights under the LianBio License Agreement.

The Company will recognize the revenue associated with the Combined Performance Obligation as the clinical supply of LYR-210 is delivered. The Company recognizes revenue associated with the Development Activities Performance Obligation as the development activities are performed using an input method, according to the costs incurred as to the development activities related to the global Phase 3 clinical trial and the costs expected to be incurred in the future to satisfy the performance obligation. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation. The amounts received that have not yet been recognized as revenue are deferred as a contract liability on the Company's consolidated balance sheet and will be recognized as the clinical supply of LYR-210 is delivered and over the remaining time it takes to conduct the global Phase 3 clinical trial, respectively.

There were no changes in the transaction price from December 31, 2023 to June 30, 2024. The following table reflects the transaction price (in thousands):

	As of June 30, 2024 Post-Milestone
Combined Performance Obligation	$ 11,862
Development Activities Performance Obligation	5,138
Total	$ 17,000

The following table reflects the revenue recognized related to each of the performance obligations and the remaining deferred revenue (in thousands):

	As of June 30, 2024		
	Combined Performance Obligation	Development Activities Performance Obligation	Total
Deferred revenue at December 31, 2022	$ 11,748	$ 3,604	$ 15,352
Revenue recognized	—	(1,558)	(1,558)
Deferred revenue at December 31, 2023	11,748	2,046	13,794
Revenue recognized	—	(1,130)	(1,130)
Deferred revenue at June 30, 2024	$ 11,748	$ 916	$ 12,664

Development and regulatory milestone fees, which are a type of variable consideration, are recognized as revenue to the extent that it is probable that a significant reversal will not occur. Note that the allocated deferred revenue associated with the clinical supply agreement has been recorded as long term deferred revenue given the potential uncertainty of delivery within the next twelve months. As of June 30, 2024, the parties still have not completed their negotiations of the clinical supply agreement. At this point, it is uncertain whether such an agreement will be completed. In view of the uncertainty around the completion of the clinical supply agreement, the Company may decide to recognize such payments as revenue on an accelerated schedule.

Entities affiliated with Perceptive Advisors, LLC are shareholders of both the Company and LianBio. Additionally, two of the Company's directors are Managing Directors at Perceptive Advisors, LLC and one of these directors is also the Executive Chairman of LianBio's board of directors.

11. Income Taxes

The Company records a provision or benefit for income taxes on pre-tax income or loss based on its estimated effective tax rate for the year. Given the Company's uncertainty regarding future taxable income, the Company maintains a full valuation allowance on its deferred tax assets. The Company recorded an income tax expense of $12,000 for the three months ended June 30, 2024 and June 30, 2023 and $26,000 for the six months ended June 30, 2024 and June 30, 2023, respectively.

12. Leases

Watertown Lease

In August 2007, the Company entered into an operating lease, as amended, for office and laboratory space in Watertown, Massachusetts. The lease includes certain rent escalations. In July 2023, the Company amended the lease to extend the expiration of the lease term from April 2024 to April 2027. Under the terms of the amended lease, the Company no longer has the right to terminate the lease after January 1, 2024.

The Company maintains a letter of credit of approximately $0.3 million securing its obligations under the operating lease which is secured by approximately $0.3 million, which are included as restricted cash in the consolidated balance sheets. Rent expense is recognized on a straight-line basis over the terms of occupancy.

The Company also has two leases for two separate spaces in the same building at 880 Winter Street in Waltham, Massachusetts. The Company refers to the first lease as the "Waltham Lease" and the second lease arrangement as the "Waltham

Sublease" as the Company, as a tenant, is subleasing space from under an existing lease arrangement whereby the lessee to the headlease has agreed to sublease the space to the Company under a sublease agreement.

Waltham Lease

In May 2022, the Company executed a lease agreement located at 880 Winter Street in Waltham, Massachusetts. The leased premises comprises approximately 29,000 square feet of office and lab space, and the lease initially provides for base rent of $2.2 million per year, which will increase 3% per year over the noncancellable term ending on June 30, 2033. The Company has the option to extend the lease for one additional five-year term and is responsible for its share of real estate taxes, maintenance, and other operating expenses applicable to the leased premises. The Company did not include the option to extend the lease for the additional five-year term in its measurement of the right-of-use asset and lease liability.

In connection with the lease, a security deposit was delivered to the landlord in the form of an irrevocable standby letter of credit collateralized by $1.1 million of deposits with the financial institution which is recorded as restricted cash.

Waltham Sublease

In December 2023, the Company executed a sublease agreement for additional lab and office space located at 880 Winter Street in Waltham, Massachusetts. The subleased premises comprise approximately 24,000 square feet, and the sublease provides for base rent of $1.8 million per year, which will increase 3% per year over the noncancellable term ending on November 30, 2032. The Company is also responsible for its share of real estate taxes, maintenance, and other operating expenses applicable to the subleased premises.

Upon sublease commencement on January 3, 2024, the Company recorded the sublease as a component of its operating lease right-of-use asset and operating lease liabilities. In connection with the sublease, a security deposit was delivered to the sublandlord in the form of an irrevocable standby letter of credit collateralized by $0.6 million of deposits with the financial institution which is recorded as restricted cash.

The components of lease cost recorded in the Company's condensed consolidated financial statements were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Lease Cost:				
Operating lease cost	$ 1,877	$ 444	$ 3,736	$ 888
Variable lease cost	$ 586	248	1,258	494
Total lease cost	$ 2,463	$ 692	$ 4,994	$ 1,382

Variable lease payments include the Company's allocated share of costs incurred and expenditures made by the landlord in the operation and management of the building.

The weighted-average remaining lease term and discount rate related to the Company's operating leases were as follows:

	As of June 30, 2024
Weighted-average remaining lease term (in years)	7.9
Weighted-average discount rate	6.20%

Maturity of the Company's operating lease liabilities in accordance with ASC 842 as of June 30, 2024 were as follows (in thousands):

Period ended December 31,	
From July 1, 2024 to December 31, 2024	3,532
2025	6,121
2026	6,494
2027	5,131
2028	4,507
Thereafter	20,652
Total maturities	46,437
Less: Imputed interest	(9,689)
Present value of operating lease liability	36,748
Less: current portion of operating lease liability	(4,269)
Total operating lease liability, net of current portion	$ 32,479

The Company evaluated the above leases for impairment indicators and determined that the right-of-use asset is impaired. Additional details are included within Note 6 above.

13. Commitments and Contingencies

On May 10, 2023, the Company filed a complaint in the Superior Court of the State of Delaware against a former contract manufacturer alleging breach of contract. The Company alleged in its complaint that the former contract manufacturer breached the Master Clinical Supply Agreement ("MCSA"). The Company's complaint sought monetary damages and the return of equipment and materials that the Company owned. On July 20, 2023, the same contract manufacturer filed an answer and amended counterclaims to the Company's May 10, 2023 complaint (the "Litigation"). Due to the legal proceeding and termination of agreement with this manufacturer, the Company recognized $1.6 million loss on impairment of long-lived assets during the year-ended December 31, 2023.

On November 2, 2023, the Company entered into a settlement and release agreement, related to the Litigation, pursuant to which each of the Company and the contract manufacturer provided broad mutual releases of all claims relating to or arising out of the MCSA, including without limitation, all claims brought in the Litigation or that could have been brought in the Litigation. The Company and the former contract manufacturer agreed to jointly file a Stipulation of Dismissal with prejudice relating to the Litigation. The Company has a remaining liability of $0.4 million to be paid to the contract manufacturer during 2024 included within accrued liabilities and other current liabilities.

14. Subsequent Events

On July 19, 2024, we received a written notice (the "Notice") from The Nasdaq Stock Market, LLC ("Nasdaq") notifying us that for the last 30 consecutive business days, the bid price for our common stock, par value $0.001 per share, had closed below the $1.00 per share minimum bid price requirement for continued inclusion on The Nasdaq Global Market as set forth in Nasdaq Listing Rule 5450(a)(1) ("the Minimum Bid Price Requirement"). The Notice has no effect at this time on the listing of our common stock, which continues to trade on The Nasdaq Global Market under the symbol "LYRA."

In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we have a period of 180 calendar days, or until January 15, 2025 (the "Compliance Date") to regain compliance with the Minimum Bid Price Requirement. To regain compliance with the Minimum Bid Price Requirement, the closing bid price of the common stock must be at least $1.00 per share for a minimum of 10 consecutive business days prior to the Compliance Date.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties.

Our actual results and timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition, and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report on Form 10-Q. In addition, even if our results of operations, financial condition, and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report on Form 10-Q, they may not be predictive of results or developments in future periods.

The following information and any forward-looking statements should be considered in light of factors discussed elsewhere in this Quarterly Report on Form 10-Q, including those risks identified under Part II, Item 1A. Risk Factors.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are a clinical-stage biotechnology company focused on the development and commercialization of innovative, anti-inflammatory therapies for the localized treatment of patients with chronic rhinosinusitis, or CRS. Our product candidates, LYR-210 and LYR-220, are bioabsorbable nasal implants designed to be administered in a simple in-office procedure and intended to deliver six months of continuous anti-inflammatory drug therapy to the sinonasal passages for the treatment of CRS with a single administration. The drug embedded within LYR-210 and LYR-220 is mometasone furoate, or MF, which is the active ingredient in various U.S. Food and Drug Administration, or FDA, approved drugs and has a well-established efficacy and safety profile. CRS is an inflammatory disease of the paranasal sinuses which leads to debilitating symptoms and significant morbidities and affects approximately 14 million people in the United States.

LYR-210

LYR-210 is designed to treat CRS patients who have failed previous medical management. LYR-210 has a smaller dimension and is intended for patients with narrow anatomy, primarily patients who have not undergone ethmoid sinus surgery. In May 2024, we announced topline results from the Company's Phase 3 ENLIGHTEN 1 trial evaluating LYR-210 for the treatment of CRS. ENLIGHTEN 1 did not meet its primary endpoint of demonstrating statistically significant improvement compared to sham control in the composite score of the three cardinal symptoms (3CS) of CRS (nasal obstruction, nasal discharge, facial pain/pressure) at 24 weeks.

At 24 weeks, the ENLIGHTEN 1 trial demonstrated the following results compared to baseline, which did not achieve statistical significance:

- In the primary efficacy analysis, treatment with LYR-210 resulted in a mean (standard deviation; SD) improvement in the 3CS score of 2.13 (2.17) points, compared to 2.06 (2.14) points in sham control.
- In the intent-to-treat (ITT) population, treatment with LYR-210 resulted in a mean (SD) improvement in the 3CS score of 2.35 (2.28) points, compared to 1.89 (2.07) points in sham control.
- In the ITT population, treatment with LYR-210 resulted in a mean (SD) improvement in the Sino-Nasal Outcome Test (SNOT-22) score of 20.2 (21.38) points, compared to 15.70 (18.55) points in sham control.
- Ethmoid sinus opacification (evaluated by computed tomography (CT) scans), did not achieve statistically significant improvement after treatment with LYR-210 compared to sham control.

LYR-210 was generally well tolerated, with no product-related serious adverse events. The most commonly reported adverse events in the study population were epistaxis, nasal odor, upper respiratory tract infection and sinusitis. The Company continues to analyze the data from the ENLIGHTEN 1 trial and intends to use this analysis to inform its approach on the completion of the ongoing 52-week extension phase of the ENLIGHTEN 1 trial with data expected in Q4 2024 and its approach to the ongoing ENLIGHTEN 2 trial, the second pivotal Phase 3 trial of LYR-210 in CRS, with enrollment expected to be complete in the second half of 2024 and topline results expected in the first half of 2025.

LYR-220

Our second pipeline product candidate, LYR-220, is designed for use in CRS patients who have failed previous medical management and who continue to require treatment to manage CRS symptoms despite having had ethmoid sinus surgery. LYR-220 employs a larger implant designed for patients whose nasal cavity is larger including those patients whose nasal cavity is larger after having undergone ethmoid sinus surgery. We conducted a Phase 2 clinical trial of LYR-220, called BEACON. The BEACON trial was a controlled parallel-group study to evaluate safety, tolerability, pharmacokinetics, and efficacy comparing two designs of the LYR-220 (7500µg MF) matrix to control, over a 24-week period, in approximately 70 symptomatic adult CRS subjects who have had a prior bilateral sinus surgery. In September 2023, we reported positive topline results from BEACON, demonstrating statistically significant and clinically relevant improvements in the 3 Cardinal Symptoms and SNOT-22 scores at 24 weeks. In connection with the cost-cutting efforts announced in May 2024, the Company halted development efforts for LYR-220.

Our Technology

Our innovative and proprietary drug delivery technology is designed to locally and continuously deliver small molecule drugs to the affected tissue over a sustained period of time from a single administration. The technology is comprised of three interrelated components:

- a bioabsorbable mesh scaffold, which is designed to maximize surface area for drug release while maintaining underlying tissue function;
- an engineered elastomeric matrix, a polymeric matrix composed of polymers having elastic characteristics, which has advanced physical properties resulting in implants with “shape memory” that dynamically adapt to nasal anatomy; and
- a versatile polymer-drug complex, which is designed to deliver six months of continuous local drug therapy with a single treatment.

Our operations to date have been limited to organizing and staffing our Company, business planning, raising capital, developing our technology, building our intellectual property portfolio and conducting research and development activities, including clinical manufacturing for our product candidates. We do not have any products approved for sale and have not generated any revenue from product sales.

On May 5, 2020, we completed our IPO in which we issued and sold 4,025,000 shares of our common stock (including shares issued upon the underwriters’ exercise in full of their option to purchase additional shares of our common stock) at a public offering price of $16.00 per share, par value $0.001, for aggregate gross proceeds of $64.4 million. We received approximately $57.3 million in net proceeds after deducting underwriting discounts and commissions and offering expenses paid by us. The shares began trading on The Nasdaq Global Market on May 1, 2020. Upon completion of our IPO, all of our outstanding shares of convertible preferred stock converted into 8,335,248 shares of our common stock, par value $0.001.

From inception through June 30, 2024, we have raised an aggregate of $424.8 million to fund our operations, of which $162.1 million were gross proceeds from sales of our redeemable convertible preferred stock, $96.3 million were net proceeds from our April 2022 financing, $46.5 million were net proceeds from our May 2023 Financing, $57.3 million were net proceeds from our initial public offering, $23.9 million were net proceeds related to our Controlled Equity Offering Agreement (the “Original Sales Agreement”) dated September 1, 2023, $16.8 million were gross proceeds from government contracts, $17.0 million were gross proceeds from the LianBio License Agreement, and $3.8 million were gross proceeds from the exercise of common stock warrants. Further, we currently have an effective shelf registration statement on Form S-3 (No. 333-278163) filed with the SEC on March 22, 2024 (“Form S-3”), under which it may offer from time to time in one or more offerings any combination of common and preferred stock, debt securities, warrants and units of up to $300.0 million in the aggregate.

We have incurred recurring net operating losses every year since inception and expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year and could be substantial. Our net losses inception to date were $381.9 million at June 30, 2024. As of June 30, 2024, we had approximately $31.9 million of cash and cash equivalents and $35.6 million of short-term investments. These conditions raise

substantial doubt about our ability to continue as a going concern for one year from the date these condensed consolidated financial statements are issued.

In May 2024, we announced a reduction in force of approximately 75% of our workforce, impacting 87 employees, in addition to other cost-cutting measures in order to preserve capital, including the stoppage of manufacturing and commercialization efforts for LYR-210 and pausing development efforts for LYR-220. Nevertheless, we anticipate that we will continue to incur expenses as we continue the two ongoing ENLIGHTEN Phase 3 clinical trials of LYR-210.

We do not expect to generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for a product candidate. In the future, in the event we obtain financing and decide to restart our manufacturing activities, we may engage third party contract manufacturers to manufacture our products. We do not yet have a sales organization. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. Furthermore, we will continue to incur additional costs associated with operating as a public company. As a result, we will need substantial additional funding to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we expect to fund our operations through public or private equity or debt financings or other sources, including strategic collaborations and licensing arrangements. We may, however, be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our current product candidate or any additional product candidates, if developed.

Because of the numerous risks and uncertainties associated with therapeutics product development, we are unable to accurately predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

Based on our current operating plan, management has concluded that there is substantial doubt regarding our ability to continue as a going concern. As of June 30, 2024, we had cash and cash equivalents totaling $31.9 million and short-term investments totaling $35.6 million. Management believes that our existing cash, cash equivalents, and short-term investments will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2026. We have based these estimates on assumptions that may prove to be imprecise or incorrect, and we may use our available capital resources sooner than we currently expect. See “Liquidity and Capital Resources.” Because of the numerous risks and uncertainties associated with the development of our product candidates and any future product candidates and technology, and because the extent to which we may enter into collaborations with third parties for development of any of our product candidates is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research, development and manufacturing of our product candidates.

If we raise additional funds through additional collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Nasdaq Listing Notification

On July 19, 2024, we received a written notice (the “Notice”) from The Nasdaq Stock Market, LLC (“Nasdaq”) notifying us that for the last 30 consecutive business days, the bid price for our common stock, par value $0.001 per share, had closed below the $1.00 per share minimum bid price requirement for continued inclusion on The Nasdaq Global Market as set forth in Nasdaq Listing Rule 5450(a)(1) (“the Minimum Bid Price Requirement”). The Notice has no effect at this time on the listing of our common stock, which continues to trade on The Nasdaq Global Market under the symbol “LYRA.”

In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we have a period of 180 calendar days, or until January 15, 2025 (the “Compliance Date”) to regain compliance with the Minimum Bid Price Requirement. To regain compliance with the Minimum Bid Price Requirement, the closing bid price of the common stock must be at least $1.00 per share for a minimum of 10 consecutive business days prior to the Compliance Date.

In the event we do not regain compliance with the Minimum Bid Price Requirement by the Compliance Date, we may be eligible for a second 180 calendar day compliance period. To qualify, we must submit an application to transfer the listing of the

common stock to The Nasdaq Capital Market, which requires us to meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement. We would also need to pay an application fee to Nasdaq and to provide written notice of its intention to cure the deficiency during the additional compliance period. As part of its review process, Nasdaq will make a determination of whether it believes we will be able to cure this deficiency. If the Company does not qualify for or fails to regain compliance during the additional compliance period, then Nasdaq will notify us of its determination to delist our common stock, at which point we would have an opportunity to appeal the delisting determination to a Nasdaq hearings panel. There can be no assurance that, if we decide to appeal any delisting determination, such appeal would be successful.

We intend to actively monitor the closing bid price of our common stock and may, if appropriate, consider implementing available options to regain compliance with the Minimum Bid Price Requirement. There can be no assurance that we will be able to regain compliance with the Minimum Bid Price Requirement or maintain compliance with any other listing requirements. For more information, see “Risk Factors—Our common stock may be delisted from The Nasdaq Global Market if we cannot regain compliance with Nasdaq’s continued listing requirements, which could harm our business, the trading price of our common stock, our ability to raise additional capital and the liquidity of the market for our common stock” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Recent Developments

In connection with the ENLIGHTEN 1 trial failing to meet its primary endpoint, on May 16, 2024, the Board approved a reduction in the Company’s workforce impacting 87 employees, which occurred during May and June 2024. Moreover, we stopped manufacturing and commercialization efforts for LYR-210, as well as development efforts for LYR-220 in an effort to reduce operating expenses.

We are currently considering various operational and strategic options in light of the failure of the ENLIGHTEN 1 trial to meet its primary endpoint, including additional clinical trials, the sale of assets, or a strategic business combination. The Board has not decided on a specific plan other than to reduce operating expenses in order to manage its cash position. Furthermore, we are currently in the process of marketing all of our leased properties for sub-leasing arrangements, and, we may also seek to negotiate an early termination of our leases with our landlords.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the foreseeable future. As of June 30, 2024, we have recognized $4.3 million of collaboration revenue from our LianBio License Agreement.

If our development efforts for our product candidates are successful and result in regulatory approval and successful commercialization efforts, or additional collaboration agreements, we may generate revenue in the future from product sales, payments from additional collaboration or license agreements that we may enter into with third parties, or any combination thereof. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

We expect that any revenue over the next several years would be derived primarily from our collaboration agreement with LianBio. We cannot provide assurance as to the timing of future milestones or royalty payments from LianBio or that we will receive any of these payments at all, especially in view of LianBio’s wind down activities.

Collaboration Agreement

On September 26, 2022, we entered into an amended LianBio License Agreement with LianBio to develop and commercialize LYR-210 in Greater China (mainland China, Hong Kong, Taiwan, and Macau), South Korea, Singapore and Thailand. Under the terms of the LianBio License Agreement, we received an upfront payment of $12.0 million. In February 2022, the Company achieved a development milestone of $5.0 million for dosing the first patient in the U.S., and the related cash amount was achieved in April 2022. The Company is eligible to receive up to $135.0 million in future payments based upon the achievement of specified development, regulatory and commercialization milestones. Upon commercialization on a region-by-region basis, we will be entitled to receive low double-digit royalties based on net sales of LYR-210 in the licensed territories. LianBio will be responsible for the clinical development and commercialization of LYR-210 in the licensed territories, and we will retain all rights to LYR-210 in all

other geographies. As part of the LianBio License Agreement, LianBio will also have the first right to obtain development and commercial rights in the licensed territories to our LYR-220 product candidate.

We assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, LianBio, is a customer. At the commencement of the arrangement, we identified the following material promises: (1) license to develop and commercialize LYR-210, (2) manufacturing activities related to the clinical supply of LYR-210, (3) a non-exclusive license to manufacture LYR-210 and obligation to transfer manufacturing technology in the case of a supply failure, and (4) the Company's performance of the development activities related to the global Phase 3 clinical trial. We determined that the license to develop and commercialize LYR-210, the manufacturing activities related to the clinical supply of LYR-210, and the non-exclusive license to manufacture LYR-210 and obligation to transfer manufacturing technology in the case of a supply failure represent a single performance obligation because of the specialized nature of the LYR-210 manufacturing process whereby the license cannot be separated from the manufacturing activities related to the supply of LYR-210 and the right to manufacture LYR-210 is only available if there is a supply failure. For the purposes of ASC 606, we determined there were two distinct performance obligations: (1) the license to develop and commercialize LYR-210, manufacturing activities related to the clinical supply of LYR-210, and the non-exclusive license to manufacture LYR-210 and obligation to transfer manufacturing technology in the case of a supply failure, and (2) the Company's performance of the development activities related to the global Phase 3 clinical trial.

Under the LianBio License Agreement, in order to evaluate the transaction price for purposes of ASC 606, we determined that the upfront payment of $12.0 million and the reimbursable cost of the clinical supply of LYR-210 constitute the entirety of the consideration to be included in the transaction price as of the outset of the arrangement, which was allocated to the two performance obligations. The potential milestone payments that we are eligible to receive were excluded from the transaction price, as all milestone amounts were fully constrained based on the probability of achievement.

Additionally, we determined that LianBio's right of first refusal to obtain development and commercial rights in the licensed territories to LYR-220 is an option as any agreement would be negotiated at arm's length and as a result does not provide a material right to LianBio and as such, is not considered a performance obligation.

We will recognize the revenue associated with the license to develop and commercialize LYR-210, manufacturing activities related to the clinical supply of LYR-210, and the non-exclusive license to manufacture LYR-210 and obligation to transfer manufacturing technology in the case of a supply failure combined performance obligation as the clinical supply of LYR-210 is delivered. We recognize revenue associated with the development activities related to the global Phase 3 clinical trial performance obligation as the development activities are performed using an input method, according to the costs incurred as to the development activities related to the global Phase 3 clinical trial and the costs expected to be incurred in the future to satisfy the performance obligation. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation. The amounts received that have not yet been recognized as revenue are deferred as a contract liability on our consolidated balance sheet and will be recognized as the clinical supply of LYR-210 is delivered and over the remaining time it takes to conduct the global Phase 3 clinical trial, respectively.

LianBio announced that in October 2023 its Board of Directors commenced a comprehensive strategic review of its business. The LianBio Board ultimately concluded that selling off assets and winding down operations was the best way to realize maximum shareholder value. LianBio reported that a substantial portion of the wind down activities, including fulfillment of transition service obligations under its existing agreements and gradual cessation of currently active clinical trials, will be completed by the end of 2024. LianBio announced in February 2024 that it was further reducing the size of its workforce to approximately 50 employees with plans to reduce that number further over the course of 2024. LianBio stated it will maintain a core group of employees necessary to implement an orderly wind down and support its efforts to maximize the value of its remaining business and assets including the collaboration with the Company. Due to these developments, the future of the Company's collaboration with LianBio is uncertain as LianBio continues its wind down, while seeking a third party to acquire LianBio's rights under the LianBio License Agreement.

Operating Expenses

Our operating expenses since inception have consisted solely of research and development costs and general and administrative costs.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including the development of and pursuit of regulatory approval of our most advanced product candidate, LYR-210, for the treatment of CRS, which include:

- employee-related expenses, including salaries, benefits, and stock-based compensation expense for personnel engaged in research and development functions;

- expenses incurred in connection with the preclinical and clinical development of our product candidates, including under agreements with CROs, investigative sites, and consultants;

- costs of manufacturing our product candidates for use in our clinical trials, including fees paid to CMOs as well as other manufacturers that provide components of our product candidates for use in our potential future clinical trials;

- consulting and professional fees related to research and development activities;

- costs related to compliance with clinical regulatory requirements; and

- facility costs and other allocated expenses, which include expenses for rent and maintenance of our facility, utilities, depreciation, and other supplies; and

- costs related to the termination of an agreement with a former contract manufacturer organization; and

We expense research and development costs as incurred. We recognize costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as clinical site activations, patient enrollment, or information provided to us by our vendors and our clinical investigative sites. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and may be reflected in our consolidated financial statements as prepaid or accrued research and development expenses.

Our research and development expenses consist primarily of costs such as employee compensation, consulting fees, fees paid to CMOs and CRO expenses in connection with our preclinical and clinical development activities. We typically use our employee and infrastructure resources across our development programs and we do not allocate personnel costs and other internal costs to specific product candidates or development programs with the exception of the costs to manufacture our product candidates.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will decrease for the foreseeable future as we implemented a layoff of 75% of our workforce in May 2024 and ceased most manufacturing and CMC-related activities. Research and development expenses will be primarily focused on continuing the two ongoing ENLIGHTEN Phase 3 clinical trials of LYR-210.

The successful development of LYR-210, and other potential future product candidates is highly uncertain. Accordingly, at this time, we cannot reasonably estimate or know the nature, timing, and costs of the efforts that will be necessary to complete the development of these product candidates. We are also unable to predict when, if ever, we will generate revenue and material net cash inflows from the commercialization and sale of any of our product candidates for which we may obtain marketing approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs, and timing of preclinical studies, clinical trials, and development of our product candidates will depend on a variety of factors, including:

- successful completion of clinical trials with safety, tolerability, and efficacy profiles for LYR-210, and any potential future product candidates that are satisfactory to the FDA or any comparable foreign regulatory authority;

- approval of an IND for any potential future product candidate to commence planned or future clinical trials in the United States or foreign countries;

•significant and changing government regulation and regulatory guidance;

•timing and receipt of marketing approvals from applicable regulatory authorities;

•making arrangements with CMOs for third-party clinical and commercial manufacturing to obtain sufficient supply of our product candidates;

•obtaining and maintaining patent and other intellectual property protection and regulatory exclusivity for our product candidates;

•commercializing the product candidates, if and when approved, whether alone or in collaboration with others;

•competition with other therapies; and

•business interruptions resulting from COVID-19.

A change in the outcome of any of these variables with respect to the development, manufacture, or commercialization enabling activities of any of our product candidates would significantly change the costs, timing, and viability associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to patient enrollment or other reasons, we may be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, investor, public relations, accounting, auditing, tax services, and insurance costs.

We expect that our general and administrative expenses will remain stable in the future to support existing research and development activities. Additionally, we will continue to incur expenses associated with being a public company, including costs of accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, and investor and public relations costs.

Interest Income

Interest income consists of interest income earned on our cash and cash equivalents and short-term investments.

Income Tax Expense

Income tax consists of income tax related to the Company's Massachusetts Security Corporation. The Company has not recorded any benefits related to its operating losses due to uncertainty regarding future taxable income.

Critical Accounting Estimates

Our management’s discussion and analysis of financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, the disclosure of contingent assets and liabilities in our consolidated financial statements during the reporting periods and estimates used to assess our ability to continue as a going concern. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. 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 value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting estimates from those described in Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Estimates” in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on March 22, 2024.

Recently Issued and Adopted Accounting Pronouncements

We have reviewed all recently issued standards and have determined that, other than as disclosed in Note 2 in our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, such standards will not have a material impact on our consolidated financial statements or do not otherwise apply to our operations.

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	Dollar Change
Collaboration revenue	$ 598	$ 458	$ 140
Operating expenses:			
Research and development	13,264	10,799	2,465
General and administrative	5,139	4,570	569
Impairment of property and equipment	1,883	1,592	291
Impairment of right-of-use assets	22,836	—	22,836
Restructuring and other related charges	6,450	—	6,450
Total operating expenses	49,572	16,961	32,611
Loss from operations	(48,974)	(16,503)	(32,471)
Other income:			
Interest income	855	897	(42)
Total other income	855	897	(42)
Loss before income tax expense	(48,119)	(15,606)	(32,513)
Income tax expense	(12)	(12)	—
Net loss	$ (48,131)	$ (15,618)	$ (32,513)

Collaboration Revenue

Collaboration revenue for the three months ended June 30, 2024 and 2023 was a result of revenue recognized under the LianBio License Agreement, which we entered into on May 31, 2021. This remained relatively consistent period over period.

Research and Development Expenses

Research and development expenses increased by $2.5 million from $10.8 million to $13.3 million for the three months ended June 30, 2024 and the three months ended June 30, 2023.

The increase in research and development expenses for the three months ended June 30, 2024 was primarily attributable to an increase of $1.7 million in allocated and support costs for shared activities within the organization driven by headcount allocation and rent increases which occurred prior to the reduction in force, an increase of $0.5 million in professional and consulting fees as we moved good manufacturing practices (“GMP”), manufacturing in house prior to the reduction in force and increased clinical and product manufacturing costs of $0.9 million as we continued to progress on our clinical trials and internal manufacturing efforts prior to the reduction in force. These costs were offset by $0.8 million in headcount related costs period over period due to the recent restructuring.

General and Administrative Expenses

General and administrative expenses increased by $0.5 million to $5.1 million for the three months ended June 30, 2024 from $4.6 million for the three months ended June 30, 2023.

The increase in general and administrative expenses for the three months ended June 30, 2024 was primarily driven by an increase of $0.4 million for consulting costs, as well as an increase of $0.2 million in costs shared between the General & Administrative and Research & Development functions including headcount and rent. These costs were partially offset by a decrease in the amount of $0.1 million for employee related costs due to the recent restructuring.

Interest Income

Interest income remained relatively consistent at $0.9 million for the three months ended June 30, 2024 and 2023. This interest income was primarily attributable to interest earned on the Company's short-term investments during both periods.

Income Tax Expense

During the three months ended June 30, 2024 and 2023 we recorded an income tax expense of $12,000 related to our Massachusetts Securities Corporation.

Impairment & Restructuring

The Company incurred impairment costs related to property and equipment of $1.9 million for the three months ended June 30, 2024 compared to $1.6 million for the same period in 2023.

The Company incurred impairment costs related to our right-of-use asset of $22.8 million for the three months ended June 30, 2024 compared to no such charges for the same period in 2023.

The Company incurred a restructuring charge in the amount of $6.5 million primarily related to severance and retention costs for the three months ended June 30, 2024 compared to no such charges for the same period in 2023.

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):

	Six Months Ended June 30, 2024	2023	Dollar Change
Collaboration revenue	$ 1,130	$ 868	$ 262
Operating expenses:			
Research and development	31,502	23,395	8,107
General and administrative	10,957	9,697	1,260
Impairment of property and equipment	1,883	1,592	291
Impairment of right-of-use assets	22,836	—	22,836
Restructuring and other related charges	6,450	—	6,450
Total operating expenses	73,628	34,684	38,944
Loss from operations	(72,498)	(33,816)	(38,682)
Other income:			
Interest income	1,941	1,969	(28)
Loss before income tax expense	(70,557)	(31,847)	(38,710)
Income tax expense	(26)	(26)	—
Net loss	$ (70,583)	$ (31,873)	$ (38,710)

Collaboration Revenue

Collaboration revenue for the six months ended June 30, 2024 and 2023 was a result of revenue recognized under the LianBio License Agreement, which we entered into on May 31, 2021. This remained relatively consistent period over period.

Research and Development Expenses

Research and development expenses increased by $8.1 million from $23.4 million to $31.5 million for the six months ended June 30, 2024 and the six months ended June 30, 2023.

The increase in research and development expenses for the six months ended June 30, 2024 was primarily attributable to an increase of $3.9 million in allocated and support costs for shared activities within the organization driven by headcount allocation and rent increases, which occurred prior to the reduction in force, an increase of $1.5 million in professional and consulting fees as we moved GMP manufacturing in house prior to the reduction in force, employee related fees of $1.3 million due to the increased research and development headcount prior to the reduction in force, increased clinical costs of $1.4 million as we continued to progress on our clinical trials, and enhanced our in-house product manufacturing.

General and Administrative Expenses

General and administrative expenses increased by $1.3 million to $11.0 million for the six months ended June 30, 2024 from $9.7 million for the six months ended June 30, 2023.

The increase in general and administrative expenses for the six months ended June 30, 2024 was primarily attributable to an $0.5 million increase in employee related costs prior to the reduction in force, a $0.5 million increase in costs for consulting and professional fees, as well as an increase of $0.4 million in costs shared between the General & Administrative and Research & Development functions including headcount and rent. These costs were partially offset by a decrease in other fees of $0.4 million due to prior year write-off of deferred financing costs.

Interest Income

Interest income remained consistent at approximately $1.9 million for the six months ended June 30, 2024 and 2023. This interest income was primarily attributable to interest earned on the Company's short-term investments during both periods.

Income Tax Expense

During the six months ended June 30, 2024 and 2023 we recorded an income tax expense of $26,000 related to our Massachusetts Securities Corporation.

Impairment & Restructuring

The Company incurred impairment costs related to property and equipment of $1.9 million for the six months ended June 30, 2024 compared to $1.6 million for the same period in 2023.

The Company incurred impairment costs related to our right-of-use asset of $22.8 million for the six months ended June 30, 2024 compared to no such charges for the same period in 2023.

The Company incurred a restructuring charge in the amount of $6.5 million primarily related to severance and retention costs for the six months ended June 30, 2024 compared to no such charges for the same period in 2023.

Liquidity and Capital Resources

Sources of Liquidity

From inception through June 30, 2024, we have raised an aggregate of $424.8 million to fund our operations, of which $162.1 million were gross proceeds from sales of our redeemable convertible preferred stock, $96.3 million were net proceeds from our April 2022 financing, $46.5 million were net proceeds from our May 2023 Financing, $57.3 million were net proceeds from our initial public offering, $23.9 million were net proceeds related to our Original Sales Agreement dated September 1, 2023, $16.8 million were gross proceeds from government contracts, $17.0 million were gross proceeds from the LianBio License Agreement, and $3.8 million were gross proceeds from the exercise of common stock warrants. As of June 30, 2024, we have not sold any securities under the Form S-3. On March 22, 2024, we entered into an Amended and Restated Controlled Equity Offering Agreement with Cantor pursuant to which the Company may offer and sell, from time to time through Cantor, shares of the Company's common stock for aggregate gross proceeds of up to $75.0 million.

The following table provides information regarding our total cash and cash equivalents and short-term investments at June 30, 2024 and December 31, 2023 (in thousands):

	As of June 30, 2024	As of December 31, 2023
Cash and cash equivalents	$ 31,905	$ 22,353
Short term investments	35,593	80,400
Total	$ 67,498	$ 102,753

We maintain the majority of our cash and cash equivalents in accounts with major highly rated multi-national and local financial institutions, and our deposits at these institutions exceed insured limits. Market conditions can impact the viability of these institutions, and any inability to access or delay in accessing these funds could adversely affect our business and financial position.

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2024 and 2023 (in thousands):

	Six Months Ended June 30, 2024	2023
Net cash used in operating activities	$ (42,436)	$ (30,132)
Net cash provided by investing activities	44,033	4,754
Net cash provided by financing activities	8,555	47,189
Net increase in cash, cash equivalents and restricted cash	$ 10,152	$ 21,811

Net Cash Used in Operating Activities

The cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital.

Net cash used in operating activities was $42.4 million for the six months ended June 30, 2024, primarily resulting from our net loss of $70.6 million, partially offset by non-cash adjustments of $26.8 million and cash provided by changes in our operating assets and liabilities of $1.2 million. Our net loss was primarily attributed to research and development activities, our general and administrative expenses as well as restructuring charges and impairments taken on our long-lived assets. Our net non-cash charges during the six months ended June 30, 2024 primarily consisted of a $22.8 million impairment loss on our right-of-use assets, $3.3 million of share-based compensation expense, $0.3 million of depreciation expense and $1.9 million of impairment of long-lived assets, which were partially offset by $1.5 million of net amortization of discounts on short-term investments. Net cash provided by changes in our operating assets and liabilities during the six months ended June 30, 2024 consisted primarily of a decrease of $1.2 million in prepaid expenses and other assets and a $3.1 million increase in restructuring liability, partially offset by a $0.7 million decrease in accounts payable and accrued expenses, a $1.2 million decrease in net operating lease assets and a decrease in deferred revenue of $1.2 million.

Net cash used in operating activities was $30.1 million for the six months ended June 30, 2023, primarily resulting from our net loss of $31.9 million and cash used by changes in our operating assets and liabilities of $1.7 million, partially offset by non-cash adjustments of $3.5 million. Our net loss was primarily attributed to research and development activities and our general and administrative expenses. Net cash used by changes in our operating assets and liabilities during the six months ended June 30, 2023 consisted primarily of a decrease of $1.4 million in prepaid expenses and other assets and a $0.9 million decrease in deferred revenue, partially offset by a $0.3 million increase in accounts payable and accrued expenses and a $0.3 million decrease in net operating lease assets. Our net non-cash charges during the six months ended June 30, 2023 primarily consisted of $3.0 million of share-based compensation expense, $0.3 million of depreciation expense and $1.6 million of impairment of long-lived assets, which were partially offset by $1.4 million of net amortization of premiums on short-term investments.

Net Cash Provided By Investing Activities

Net cash provided by investing activities was $44.0 million for the six months ended June 30, 2024 compared to $4.7 million of cash used for investing activities for the six months ended June 30, 2023. The increase in cash provided by investing activities of $39.4 million was primarily due to the net proceeds from the maturities of short-term investments.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $8.6 million for the six months ended June 30, 2024 compared to $47.2 million for the six months ended June 30, 2023 due to less cash raised from equity financings in 2024.

Funding Requirements

We expect to continue to incur expenses in connection with our ongoing activities, primarily the two ongoing ENLIGHTEN Phase 3 trials evaluating LYR-210. To the extent we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. Furthermore, we will continue 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 attractive terms, we would be forced to delay, reduce, or eliminate our research and development programs or future commercialization efforts.

Although management has concluded that there is substantial doubt regarding our ability to continue as a going concern, this conclusion is based on our analysis under applicable accounting standards. Based on our current business plan, we anticipate that our cash, cash equivalents and short-term investment balance is sufficient to fund our operating expenses and capital expenditures into the first quarter of 2026. However, we have based this estimate on assumptions that may prove to be wrong. If, for any reason, our expenses differ materially from our assumptions or we utilize our cash more quickly than anticipated, or if we are unable to obtain funding on a timely basis we may be required to revise our business plan and strategy, which may result in us further curtailing, delaying or discontinuing one or more of our research or development programs. As a result, our business, financial condition, and results of operations could be materially adversely affected.

Management's plans to obtain resources for the Company include obtaining capital from the sale of its equity securities, entering into strategic partnership arrangements and short-term borrowings from banks, stockholders or other related parties, if needed. However, management cannot provide any assurance that the Company will be successful in accomplishing any of its plans.

Our future capital requirements will depend on many factors, including:

•the costs of conducting current and future clinical trial of LYR-210;

•the costs of manufacturing and testing additional material for one or more pivotal Phase 3 clinical trials of LYR-210 as well as potential future clinical studies we might conduct;

•the costs of scaling up our supply chain capacity to meet commercial demand;

•the scope, progress, results, and costs of discovery, pre-clinical development, laboratory testing, and clinical trials for other potential product candidates we may develop, if any;

•the costs, timing, and outcome of regulatory review of our product candidates;

•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 might have at such time;

•the costs and timing of future commercialization activities, including cost of goods, product sales, marketing, manufacturing, and distribution, for any of our product candidates for which we receive marketing approval;

•the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;

•the costs of preparing, filing, and prosecuting patent applications, obtaining, maintaining, and enforcing our intellectual property rights, and defending intellectual property-related claims;

•the costs of operating as a public company; and

•the cost of potential business interruptions resulting from COVID-19.

Identifying potential product candidates and conducting pre-clinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Further, the global economy, including credit and financial markets, has periodically experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest and inflation rates, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. All of these factors could impact our liquidity and future funding requirements, including but not limited to our ability to raise additional capital when needed on acceptable terms, if at all. The duration of any economic slowdown is uncertain and the impact on our business is difficult to predict. See “Risk Factors— Unstable global political or economic conditions may have serious adverse consequences on our business, financial condition and share price.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and licensing arrangements. We do not 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 interests may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect your rights as a common stockholder. We may have access to additional funds to be earned in connection with our LianBio License Agreement, if development activities are successful under that agreement. However, the future of this collaboration is uncertain in view of LianBio’s major restructuring, as discussed herein. Any debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends, that could adversely impact our ability to conduct our business.

If we raise funds through additional collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates, or to grant licenses on terms that may not be favorable to us. 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.

Emerging Growth Company Status

The JOBS Act permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to use this extended transition period under the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, or December 31, 2025, (b) in which we have total annual gross revenues of $1.235 billion or more, or (c) in which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our outstanding common stock held by non-affiliates exceeds $700 million as of last business day of our most recently completed second fiscal quarter, and (2) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 4. Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2024.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(f) or 15d-15(f) of the Exchange Act during the three months 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 litigation relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations or financial condition.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information contained in this Quarterly Report on Form 10-Q before making an investment in our common stock. Our business, financial condition, results of operations, or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common stock could decline and you could lose all or part of your investment. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below.

Risks Related to Our Exploration of Strategic Options

Any potential financial or strategic option we pursue in an effort to maximize shareholder value may not result in the identification of a suitable transaction, or if one is identified and pursued, may not be completed on attractive terms, or at all.

In May 2024, in connection with the Company's announcement that we failed to meet the primary endpoint of our ENLIGHTEN 1 Phase 3 clinical trial, we announced our interest in potential strategic alternatives. We have not yet engaged a financial adviser to assist us in this effort. Such alternatives may include a merger, sale, divestiture of assets, licensing, or other strategic transaction.

The process of continuing to evaluate these strategic options may be costly, time-consuming and complex and we may incur significant costs related to this continued evaluation, such as legal, accounting and advisory fees and expenses and other related charges. Moreover, any potential financial or strategic option we pursue may not result in the identification of a suitable transaction, or if one is identified and pursued, may not be completed on attractive terms, or at all. There can be no assurance of completion of any particular course of action or a defined timeline for completion, and we can provide no assurance that any strategic alternative we pursue will have a positive impact on our results of operations or financial condition.

We are attempting to sublease or assign our three leaseholds, which represent significant operating costs, and there can be no assurance that we will accomplish this effort on favorable terms, or at all, which could adversely affect our business, results of operations and financial condition.

The Company has three leaseholds including two in Waltham, Massachusetts and one in Watertown, Massachusetts. These leaseholds represent significant operating costs for the Company. The Company has retained a broker to sublease or assign all three of the leaseholds in connection with the Company's capital preservation efforts. There can be no assurance that the Company will find third parties to enter into a sublease or assignment of these leaseholds at terms that are favorable to the Company, on a timetable that is advantageous to the Company, or at all.

The operating lease, as amended, for office and laboratory space in Watertown expires in April 2027 and comprises approximately 27,311 square feet. The lease provides for base rent of $2.0 million per year. The Company maintains a letter of credit of approximately $300,000 securing its obligations under the Watertown operating lease.

The Company has two leases for space at 880 Winter Street in Waltham. The first lease comprises approximately 29,000 square feet of office and lab space, and the lease provides for base rent of $2.2 million per year, which will increase 3% per year over the noncancellable term ending on June 30, 2033. In connection with the lease, a security deposit was delivered to the landlord in the form of an irrevocable standby letter of credit collateralized by $1.1 million of deposits with the financial institution.

In December 2023, the Company executed a sublease agreement for additional laboratory and office space located at 880 Winter Street in Waltham. The subleased premises comprise approximately 24,000 square feet, and the sublease provides for base rent of $1.8 million per year, which will increase 3% per year over the noncancellable term ending on November 30, 2032. The Company provided the landlord with a security deposit in the form of a letter of credit in the amount of approximately $600,000.

Under all three leases, the Company is responsible for its share of real estate taxes, maintenance, and other operating expenses applicable to the respective leased premises. An inability to successfully sublease or assign all three of the leaseholds will negatively impact our capital preservation efforts and could materially and adversely affect our business, financial condition and the results of operations.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since inception and expect to incur significant additional losses for the foreseeable future. We may never achieve or maintain profitability.

We have incurred significant operating losses in each year since our inception, including operating losses of approximately $22.5 million and $16.3 million for the three months ended June 30, 2024 and 2023 respectively. In addition, we have not commercialized any products and have never generated any revenue from product sales. We have devoted almost all of our financial resources to research and development, including our pre-clinical development activities.

In May 2024, our Board approved a reduction in force by up to 87 employees, effective on or about May 21, 2024 with respect to approximately 80 employees and effective on or about June 20, 2024 with respect to approximately seven employees (the “May 2024 RIF”). The Board’s decision was based on the need to implement cost-reduction initiatives intended to reduce the Company’s ongoing operating expenses and maximize shareholder value. The Company currently estimates that it will incur charges of approximately $3.9 to $4.1 million in connection with this workforce reduction, primarily consisting of severance payments, employee benefits and related costs. The Company has incurred the majority of these charges in the second quarter of 2024.

We expect to continue to incur significant additional operating losses for the foreseeable future and we may not achieve or maintain profitability in the future. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as non-clinical or pre-clinical studies, as well as human tests, which are referred to as clinical trials. Furthermore, the costs of advancing product candidates into each succeeding clinical phase tend to increase substantially over time. The total costs to advance any of our product candidates to marketing approval in even a single jurisdiction would be substantial. Because of the numerous risks and uncertainties associated with CRS treatment product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of products or achieve or maintain profitability. Our expenses will also increase substantially if we:

- continue the two pivotal Phase 3 ENLIGHTEN clinical trials of our most advanced product candidate, LYR-210;
- seek regulatory and marketing approvals for LYR-210 if it successfully completes clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval in geographies in which we plan to commercialize our products ourselves;
- maintain, expand, and protect our intellectual property portfolio;
- utilize external vendors for support with respect to research, development, commercialization, regulatory, pharmacovigilance, and other functions;
- acquire or in-license other commercial products, product candidates, and technologies;
- make royalty, milestone, or other payments under any future in-license agreements;
- implement additional internal manufacturing capabilities, systems and infrastructure; and
- operate as a public company.

Furthermore, our ability to successfully develop, commercialize, and license our products and generate product revenue is subject to substantial additional risks and uncertainties. Each of our product candidates will require additional pre-clinical and/or clinical development, potential regulatory approval in multiple jurisdictions, the development of or securing of manufacturing supply, capacity, and expertise, the use of external vendors, the building of a manufacturing and commercial organization, substantial investment, and significant marketing efforts before we generate any revenue from product sales. As a result, we expect to continue to

incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

The amount of future losses and when, if ever, we will achieve profitability are uncertain. We have no products that have generated any commercial revenue, do not expect to generate revenues from the commercial sale of products in the foreseeable future, and might never generate revenues from the sale of products. Our ability to generate revenue and achieve profitability will depend on, among other things, successful completion of the clinical development of our product candidates; obtaining necessary regulatory approvals from the FDA and international regulatory agencies; establishing cost-effective manufacturing, generating sales, and achieving market acceptance of our products and marketing infrastructure to commercialize our product candidates for which we obtain approval; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected.

Our recurring losses from operations raise substantial doubt regarding our ability to continue as a going concern.

We currently operate with limited resources. We have incurred significant losses since our inception and have never generated revenue or profit, and it is possible we will never generate revenue or profit. Based on our current operating plans, and without additional funding there is substantial doubt about our ability to continue as a going concern. See Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this *Quarterly Report on Form 10-Q* for a discussion of our expected cash runway. This cash runway estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Until such time as the Company can generate significant revenue from product sales, if ever, it plans to finance its operations through a combination of equity or debt financings, collaboration agreements, strategic alliances and licensing arrangements, but there can be no assurances that such financing will continue to be available to us on satisfactory terms, or at all.

Securing additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize any of our product candidates. If we are unable to obtain funding, we would be forced to delay, reduce or eliminate our research and development programs, which would adversely affect our business prospects. In addition, if we are unable to raise capital, we will also need to implement cost reductions, and any failure to effectively do so will harm our business, results of operations and future prospects. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations. If we are unable to continue as a going concern, investors could lose all or part of their investment in our Company.

We will need significant additional funding in order to complete development of, manufacture, and obtain regulatory approval for our product candidates and commercialize our products, if approved. Moreover, the failure of our ENLIGHTEN 1 Phase 3 trial to meet its primary endpoint has made it more difficult for us to raise capital. If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts, and/or discontinue operations.

We will continue to need additional capital, which we may raise through equity offerings, debt financings, marketing, and distribution arrangements and other collaborations, strategic alliances, and licensing arrangements or other sources. The failure to meet the primary endpoint of our ENLIGHTEN 1 Phase 3 clinical trial has made it significantly more difficult for us to raise more capital. Additional sources of financing might not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we might be unable to complete planned clinical trials or obtain approval of any of our product candidates from the FDA, or any foreign regulatory authorities, and could be forced to discontinue product development or reduce our operations. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts.

We will require substantial funds to further develop, manufacture, obtain approval for, and commercialize our product candidates, including LYR-210, for which we initiated two pivotal Phase 3 clinical trials. We announced in May 2024 that we have suspended further development of LYR-220, which has completed a Phase 2 clinical trial. We would also require substantial additional funds to further develop, obtain approval for, and commercialize, LYR-220.

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

- the scope and results of our pre-clinical studies and clinical trials, including any unforeseen costs we may incur as a result of pre-clinical study or clinical trial delays due to COVID-19 or other causes;

•the scope and results of our pre-clinical studies and clinical trials, including any unforeseen costs we may incur as a result of pre-clinical study or clinical trial delays;

•the timing of, and the costs involved in, obtaining regulatory approvals for LYR-210;

•the costs and timing of changes in the regulatory environment and enforcement rules;

•the costs and timing in changes in pharmaceutical pricing and reimbursement infrastructure;

•the costs involved in preparing, filing, prosecuting, maintaining, and enforcing patent claims and other patent-related costs, including any litigation costs and the results of such litigation;

•the effect of competing technological and market developments;

•the extent to which we in-license or acquire other products and technologies; and

•the cost of establishing sales, marketing, manufacturing, and distribution capabilities for our product candidates in regions where we choose to commercialize our products.

Depending on our business performance, the economic climate, and market conditions, we may be unable to raise additional funds through any sources. Market volatility could also adversely impact our ability to access capital as and when needed.

We maintain our cash and cash equivalents in accounts with major U.S. and multi-national financial institutions, and U.S. treasury bills and our deposits at these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

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, debt financings, marketing, and distribution arrangements and other collaborations, strategic alliances, and licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our operations and our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, redeeming our stock, making certain investments, and engaging in certain merger, consolidation, or asset sale transactions, among other restrictions. If we raise additional funds through additional 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 or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings 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.

We have no approved products.

To date, we have no approved product on the market and have generated no product revenues. Unless we receive approval from the FDA or other regulatory authorities for our product candidates, we will not have product revenues. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from cash on hand and licensing fees and grants, if any.

LYR-210 is at a development stage and we have suspended further efforts on LYR-220.

We are a biotechnology company focused on the development and commercialization of novel integrated drug and drug delivery solutions for the localized treatment of patients with CRS. Our product candidates are in clinical development, and favorable results in early-stage clinical trials may not be predictive of success in later clinical trials and may not lead to commercially viable products for any of several reasons. For example, we failed to meet the primary endpoint in our ENLIGHTEN 1 Phase 3 trials for LYR-210 which has a material adverse effect on our development plans for LYR-210. We also announced in May 2024 we were suspending further development of LYR-220. LYR-210 will require significant additional development, clinical trials, regulatory authorizations, and additional investment by us before it can be commercialized.

Our business is highly dependent on the success of our most advanced product candidate, LYR-210, which requires on-going clinical testing before we can seek regulatory approval and potentially launch our product. If LYR-210 does not receive regulatory approval or is not successfully commercialized, or is significantly delayed in doing so, our business will be harmed.

A substantial portion of our business and future success depends on our ability to develop, obtain regulatory approval for, and successfully commercialize our most advanced product candidate, LYR-210. We currently have no products that are approved for commercial sale and have not completed the development of any product candidates, and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to LYR-210, which will each require continued clinical development and potential additional pre-clinical development, management of clinical and medical affairs and manufacturing activities, regulatory approval in multiple jurisdictions, the securing of manufacturing supply, the building of a manufacturing and commercial organization, substantial investment, and significant marketing efforts before we can generate any revenues from any commercial sales. We cannot be certain that LYR-210 will be successful in ongoing or future clinical trials, receive regulatory approval, or be successfully commercialized even if we receive regulatory approval. Even if we receive approval to market LYR-210 from the FDA or other regulatory bodies, we cannot be certain that our product candidates will be successfully commercialized, profitable, widely accepted in the marketplace, or more effective than other commercially available alternatives. Nor can we be certain that, if and when approved, the safety and efficacy profile of LYR-210 and will be consistent with the profiles observed in clinical trials.

We advanced LYR-210 through our Phase 2 randomized, controlled, patient blinded LANTERN clinical trial, evaluating the safety and efficacy in surgically-naïve CRS patients who have failed previous medical management. The trial was designed to enroll 99 evaluable patients with the potential to increase to up to 150 patients and was initiated in May 2019 at sites in Australia, Austria, Czech Republic, New Zealand, and Poland. In December 2019, the FDA authorized our investigational new drug application, and, prior to the COVID-19 pandemic, we planned to enroll patients in the United States. However, in light of developments relating to the COVID-19 pandemic, as described below, we discontinued enrollment at 67 patients in our Phase 2 LANTERN clinical trial and did not enroll any patients in the United States.

On December 7, 2020, we reported top-line results from our Phase 2 LANTERN clinical trial, including that LYR-210 failed to meet the primary endpoint of the trial. We believe this was primarily due to the discontinuation of enrollment related to the COVID-19 pandemic. As a result of the decrease in the number of patients enrolled from planned (99 evaluable) to actually enrolled (67) patients in our Phase 2 LANTERN clinical trial, a greater magnitude of change in composite score of the seven-day average of four cardinal symptoms from baseline at week 4 and/or a smaller standard deviation associated with the change from baseline at week 4 was required in order for the trial to achieve statistical significance for the primary endpoint. On May 6, 2024, we reported top-line results from our Phase 3 ENLIGHTEN 1 clinical trial, including that LYR-210 failed to meet its primary endpoint of demonstrating statistically significant improvement compared to sham control in the composite score of the three cardinal symptoms of CRS (nasal obstruction, nasal discharge, facial pain/pressure) at 24 weeks. The Phase 3 ENLIGHTEN 1 trial is ongoing and data from the 52-week extension phase are expected in the fourth quarter of 2024. ENLIGHTEN 2, the second pivotal Phase 3 trial of LYR-210 in CRS, is ongoing. There can be no assurance that we will achieve the primary endpoint or any other endpoints in the ENLIGHTEN 2 Phase 3 clinical trials for LYR-210.

If the required regulatory approvals for LYR-210 are not obtained or are significantly delayed, or any approved products are not commercially successful, our business, financial condition, and results of operations may be materially harmed. For example, the Company may need to revise its regulatory strategy for LYR-210 since the Company failed to meet the primary endpoint of the ENLIGHTEN 1 Phase 3 clinical trial.

LYR-210 is our most advanced product candidate, and if we experience further regulatory or developmental issues with respect to LYR-210, such as the failure to meet the primary endpoint of the ENLIGHTEN 1 Phase 3 clinical trial, our development plans and business could be significantly harmed. Further, our competitors may be developing products with similar mechanisms of action and may experience problems with their products that could identify problems that would potentially harm our business.

Managing our obligations under our license and other strategic agreements may divert management time and attention, causing delays or disruptions to our business.

We are party to the LianBio License Agreement, as amended. The LianBio License Agreement grants an exclusive license to develop and commercialize LYR-210 in Greater China (mainland China, Hong Kong, Macau, and Taiwan), Singapore, South Korea, and Thailand, or the Territory. Furthermore, under the LianBio License Agreement, LianBio has the first right to obtain a license to develop and commercialize LYR-220.

Under the LianBio License Agreement, as amended, both parties agreed to negotiate prior to December 31, 2022 a clinical supply agreement to support clinical trials to be conducted by LianBio in the territory, i.e., PRC, Hong Kong, Macau, Taiwan, Singapore, South Korea, and Thailand. Subsequently, there was a side letter executed on December 27, 2022 which extended the negotiations of a supply agreement. Payments made by LianBio to the Company that have not yet been recognized as revenue are deferred as a contract liability on the Company's consolidated balance sheet. The Company anticipated that the payments treated as a contract liability would be recognized as revenue as the clinical supply of LYR-210 was delivered and over the remaining time it takes to conduct the applicable trials. As of June 30, 2024, the parties still have not completed their negotiations of the clinical supply agreement. At this point, it is uncertain whether such an agreement will be completed. In view of the uncertainty around the completion of the clinical supply agreement, the Company may decide to recognize such payments as revenue on an accelerated schedule.

We also may in the future enter into license and strategic agreements, which, subject us to various obligations, including diligence obligations, reporting and notification obligations, payment obligations for achievement of certain milestone as well as other material obligations. We may need to devote substantial time and attention to ensuring that we successfully integrate these transactions into our existing operations and are compliant with our obligations under these agreements, which may divert management's time and attention away from our research and development programs or other day-to-day activities.

Our license and strategic agreements are also complex and certain provisions in those agreements may be susceptible to multiple interpretations. In the event of any disagreement about the interpretation of these provisions, our management may need to devote a disproportionate amount of its attention to resolving these disagreements. Such disruptions may cause delays in our research and development programs and other business objectives.

If LianBio is unable to find a third party to acquire its rights under the LianBio License Agreement, it may materially harm our business, financial condition, results of operations and prospects.

LianBio announced that in October 2023 its board of directors commenced a comprehensive strategic review of its business. The LianBio Board ultimately concluded that selling off assets and winding down operations was the best way to realize maximum shareholder value. LianBio reported that a substantial portion of the wind down activities, including fulfillment of transition service obligations under its existing agreements and gradual cessation of currently active clinical trials, will be completed by the end of 2024. LianBio announced in 2024 that it was further reducing the size of its workforce to approximately 50 employees with plans to reduce that number further over the course of 2024. LianBio stated it will maintain a core group of employees necessary to implement an orderly wind down and support its efforts to maximize the value of its remaining business and assets including the collaboration with the Company. Due to these developments, the future of the Company's collaboration with LianBio is uncertain as LianBio continues its wind down, while seeking a third party to acquire LianBio's rights under the LianBio License Agreement. If LianBio is unable to find a third party to acquire LianBio's rights under the LianBio License Agreement, it may materially harm our business, financial condition, results of operations and prospects.

Our operating activities may be restricted by certain covenants in our license and strategic agreements, which could limit our development and commercial opportunities.

In connection with our license and strategic agreements, we may agree to and be bound by negative covenants which may limit our development and commercial opportunities. For example, pursuant to the LianBio License Agreement, we made certain covenants to not commercialize a competing product anywhere in the Territory, nor collaborate with, enable, or otherwise authorize, license, or grant any right to any third party to commercialize a competing product anywhere in the Territory, subject to certain carve-outs. We also made certain covenants to grant an exclusive option to LianBio for the development and commercialization of LYR-220 in the Territory. These provisions may inhibit our development efforts, prevent us from forming strategic collaborations to develop and potentially commercialize any other product candidates and may materially harm our business, financial condition, results of operations and prospects.

Failure to obtain marketing approval in international jurisdictions would prevent our products from being marketed in such jurisdictions.

In order to market and sell our products in jurisdictions outside of the United States, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. Additionally, we may be dependent on third-party collaborators to develop and commercialize our product candidates in certain international jurisdictions, such as in the case of our exclusive license agreement with LianBio for the development and commercialization of LYR-210 in the Territory. In the agreement with LianBio, while we have agreed that we must use commercially reasonable efforts to complete a global Phase 3 clinical trial for LR-210 and seek regulatory approval in the United States, LianBio must also use commercially reasonable efforts to develop, seek regulatory approval for, and commercialize LYR-210 in the Territory. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval in other jurisdictions. We and our third-party collaborators may not be able to file for marketing approvals, and even if we do, we may not obtain necessary approvals to commercialize our medicines in any market.

We are party to a collaboration agreement, and may enter into other collaborations, that place the development and commercialization of our product candidates outside our control, require us to relinquish important rights or may otherwise be on terms unfavorable to us, and if our collaborations are not successful, our product candidates may not reach their full market potential.

Our drug development programs and the potential commercialization of our drug candidates will require substantial additional cash to fund expenses. For some of our drug candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies for the development and potential commercialization of those drug candidates in selected geographic territories or for selected patient populations. For example, we are party to the LianBio License Agreement to develop and commercialize LYR-210 in the Territory. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration or successfully maintain a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed or existing collaboration and the proposed or existing 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 drug candidate, the costs and complexities of manufacturing and delivering such drug candidate to patients, the potential of competing therapies, 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 drug candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our drug candidate. The terms of any existing or additional collaborations or other arrangements that we may establish may not be favorable to us.

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

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications 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.

Risks Related to Discovery, Development, Clinical Testing, Manufacturing, and Regulatory Approval

Clinical trials required for our lead product candidate and any future product candidates are expensive and time-consuming, their outcome is uncertain, and if our clinical trials do not meet safety or efficacy endpoints in these evaluations, or if we experience significant delays in these trials, our ability to commercialize our product candidates and our financial position will be impaired.

We initiated the pivotal Phase 3 clinical trials for our most advanced product candidate, LYR-210. We recently announced in May 2024 that we suspended further clinical development on our other product candidate, LYR-220, in view of our failure to meet our primary endpoint in the ENLIGHTEN 1 Phase 3 clinical trial for LYR-210 and the need to preserve capital. It is impossible to predict if LYR-210 will prove effective and safe in humans or if we will receive regulatory approval, and the risk of failure through the development process is high. Given the similarities in the design of the ENLIGHTEN 1 and ENLIGHTEN 2 Phase 3 clinical trials, the risk that we fail to meet the primary endpoint in the ENLIGHTEN 2 Phase 3 clinical trial has increased since we failed to meet our primary endpoint in the ENLIGHTEN 1 Phase 3 clinical trial. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we may need to complete pre-clinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans.

Clinical development is a long, expensive, and uncertain process that is subject to significant delays. Due to known or unknown circumstances beyond our control, it may take us several years to complete our testing, and failure can occur at any stage of testing. The outcome of pre-clinical testing and early clinical trials may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. We cannot assure you that any clinical trial that we are conducting, or may conduct in the future, will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analysis, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

Delays associated with products for which we are directly conducting pre-clinical studies or clinical trials may cause us to incur additional operating expenses. The commencement and rate of completion of pre-clinical studies or clinical trials may be delayed by, or terminated because of, many factors, including:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our pre-clinical studies or clinical trials;
- failure to obtain regulatory approval to commence a trial;
- failure to reach, or delays in reaching, an agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- slower than expected rates of recruitment of patients or failure to recruit a sufficient number of patients;
- modification of pre-clinical studies or clinical trial protocols;
- changes in regulatory requirements for pre-clinical studies or clinical trials;
- the impact of unusual placebo effects;
- the lack of effectiveness during pre-clinical studies or clinical trials;
- the emergence of unforeseen safety issues or undesirable side effects;
- failure to obtain institutional review board, or the IRB, approval at each site;
- delays, suspension, or termination of clinical trials by the IRB responsible for overseeing the trial at a particular trial site;
- failure of patients in completing a trial or returning for post-treatment follow-up;

•clinical sites deviating from trial protocol, dropping out of a trial, or failing to comply with regulatory requirements;

•failure to address patient safety concerns that arise during the course of a trial;

•failure to manufacture sufficient quantities of product candidate for use in clinical trials;

•government, IRB, or other regulatory delays or “clinical holds” requiring suspension or termination of the trials; and

•business interruptions resulting from pandemics.

•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 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 abandon 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 or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- ▪we may be unable to enroll a sufficient number of patients in our clinical trials to ensure adequate statistical power to detect any statistically significant treatment effects;
- ▪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;
- ▪regulators, IRBs, or independent ethics committees, or IECs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or may require that we or our investigators 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;
- ▪we may experience delays in reaching or fail to reach agreement on acceptable pre-clinical study or clinical trial contracts or pre-clinical study or clinical trial protocols with prospective trial sites;
- ▪the cost of pre-clinical studies or 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 pre-clinical studies or clinical trials of our product candidates, or commercialize our products, may be insufficient or inadequate;
- ▪regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- ▪recruitment for our clinical trials may be adversely affected by recruiting for competing trials or the approval of products competitive with our product candidates; and
- ▪any current or future collaborators that conduct pre-clinical studies or clinical trials may face any of the above issues, and may conduct pre-clinical studies or clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to extend the duration of current pre-clinical studies or clinical trials or to conduct additional pre-clinical studies or clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete pre-clinical studies or clinical trials of our product candidates or other testing, if the results of these trials, studies, or tests are not positive or are only modestly positive, if there are safety concerns, or if we determine that the observed safety or efficacy profile would not be competitive in the marketplace, 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 indications 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;

•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 materially modified, suspended, or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial, or by the FDA or other regulatory authorities. Such authorities may impose a material modification, 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 or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects for our product candidates, or other products or product candidates in the same drug class, 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. Furthermore, we may rely on CROs and clinical trial sites to ensure the proper and timely conduct of clinical trials and while we would have agreements governing their committed activities, we would have limited influence over their actual performance, as described in "—Risks Related to Our Dependence on Third Parties."

Our most advanced product candidate, LYR-210, is in clinical development and will require the completion of clinical testing before we are prepared to submit an NDA for regulatory approval. We cannot predict if or when we might complete the development of LYR-210 and submit an NDA or whether any such NDA will be approved by the FDA. We may also seek feedback from the FDA or other regulatory authorities on our clinical development programs, and the FDA 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. If the results of ongoing and future clinical trials for LYR-210 are positive, we plan to submit an NDA in the United States. However, no assurance can be given that we will be successful in the near term, obtain regulatory approval, or have any commercial sales of LYR-210.

Any clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities. Pre-clinical and clinical data can be interpreted in different ways by different reviewers and regulators, which could delay, limit, or prevent regulatory approval. Drug-related adverse events during a pre-clinical study or clinical trial could cause us to repeat a trial or study, perform an additional trial or study, expand the size and/or duration of a trial or study, terminate a trial or study, or even cancel a pre-clinical or clinical program. The failure of pre-clinical studies or clinical trials to demonstrate safety and effectiveness for the desired indications could harm the development of that product candidate and other product candidates. This failure could cause us to abandon a product candidate and could delay development of other product candidates. Any delay in, or termination of, our clinical trials would delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. A number of companies in the biotechnology and pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Even if our future and ongoing pre-clinical studies and clinical trials are completed as planned, we cannot be certain that their results will support the safety and effectiveness of LYR-210, and/or any future product candidate.

If we experience delays in the commencement or completion of, or have to extend or expand, our pre-clinical studies or clinical trials, or if we terminate a pre-clinical study or clinical trial prior to completion, the commercial prospects of LYR-210, or any future product candidate could be harmed, and our ability to generate revenues from LYR-210, or any future product candidate may be delayed. In addition, any delays in our pre-clinical studies or 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 pre-clinical studies or clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We are no longer engaged in manufacturing our product candidates.

We previously transitioned most of our clinical manufacturing from a contract manufacturing organization, or CMO, to an in-house manufacturing facility at our Watertown headquarters to produce LYR-210 and LYR-220. We have never completed a technical

transfer process to an in-house facility, built, owned or operated a commercial manufacturing facility, and there is no guarantee that we will be successful doing so. Since the May 2024 RIF, we are no longer engaged in the manufacture of our product candidates and we no longer intend to build out a commercial manufacturing capability. We believe we have sufficient supply of LYR-210 to complete our ENLIGHTEN 1 and ENLIGHTEN 2 Phase 3 clinical trial. We are also engaged in an effort to sublease or assign our three leaseholds which include manufacturing space. Throughout Item 1A, we refer to manufacturers, CMOs and suppliers interchangeably.

Parts of our manufacturing process are still outsourced and we expect them to remain outsourced. Our CMOs provide multiple different types of services to us. For example, some CMOs provide raw materials for our in-house manufacturing effort; some CMOs perform analytical testing for our starting materials, intermediates, drug product, and stability studies; and some CMOs provide services like sterilizing, packaging, and labeling. Currently, our manufacturing activities are suspended and that suspension applies to third party CMOs that provide materials and services related to our manufacturing.

If we restart our in-house manufacturing, it is common that various aspects of the development program, such as manufacturing methods and equipment, are altered along the way in an effort to optimize cost of goods, processes and results. Such changes carry the risk that these manufacturing efforts will not achieve these successfully or in a cost-efficient manner, or that we will be subject to additional requirements by the FDA or other regulatory bodies. Slight deviations resulting from technology transfer, 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. Problems with our in-house manufacturing process could restrict our ability to meet our clinical and regulatory timelines, and market demand for our products.

As a result of the May 2024 RIF, we no longer have a sufficient number of experienced scientific, quality and manufacturing personnel needed to operate our clinical and commercial manufacturing processes, which in the event we restart our manufacturing efforts, could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements.

Any problems in our manufacturing process or facilities, or that of our CMOs, licensees and suppliers, could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional capital or capabilities.

Our pre-clinical studies and clinical trials may fail to demonstrate adequately the safety and efficacy of any of our product candidates and the development of our product candidates may be delayed or unsuccessful, which could prevent or delay regulatory approval and commercialization.

Currently LYR-210 is our only product candidate still in clinical development. Notwithstanding the data obtained to date with respect to LYR-210 and LYR-220 in CRS, LYR-210 will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts before we can generate any revenue from our product sales. In addition, if we encounter safety or efficacy problems, developmental delays or regulatory issues, delays caused by COVID-19, or other problems, our developmental plans and business could be significantly harmed.

If the development of LYR-210, or any other future product candidate is unsuccessful, our ability to generate revenues will be significantly and adversely affected. Our development of current and future product candidates is subject to the risks of failure and delay inherent in the development of new products and product candidates, including:

- delays in product development, pre-clinical, or clinical testing or manufacturing;
- unplanned expenditures in product development, pre-clinical, or clinical testing or manufacturing;
- failure to receive regulatory approvals;
- failure to secure rights from third parties for new technology;
- failure to achieve market acceptance; and
- emergence of superior or equivalent products.

In addition, product candidates in later stages of clinical trials may fail to show the desired safety profiles and efficacy results despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or pre-clinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit, or prevent regulatory approval.

Additionally, we have not conducted, nor do we believe we are required to conduct, any head-to-head trials comparing LYR-210 to other approved or experimental treatments for CRS. Any such head-to-head trial, if conducted, may show that LYR-210 is not more effective than any of such other drugs. Material adverse differences in the relative efficacy of LYR-210 could significantly harm the adoption of LYR-210 and our business prospects.

Because of these risks, our research and development efforts may not result in any commercially viable products. If a significant portion of these development efforts are not successfully completed, required regulatory approvals are not obtained, or any approved products are not commercially successful, our business, financial condition, and results of operations may be materially harmed.

Success in pre-clinical or earlier clinical trials may not be indicative of results in future clinical trials.

Success in pre-clinical studies 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. Pre-clinical studies and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, study pharmacokinetics and pharmacodynamics, and understand the side effects of product candidates at various doses and schedules. Success in pre-clinical studies and early clinical trials does not ensure that later, large-scale efficacy trials will be successful nor does it predict final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in pre-clinical studies or having successfully advanced through initial clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced, or later. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in pre-clinical studies and earlier-stage clinical trials. Data obtained from pre-clinical 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.

If the FDA does not conclude that LYR-210 satisfies the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for LYR-210 under Section 505(b)(2) are not as we expect, the approval pathway for LYR-210 may take significantly longer, cost significantly more, and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We intend to seek FDA approval for LYR-210 through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from trials that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved drugs, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as we anticipate, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates, and complications and risks associated with the development of our product candidates, would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in competitive products reaching the market before our product candidates, which could impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization, or that a competitor would not obtain approval first along with subsequent market exclusivity from the FDA, thereby delaying potential approval of our product.

In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

We have conducted, are conducting, and, in the future, may conduct clinical trials for our product candidates in sites outside the United States, and the FDA may not accept data from trials conducted in foreign locations.

We have conducted and are conducting clinical trials for LYR-210 outside the United States, primarily in Europe, and we may in the future choose to conduct other clinical trials outside the United States for LYR-210, or any of our other future product candidates. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with GCP, including review and approval by an IEC and receipt of informed consent from subjects. In general, the patient population for any clinical trials conducted outside of the United States must be representative of the population for which we intend to seek approval for the product in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from our clinical trials of our product candidates, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of our product candidates.

In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the United States, such as:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct our clinical trials;
- foreign exchange fluctuations;
- manufacturing, customs, shipment, and storage requirements;
- cultural differences in medical practice and clinical research; and
- the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought.

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

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

LYR-210 will be regulated as a drug-device combination products, which may result in additional regulatory and other risks.

LYR-210 is a drug-device combination products. We may experience delays in obtaining regulatory approval of LYR-210 given the increased complexity of the review process when approval of a combination product is sought under a single marketing application. LYR-210 will be regulated as drug-device combination products, which require coordination within the FDA and similar foreign regulatory agencies for review of the product candidates' device and drug components. The determination whether a combination product requires a single marketing application or two separate marketing applications for each component is made by the FDA on a case-by-case basis. Although we believe a single marketing application for the approval of a combination product would be successful, there can be no assurance that the FDA will not determine that separate marketing applications are necessary. This determination could significantly increase the resources and time required to bring a particular combination product to market. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products such as ours, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process, as well as coordination between two different centers within FDA responsible for review of the different components of the combination product.

Failure to successfully develop or supply the device component, delays in or failure of the studies conducted by us, our collaborators, or third-party providers, or failure of our Company, our collaborators, or third-party providers to obtain or maintain regulatory approval or clearance of the device component of LYR-210, as appropriate, could result in increased development costs, delays in or failure to obtain regulatory approval, and associated delays in these product candidates reaching the market. Further, failure to successfully develop or supply the device, or to gain or maintain its approval, could adversely affect sales of LYR-210.

If we fail to obtain the necessary U.S. regulatory approvals to commercialize any product candidate, we will not be able to generate revenue in the U.S. market.

We cannot assure you that we will receive the approvals necessary to commercialize our product candidates, or any product candidate we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the United States and approvals from equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity, and novelty of the product candidate, and requires substantial resources for research, development, and testing. We cannot predict whether our research and clinical efforts will result in drugs that the FDA will determine are safe for humans and effective for their intended uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional pre-clinical and clinical testing, perform post-marketing studies, address manufacturing concerns, or otherwise limit or impose conditions on any approval we obtain. The approval process may also be delayed by changes in government regulation, the impact of COVID-19, future legislation or administrative action, or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

Even if we receive approval of an NDA or comparable foreign regulatory filing for our product candidates, the FDA or the applicable foreign regulatory body may approve our product candidates for a more limited indication than we originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs. We cannot be sure that we will ever obtain regulatory clearance for our product candidates. Failure to obtain FDA approval of our product candidates will severely undermine our business by leaving us without a commercially available product, and therefore without any source of revenues, until another product candidate can be developed or obtained and ultimately approved. There is no guarantee that we will ever be able to develop or acquire another product candidate or that we will be able to obtain FDA approval to commercialize such product candidate.

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

We intend, either on our own or through collaborations or partnerships, to market our products in international markets. In order to market any products in the European Union and many other foreign jurisdictions, 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 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 pre-clinical 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, and we do not have experience in obtaining regulatory approval 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.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, costly, time-consuming, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. We cannot predict when or if, and in which territories, we, or any of our potential future collaborators, will obtain marketing approval to commercialize a product candidate.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of regulatory authorities. In addition, approval policies, regulations, or 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 neither LYR-210, nor any future product candidates we may seek to develop in the future will ever obtain regulatory approval. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of an NDA from the FDA. It is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators 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 and effective for their intended uses in patients. Results from non-clinical studies and clinical trials can be interpreted in different ways. Even if we believe the non-clinical or clinical data for our product candidates are promising, 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 pre-clinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program. Depending on the extent of these or any other FDA-required studies, approval of any NDA or other application that we submit may be delayed by several years, or may require us to expend significantly more resources than we have available.

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

Moreover, 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 or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authorities 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 or comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

Separately, in response to the COVID-19 pandemic the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to future COVID-19 related concerns, including providing guidance regarding the conduct of clinical trials. If global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

If we encounter delays or difficulties enrolling patients in our clinical trials, our clinical development activities and receipt of regulatory approvals could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. For example, we were unable to enroll patients in our Phase 2 LANTERN clinical trial in the United States from whom we intended to collect certain additional pharmacokinetic data due to the COVID-19 pandemic, and, as a result, we initiated a separate characterization study in September 2020 as a follow-on to our Phase 2 LANTERN clinical trial in order to collect such data. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. 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 or similar regulatory authorities outside the United States. We cannot predict how successful we will be at enrolling subjects in future clinical trials. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- the perceived risks and benefits of the product candidate in the trial;
- the availability of alternative therapies;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- the impact of geopolitical events or other events such as the evolving COVID-19 pandemic.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site.

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays, or both, which could have a harmful effect on our ability to develop LYR-210 and/or any other future product candidates, or could render further development impossible.

Our product candidates may cause serious adverse events or undesirable side effects including injury and death or have other properties which may delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval. If any of our product candidates receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability, or that of any potential future collaborators, to market the drug could be compromised.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex, and expensive pre-clinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety and efficacy of the product candidate studied for the target indication. Serious adverse events, or SAEs, or undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our clinical trials or pre-clinical studies could reveal a high and unacceptable severity and prevalence of side effects, toxicities, or unexpected characteristics, including death. For example, in our Phase 1 clinical trial for our most advanced product candidate, LYR-210, there was one SAE in the active group (acute myocardial infarction), which was considered not related to LYR-210.

In addition, subjects treated with LYR-210 have experienced adverse events, including epistaxis, rhinitis, rhinorrhea, facial pain, nasopharyngitis, sinusitis, upper respiratory tract infection, procedural headache, nasal discomfort, and nasal odor, among others. In our Phase 2 LANTERN clinical trial, treatment-related adverse events were reported in 16 patients, and all treatment-related adverse events except one (increased viscosity of upper respiratory secretion) were mild or moderate in nature. In addition, there was one patient in the LYR-210 (2,500 µg) group who had a serious adverse event of acarodermatitis in our Phase 2 LANTERN clinical trial, which was deemed to be not related to treatment. In the 24-week treatment phase of the Phase 3 ENLIGHTEN 1 clinical trial, the most commonly reported adverse events in the study population were epistaxis, nasal odor, upper respiratory tract infection and sinusitis.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, the IRBs at the institutions in which our studies are conducted, could materially modify, suspend, or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease pre-clinical studies or clinical trials, require us to conduct additional animal or human studies regarding the safety and efficacy of our product candidates which we have not planned or anticipated, or deny approval of our product candidates for any or all targeted indications. 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. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We have historically trained and may in the future have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition, and prospects significantly.

If any of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by any such product, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or contraindication;
- regulatory authorities may require long-term patient registries for the product;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- the product could become less competitive;

•we could be sued and held liable for harm caused to patients; and

•our reputation 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 any regulatory agency in a timely manner or at all. 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.

Our employees and independent contractors, including principal investigators, CROs, consultants, vendors, and any third parties we may engage in connection with research, development, regulatory, manufacturing, quality assurance, and other pharmaceutical functions and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

Misconduct by our employees and independent contractors, including principal investigators, CROs, consultants, vendors, and any third parties we may engage in connection with research, development, regulatory, manufacturing, quality assurance, and other pharmaceutical functions and commercialization, could include intentional, reckless, or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA, the European Medicines Agency, or the EMA, and other similar regulatory authorities, including those laws that require the reporting of true, complete, and accurate information to such authorities; (ii) manufacturing standards; or (iii) data privacy, security, fraud and abuse, and other healthcare laws and regulations. Specifically, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, 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. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of pre-clinical studies or clinical trials, creation of fraudulent data in pre-clinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, 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 comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 and results of operations, including the imposition of significant civil, criminal, and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

Our business and operations would suffer in the event of system failures.

Our computer systems, as well as those of our CROs and other contractors, vendors, suppliers, and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters (including the impacts of climate change), international terrorism and conflicts, and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs and our business. For example, the loss of pre-clinical studies 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 LYR-210, or any other product candidate could be delayed.

In the ordinary course of our business, we directly or indirectly collect and store sensitive data, including intellectual property, confidential information, pre-clinical and clinical trial data, proprietary business information, personal data, and personally identifiable health information of our clinical trial subjects and employees, in our data centers and on our networks, or on those of third parties. The secure processing, maintenance, and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure has been and, from time to time, may be vulnerable to attacks by hackers or internal bad actors, or breached due to employee error, a technical vulnerability, malfeasance, or other disruptions. For example, companies have experienced an increase in phishing and social engineering attacks from third parties in connection with COVID-19. Although, to our knowledge, we have not experienced any material security breach, 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 (including class actions), liability under laws that protect the

privacy of personal information, or 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 business reputation and delay our clinical development of our product candidates.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

We will be subject to extensive and costly government regulation.

Product candidates employing our technology will be subject to extensive and rigorous domestic government regulation including regulation by the FDA, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the United States Department of Health and Human Services, the United States Department of Justice, state and local governments, and their respective equivalents outside of the United States. The FDA regulates the research, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, record-keeping, reporting, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import, and export of pharmaceutical products. If products employing our technologies are marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not they have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding United States regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing, and selling our products. The regulatory review and approval process, which includes pre-clinical testing and clinical trials of each product candidate, is lengthy, expensive, and uncertain. We or our collaborators must obtain and maintain regulatory authorization to conduct pre-clinical studies and clinical trials. We or our collaborators must obtain regulatory approval for each product we intend to market, and the manufacturing facilities used for the products must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish the product's safety and efficacy, potency, and purity, for each intended use. The development and approval process takes many years, requires substantial resources, and may never lead to the approval of a product.

Even if we are able to obtain regulatory approval for a particular product, the approval may limit the indicated medical uses for the product, may otherwise limit our ability to promote, sell, and distribute the product, may require that we conduct costly post-marketing surveillance, and/or may require that we conduct ongoing post-marketing studies. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, may require further regulatory review and approval. Once obtained, any approvals may be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue.

If we, our collaborators, consultants, contract manufacturers, CROs, or other vendors fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things, delays in the approval of applications or supplements to approved applications; refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications; warning letters; fines; import and/or export restrictions; product recalls or seizures; injunctions; total or partial suspension of production; civil penalties; withdrawals of previously approved marketing applications or licenses; recommendations by the FDA or other regulatory authorities against governmental contracts; and/or criminal prosecutions.

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and could adversely affect our business.

In the United States, the EU, 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 prevent or delay marketing approval of our products in development, restrict or regulate post-approval activities involving any product candidates for which we obtain marketing approval, impact pricing and reimbursement, and impact our ability to sell any such products profitably. 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. In addition, new regulations are frequently adopted and interpretations of existing healthcare statutes may change over time.

For instance, in August 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. The IRA includes several provisions that may impact our business to varying degrees, including provisions that establish a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on many drugs reimbursed under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, and require companies to pay rebates to Medicare for drug prices that increase faster than inflation. The IRA permits the Secretary of the Department of Health and Human Services ("HHS") to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs

are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated. In addition, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare and Medicaid Services ("CMS") Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;

- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and

- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the constitutionality of the ACA, although it is unclear when or how the Supreme Court will rule. It is also unclear how other efforts to challenge, repeal, or replace the ACA will impact the law and may impact our business or financial condition.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011 resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers, and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. 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. 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. While any proposed measures will require authorization through additional legislation to become effective, Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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.

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 EU, 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 EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU 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 EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

In addition, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA's 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 the U.S. 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.

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 EU, 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.

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, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, and advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA, the EMA, and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing 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 GCP requirements for any clinical trials that we conduct post-approval. In addition, the sponsor of an approved NDA is subject to periodic inspections and other FDA monitoring and reporting

obligations, including obligations to monitor and report adverse events and other information such as the failure of a product to meet the specifications in the NDA. NDA sponsors must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials. The FDA may require changes in the labeling of already approved drug products and require that sponsors conduct post-marketing studies. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality.

Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a REMS, which could include requirements for a medication guide, physician communication plans, or additional elements to ensure safe use, such as restricted distribution methods, patient registries, and other risk mitigation tools. If any of our product candidates receives marketing approval, the accompanying label may limit the approved use of our product, which could limit sales of the product.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of our approved products. In addition, advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we market our products outside of their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the FDA's restrictions relating to the promotion of prescription products may also lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

The distribution of product samples to physicians must comply with the requirements of the FDCA. NDA sponsors must obtain FDA approval for product, manufacturing, and labeling changes, depending on the nature of the change. Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines, injunctions, consent decrees of permanent injunction, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts.

In addition, later discovery of previously unknown adverse events or other problems with our products, or manufacturing processes, including adverse events of unanticipated severity or frequency, 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;
- requirements to conduct post-marketing studies or clinical trials;
- warning 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 civil or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues. If regulatory sanctions are applied or if regulatory approval is withheld or withdrawn, the value of our Company and our operating results will be adversely affected.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of LYR-210 and/or any other future product candidate. 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.

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, approved, or commercialized in a timely manner, or at all, 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 and accept the payment of user fees, and statutory, regulatory, and policy changes, and other events that may otherwise affect the government agency's ability to perform routine functions. 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, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities.

If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, any good, facility, item, or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal civil and criminal false claims laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease, or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

•the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;

•the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items, or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

•the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics, and medical devices;

•the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Such obligations include payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse midwives;

•federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

•analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws that require the registration of pharmaceutical sales representatives; and

•similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom are compensated in the form of stock options for consulting services provided, may not comply with current or future statutes, regulations, agency guidance, 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Our business, financial condition, and results of operations may suffer in the event of information technology system failures, cyberattacks, data security incidents or deficiencies in our cybersecurity.

We rely on our information technology systems and those of our third-party service providers for both internal and external operations that are critical to our business. We face numerous and evolving cybersecurity risks that threaten the confidentiality, integrity and availability of our information technology systems and data we and our third-party providers maintain, including personal information, clinical trial data, and confidential and proprietary intellectual property, financial information, trade secrets, and other business information. Our information technology systems and data, and those of our third-party service providers, contractors and consultants are vulnerable to attack, interruption and damage from computer viruses and malware (e.g. ransomware), bugs, misconfigurations, malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. Attacks upon information technology systems and data are increasing in their frequency, levels of persistence, sophistication and intensity - including attacks conducted using artificial intelligence - and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems and data change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security incidents that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

There can also be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with, or effective in protecting our information technology systems and data. While we do not believe that we have experienced any material system failure or incident, from time to time, we and our third party providers have been the target of cybersecurity attacks, and we expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and number. While we do not believe that any incidents have had a material impact on our operations or financial results to date, we cannot guarantee that material incidents will not occur in the future. If such an incident were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We could also incur liabilities and the further development of our product candidates could be delayed. Further, any adverse impact to the availability, integrity or confidentiality of our information technology systems or data could expose us to legal claims or proceedings (including class actions), enforcement actions and investigations by regulatory authorities, and potentially result in penalties, fines and significant legal liability. We could also experience negative reputational impacts that cause an erosion of trust, and/or significant incident response, system restoration or remediation and future compliance costs. Any or all of the foregoing could materially adversely affect our business, results of operations, and financial condition. Finally, cyber insurance we maintain may not be sufficient to cover the financial, legal, business or reputational losses that may result from an incident, and we cannot guarantee that applicable insurance will be available to us in the future on economically reasonable terms or at all.

We are subject to governmental regulation and other legal obligations, particularly related to privacy, data protection, and information security, and we are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business.

We, and third parties on our behalf, receive, store, handle, transmit, use and otherwise process business information and information related to individuals, including from and about trial patients as well as our employees, business contacts, and service providers. We and our partners are subject to diverse state, federal, and international laws and regulations relating to data privacy and security, including, in the United States, the California Consumer Privacy Act, or the CCPA, and, in the EU and the European Economic Area, or EEA, the General Data Protection Regulation, or the GDPR. New privacy rules are being enacted in the United States and globally, and existing ones are being updated and strengthened, creating an ever evolving patchwork of privacy laws. For example, the CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches. Complying with these numerous, complex, and often changing laws and regulations is expensive and difficult, and failure or perceived failure to comply with any privacy laws or data security laws or any security incident or breach involving the misappropriation, loss, or other unauthorized use or disclosure of personal information, whether by us or another third-party, could adversely affect our business, financial condition, and results of operations, including but not limited to: damage to our reputation, an erosion of trust, and negative media attention; investigation costs; material fines and penalties; compensatory, special, punitive, and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services, and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; and injunctive relief.

In Europe, the GDPR requires us, among other things, to make detailed disclosures to data subjects, to disclose the legal basis on which we can process personal data, to obtain valid consent for processing, to appoint data protection officers when sensitive

personal data, such as health data, is processed on a large scale, and provides robust rights for data subjects, introduces mandatory data breach notification, imposes additional obligations on us when contracting with service providers, and requires us to adopt appropriate privacy governance including policies, procedures, training, and data audit. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws, which could increase our costs and our ability to efficiently process personal data from the EEA. If we do not comply with our obligations under the GDPR, we could be exposed to fines of up to the greater of €20.0 million or up to 4% of our total global annual revenue in the event of a significant breach. In addition, we may be the subject of litigation and/or adverse publicity, which could adversely affect our business, results of operations, and financial condition. Additionally, following the United Kingdom's withdrawal from the EEA and the EU, companies have to comply with the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover.

We cannot assure you that our third-party service providers with access to our or our customers', suppliers', trial patients', and employees' personal information and other sensitive or confidential information will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations, and financial condition. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage, and transmission of such information.

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us.

Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act. We are not currently classified as a covered entity or business associate under HIPAA. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Our clinical trial programs outside the United States may implicate international data protection laws, including the GDPR and legislation of the EU and EEA member states implementing it.

Our activities outside the United States impose additional compliance requirements and generate additional risks of enforcement for noncompliance. Failure by our CROs and other third-party contractors to comply with the strict rules on the transfer of personal data outside of the European Union into the United States may result in the imposition of criminal and administrative sanctions on such collaborators, which could adversely affect our business. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws, and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use, and dissemination of individuals' health information. The GDPR provides that EU and EEA member states may establish their own laws and regulations limiting the processing of personal data, including genetic, biometric, or health data, which could limit our ability to use and share personal data or could cause our costs to increase. Moreover, patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If we, our CROs, or other contractors or consultants fail to comply with applicable federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing, and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security, or reputational damage.

We are subject to environmental, health, and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

Our operations, including our development, testing, and manufacturing activities, are subject to numerous environmental, health, and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release, and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds, and compounds that have a toxic effect on reproduction, laboratory procedures, and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Moreover, certain environmental laws may impose liability without regard to fault or legality of the action at the time of its occurrence. Environmental, health, and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, our development efforts may be interrupted or delayed.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally.

Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our product candidates or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our policies and other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our product candidates in social media could seriously damage our reputation, brand image, and goodwill, regardless of the truthfulness of such posts. Any of these events could have a material adverse effect on our business, prospects, operating results, and financial condition and could adversely affect the price of our common stock.

Risks Related to Commercialization

Developments by competitors may render our products or technologies obsolete or non-competitive or may reduce the size of our markets.

Our industry has been characterized by extensive research and development efforts, rapid developments in technologies, intense competition, and a strong emphasis on proprietary products. We face potential competition from many different sources, including pharmaceutical, biotechnology, and specialty pharmaceutical companies either marketing or developing therapeutics to treat CRS. Academic research institutions, governmental agencies, as well as public and private institutions are also potential sources of competitive products and technologies. Our competitors may have or may develop superior technologies or approaches, which may provide them with competitive advantages. Our potential products may not compete successfully. If these competitors access the marketplace before we do with better or less expensive therapeutics, our product candidates, if approved for commercialization, may not be profitable to sell or worthwhile to continue to develop. Technology in the pharmaceutical industry has undergone rapid and significant change, and we expect that it will continue to do so. Any compounds, products, or processes that we develop may become obsolete or uneconomical before we recover any expenses incurred in connection with their development. The success of our product candidates will depend upon factors such as product efficacy, safety, reliability, availability, timing, scope of regulatory approval, acceptance, and price, among other things. Other important factors to our success include speed in developing product candidates, completing clinical development and laboratory testing, obtaining regulatory approvals, and manufacturing and selling commercial quantities of potential products.

Our product candidates are intended to compete directly or indirectly with existing products and treatments. Even if approved and commercialized, our product candidates may fail to achieve market acceptance with hospitals, physicians, or patients. Hospitals, physicians, or patients may conclude that our potential products are less safe or effective or otherwise less attractive than these existing treatments. If our product candidates do not receive market acceptance for any reason, our revenue potential would be diminished, which would materially adversely affect our ability to become profitable. In addition, physicians may prefer to treat patients with CRS by performing ethmoid sinus surgeries which may reduce demand for our product candidates, once approved.

There are a number of companies developing or marketing therapies for the treatment and management of CRS that may compete with our current product candidates, including many major pharmaceutical and biotechnology companies. These companies include, among others: Sanofi, GlaxoSmithKline, Regeneron, Optinose, Medtronic, Genentech and Novartis.

Most of our competitors, including many of those listed above, have substantially greater capital resources, robust product candidate pipelines, established presence in the market, and expertise in research and development, manufacturing, pre-clinical and clinical testing, obtaining regulatory approvals and reimbursement, and marketing approved products than we do. As a result, our competitors may achieve product commercialization or patent protection earlier than we can. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified clinical, regulatory, scientific, sales, marketing, and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop or that would render any products that we may develop obsolete or noncompetitive.

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels, and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers, and other third-party payors are essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates, assuming FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for our products or procedures using our products by governmental authorities, private health insurers, and other organizations will have an effect on our ability to successfully commercialize our product candidates. Obtaining coverage and adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Separate reimbursement for the product itself or the treatment or procedure in which our product is used may not be available. A decision by a third-party payor not to cover or separately reimburse for our products or procedures using our products could reduce physician utilization of our products once approved. Assuming there is coverage for our product candidates or procedures using our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

Similarly, our product candidates are physician-administered treatments and as such, separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. To the extent separate coverage and reimbursement should become available for LYR-210, we anticipate that it will be sold to physicians on a “buy and bill” basis. Buy and bill products must be purchased by healthcare providers before they can be administered to patients. Healthcare providers subsequently must seek reimbursement for the product from the applicable third-party payor, such as Medicare or a health insurance company. Healthcare providers may be reluctant to administer our product candidates, if approved, because they would have to fund the purchase of the product and then seek reimbursement, which may be lower than their purchase price, or because they do not want the additional administrative burden required to obtain reimbursement for the product. We do not know if, or at what level, physicians may receive reimbursement for treating patients with CRS with our product candidates, or for performing the procedure to insert our product candidates, or if such reimbursement will be deemed adequate by such physicians.

Further, the status of reimbursement codes for any of our product candidates, if approved, could also affect reimbursement. J-Codes are reimbursement codes maintained by the Centers for Medicare and Medicaid Services, or CMS, that are a component of the Healthcare Common Procedure Coding System and are typically used to report injectable drugs that ordinarily cannot be self-administered. We currently do not have a specific J-Code for any of our product candidates. If our product candidates are approved, we may apply for one but cannot guarantee that a J-Code will be granted. To the extent separate coverage or reimbursement is available for any product candidate, if approved, and a specific J-Code is not available, physicians would need to use a non-specific miscellaneous J-Code to bill third-party payors for these physician-administered drugs. Because miscellaneous J-Codes may be used for a wide variety of products, health plans may have more difficulty determining the actual product used and billed for the patient. These claims must often be submitted with additional information and manually processed, which can delay claims processing times as well as increase the likelihood for claim denials and claim errors. We cannot be sure that coverage and reimbursement in the United States, the EU, or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs and biologics when an equivalent generic drug, biosimilar, or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly-approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in the EU and other jurisdictions have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially-reasonable revenue and profits.

Moreover, increasing efforts by governmental and 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. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

Our clinical studies were designed to demonstrate the safety and efficacy of LYR-210 based on FDA requirements and may not be seen as compelling to physicians or patients.

Our success depends on the medical community's acceptance of LYR-210, if approved, as a treatment for CRS patients. LYR-210 was previously studied in an open-label, Phase 1 clinical trial with 20 patients in New Zealand and Australia, which achieved its primary endpoint of safety at week 4. In the Phase 1 trial, we also observed that patients generally experienced significant and rapid, clinically meaningful and durable improvement in SNOT-22 scores. Significant reduction in SNOT-22 scores was observed at week 1, and this reduction persisted through week 25, which was the end of the trial. In our Phase 2 LANTERN clinical trial, we reported positive top-line results but failed to achieve the primary endpoint. Although not statistically significant at week 4 (the primary endpoint), at the 7,500 µg dose, LYR-210 achieved statistically significant improvement in 4CSS in favor of the treatment arm as measured by the change from baseline at weeks 16, 20, and 24. Furthermore, at the 7,500 µg dose, LYR-210 achieved statistically significant improvement in SNOT-22 score in favor of the treatment arm at weeks 8, 16, 20, and 24. Even if the results of these clinical trials suggest a favorable safety and efficacy profile, the study designs and results, and the designs and results of future clinical trials we conduct, may not be viewed as compelling to our physician customers or patients. If physicians do not find our data compelling, even if LYR-210 receives marketing approval they may choose not to use our products or limit their use. Our Phase 3

ENLIGHTEN 1 clinical trial failed to meet its primary endpoint of demonstrating statistically significant improvement compared to sham control in the composite score of the three cardinal symptoms of CRS (nasal obstruction, nasal discharge, facial pain/pressure) at 24 weeks. ENLIGHTEN 2, the second pivotal Phase 3 trial of LYR-210 in CRS, is ongoing. There can be no assurance that we will achieve the primary endpoint or any other endpoints in the ENLIGHTEN 2 Phase 3 clinical trials for LYR-210. We also cannot assure you that any data that may be collected will be compelling to the medical community because the data may not be clinically meaningful and may not demonstrate that LYR-210 is an attractive procedure when compared against data from alternative treatments.

Even if LYR-210 receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors, or others in the medical community necessary for commercial success.

If LYR-210 receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. If it does not achieve an adequate level of acceptance, or if we are unable to achieve an optimal cost of goods, we may not generate significant product revenues or become profitable. The degree of market acceptance of LYR-210, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our technology;
- the perception by members of the healthcare community, including physicians, or patients that the process of administering LYR-210 is not unduly cumbersome;
- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of third-party coverage and adequate reimbursement;
- product labeling or product implant requirements of the FDA, the EMA, or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product together with other medications.

If our product candidates are approved, but do not achieve an adequate cost of goods or level of acceptance by physicians, healthcare payors, and patients, we may not generate sufficient revenue from these products, and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. In addition, our ability to successfully commercialize our product candidates will depend on our ability to manufacture our products at commercial scale, differentiate our products from competing products, and defend the intellectual property of our products.

Because we expect sales of LYR-210, if approved, to generate substantially all of our product revenues for a substantial period, the failure of this product to find market acceptance would harm our business and could require us to seek additional financing.

If physicians or patients are not willing to change current practices and adopt our office-based administration procedure for LYR-210 may fail to gain market acceptance, and our business will be harmed.

While we believe ENT physicians will be able to administer LYR-210, if successfully developed and approved, in conjunction with an endoscopy procedure, thereby making the placement aligned with the existing care continuum for CRS patients and eliminating the need for ENT physicians to schedule separate surgical time, ENT physicians may not adopt our in-office procedure for a number of reasons, including:

- lack of significant experience with the placement procedure via a single-use applicator;
- lack of availability of adequate insurance coverage or reimbursement for the placement procedure;
- perceived inadequacy of evidence supporting clinical benefits or cost-effectiveness of the placement procedure and/or our products in general over existing alternatives;
- a perception that patients may be unable to tolerate the placement procedure in the physician office setting; and
- liability risks generally associated with the use of new products and procedures.

If ENT physicians do not adopt the placement procedure for any reason, including those listed above, our ability to grow our business would be impaired, even if LYR-210 receives marketing approval.

We believe recommendations and support of our products by notable ENT physicians could influence market acceptance and adoption. If we do not receive support from influential ENT physicians, our ability to achieve broad market acceptance for our products may be impaired.

In addition, if patient receptivity toward treatment in an ENT physician office setting becomes less favorable in the future, this shift could negatively impact market acceptance of our products. Any negative change due to patient receptivity could also be compounded by patients reporting to physicians or other patients through word-of-mouth or social media.

Additionally, while it is currently more cost-effective to the healthcare system for providers to perform the placement procedure in an ENT physician's office than endoscopic sinus surgery in an operating room, healthcare economics are subject to change. If the use of our products were to cease being more cost-effective than endoscopic sinus surgery due to changes in reimbursement economics, our products may fail to gain market acceptance, and our business may be adversely affected.

If we are unable to successfully establish manufacturing, sales, marketing, and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing LYR-210, if approved, and we may not be able to generate any revenue.

We do not have commercial infrastructure for the manufacturing, sales, marketing, or distribution of all of our products, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. The failure to meet our primary endpoint in the ENLIGHTEN 1 Phase 3 trial has also adversely affected the Company's commercialization plans for LYR-210.

Factors that may inhibit our efforts to commercialize our product candidates on our own include

- the failure to meet the primary endpoint of our ENLIGHTEN 1 Phase 3 trial and its effects on our ability to pursue a development strategy for LYR-210 and to raise capital to operate the business;
- the loss of skilled personnel as a result of the May 2024 RIF;
- our ability to manufacture sufficient quantities of our products;
- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;

•our inability to equip medical and sales personnel with effective materials, including medical and sales literature to help them educate physicians and other healthcare providers regarding applicable diseases and our future products;

•the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;

•our inability to develop or obtain sufficient operational functions to support our commercial activities;

•unforeseen costs and expenses associated with creating an independent sales and marketing organization; and

•our inability to set a suitable price or establish reasonable reimbursement rates for our product candidates.

We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of LYR-210, or any future product candidates in markets outside of the United States. 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 intend to selectively pursue collaborative arrangements regarding the sale and marketing of LYR-210, if approved, for certain markets outside of the United States; 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 LYR-210, we may be forced to delay the potential commercialization of LYR-210 or reduce the scope of our sales or marketing activities for LYR-210. If we elect to increase our expenditures to fund commercialization activities ourselves, 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 LYR-210 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 LYR-210 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.

The success of our business may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. We are evaluating the opportunities for the development and commercialization of our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approvals in other countries we may be required to comply with numerous and varying regulatory requirements of such countries regarding the safety and efficacy of our product candidates and governing, among other things, clinical trials and commercial sales, pricing, and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

•our customers' ability to obtain reimbursement for our product candidates in foreign markets;

•our inability to directly control commercial activities if we are relying on third parties;

•the burden of complying with complex and changing foreign regulatory, tax, accounting, and legal requirements; and

•reduced protection of intellectual property rights in some foreign countries, among others.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions, and changes in tariffs.

In some countries, particularly the countries in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

The sizes of the patient populations that our product candidates are intended to treat have not been established with precision. If the market opportunities for our product candidates are smaller than we estimate, or if any approval that we obtain is based on a narrower definition of the patient population than we anticipate, our revenue and ability to achieve profitability may be materially adversely affected.

The precise incidence and prevalence of the conditions we aim to address with our programs is unknown and cannot be precisely determined. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new information may change the estimated incidence or prevalence of these diseases, and the incidence or prevalence of these diseases is subject to change.

The total addressable market across all of our product candidates will ultimately depend upon, among other things, the indications and conditions of use for which the product candidates are approved and may be marketed, acceptance by the medical community, and patient access, drug pricing, and reimbursement. The sizes of the patient populations that our product candidates are intended to treat in the United States and other major markets and elsewhere may turn out to be smaller than expected, patients may not be otherwise amenable to treatment with our product candidates, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for our product candidates, we may never achieve profitability despite obtaining such significant market share.

If we cannot compete for market share against other drug companies, we may not achieve sufficient product revenues and our business will suffer.

If our product candidates receive FDA approval, they will compete with a number of existing and future drugs and therapies developed, manufactured, and marketed by other companies. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies, and other public and private research organizations. Many of these competitors may have compounds already approved or in development in the therapeutic categories that we are targeting with our current and future product candidates. In addition, many of these competitors, either alone or together with their collaborative partners, may operate larger research and development programs or have substantially greater financial resources than we do, as well as greater experience in developing product candidates; formulating and manufacturing products; and launching, marketing, and selling products, among others.

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

If LYR-210 is approved for commercialization, we may partner with third parties to market it in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international pharmaceutical operations, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced protection for intellectual property rights;
- foreign reimbursement, pricing, and insurance regimes;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, 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.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor, and other legal requirements imposed by both the European Union and many of the individual countries in Europe with which we will need to comply. Many U.S.-based biotechnology companies have found the process of marketing their own products in Europe to be very challenging.

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

The use of LYR-210, in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. For example, complications arising from the placement procedure for LYR-210, or from the degradation or dislodgment of the LYR-210 implant within the sinuses after placement, or from foreign growth occurring in the sinus after placement, could give rise to product liability claims against us. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies, or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs, which may not be covered by insurance. In addition, regardless of merit or eventual outcome, product liability claims may result in significant consequences including:

•impairment of our business reputation and significant negative media attention; and

•product recalls, withdrawals or labeling, marketing, or promotional restrictions, among others.

Risks Related to Our Dependence on Third Parties

We suspended the manufacture our clinical materials in-house. If we restart our manufacturing, we may rely on third parties for certain development and manufacturing-related services and we do not currently have long-term contracts with any of these parties. Our continued reliance on third parties increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We have previously relied on third parties for certain development and manufacturing-related services during clinical development of our product candidates, and may rely on third parties for certain manufacturing-related services if any of our product candidates receive marketing approval. Certain of these manufacturers are critical to our production and the loss of these manufacturers to one of our competitors or otherwise, or an inability to obtain quantities at an acceptable cost or quality, could delay, prevent, or impair our ability to timely conduct pre-clinical studies or clinical trials, and would materially and adversely affect our development and commercialization efforts.

The facilities used by certain third-parties involved in the production of our product candidates or components of our product candidates may require FDA clearance pursuant to inspections that may be conducted after we submit an NDA to the FDA. While we may be able to mitigate risks through our diligence and contracting processes, when we utilize third parties for manufacturing, we are dependent on them for compliance with cGMP requirements for manufacture of drug products and other laws and regulations. If these third-party manufacturers cannot successfully manufacture or supply material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. Some of our contract manufacturers may not have produced a commercially-approved product and therefore may not have obtained the requisite FDA approvals to do so. In addition, we are limited in our ability to ensure third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for, or market our product candidates, if approved.

The failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, we may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms.

Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers or suppliers entails additional risks, including:

- breach of the manufacturing agreement by the third party;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time-consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our product candidates. The extent to which geopolitical events such as the current conflict between Russia and Ukraine, or other events such as the evolving COVID-19 pandemic impact our ability to procure sufficient supplies for the development of our products and product candidates will depend on the severity and duration of the event, and the actions undertaken to contain its negative effects and may cause delays. If our current third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We rely on third parties to conduct our pre-clinical studies and clinical trials. Any failure by a third party to conduct the clinical trials according to GCPs and in a timely manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize our product candidates.

We are dependent on third parties to conduct our pre-clinical studies and clinical trials, including our planned and ongoing clinical trials for LYR-210. If we decide to conduct future clinical trials for LYR-210 or other product candidates, we expect to rely on third parties to conduct those future clinical trials and pre-clinical studies. Specifically, we have used and relied on, and intend to continue to use and rely on, medical institutions, clinical investigators, CROs, and consultants to conduct our clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators, and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. While we have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. 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 GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any such CROs, investigators, or other third parties will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols, or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed, or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned, and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any NDA we submit to the FDA. Any such delay or rejection could prevent us from commercializing our product candidates.

If any of our relationships with these third-parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding CROs, investigators, and other third parties involve additional 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. Our relationships with these third parties may also be adversely affected by geopolitical events such as the current conflict between Russia and Ukraine, or other events such as the evolving COVID-19 pandemic. For instance, COVID-19 and government measures taken in response have had a significant impact on our CROs, and we expect that they will face further disruption which may affect our ability to initiate and complete our pre-clinical studies and clinical trials. Though we carefully manage our relationships with our CROs, investigators, and other third parties, 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.

We may collaborate with third parties for the development and commercialization of LYR-210, and any of our future product candidates. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize LYR-210, or our future product candidates successfully, if at all.

We may seek additional collaborative relationships for the development and commercialization of LYR-210, or any future product candidates. Failure to obtain a collaborative relationship for LYR-210, or any future product candidates may significantly impair the potential for these product candidates. We also may need to enter into collaborative relationships to provide funding to support our other research and development programs.

If we seek, but are not able to establish, collaborations, we may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional capital. We may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of our product candidates.

We face significant competition in seeking appropriate collaborators. We may not be able to negotiate 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.

Data provided by collaborators and others upon which we rely that has not been independently verified could turn out to be false, misleading, or incomplete.

We rely on third-party vendors, such as CROs, scientists, and collaborators to provide us with significant data and other information related to our projects, pre-clinical studies, or clinical trials and our business. If such third parties provide inaccurate, misleading, or incomplete data, our business, prospects, and results of operations could be materially adversely affected.

We do not have multiple sources of supply for some of the components used in LYR-210, nor long-term supply contracts, and certain of our suppliers are critical to our production. If we were to lose a supplier, it could have a material adverse effect on our ability to complete the development of LYR-210. If we obtain regulatory approval for LYR-210, we would need to expand the supply of their components in order to commercialize them.

We do not have multiple sources of supply for the components used in the manufacturing of LYR-210. We also do not have long-term supply agreements with any of our suppliers. We may not be able to establish additional sources of supply for our product candidates, or may be unable to do so on acceptable terms. Suppliers are subject to cGMP quality and regulatory requirements covering manufacturing, testing, quality control, and record keeping relating to our product candidates and are subject to ongoing inspections by the regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions in supply. Manufacturing suppliers are also subject to local, state, and federal regulations and licensing requirements. Failure by any of our suppliers to comply with all applicable regulations and requirements may result in long delays and interruptions in supply.

The number of suppliers of the raw material components of our product candidates is limited. In the event it is necessary or desirable to acquire supplies from alternative suppliers, we might not be able to obtain them on commercially reasonable terms, if at all. It could also require significant time and expense to redesign our manufacturing processes to work with another company. Additionally, certain of our suppliers are critical to our production and the loss of these suppliers to one of our competitors or otherwise would materially and adversely affect our development and commercialization efforts.

As part of any marketing approval, regulatory authorities conduct inspections that must be successful prior to the approval of the product. Failure of manufacturing suppliers to successfully complete these regulatory inspections will result in delays. If supply from the approved supplier is interrupted, there could be a significant disruption in commercial supply. An alternative vendor would need to be qualified through an NDA amendment or supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new supplier is relied upon for commercial production. Switching vendors may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

If we are unable to obtain the supplies we need at a reasonable price or on a timely basis, it could have a material adverse effect on our ability to complete the development of LYR-210 or, if we obtain regulatory approval for LYR-210, to commercialize them.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain, or adequately protect our intellectual property rights, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect our intellectual property and prevent others from duplicating LYR-210, and any future product candidates.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal, factual, and scientific questions and can be uncertain. It is possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfullry issue and even if such patents cover our product candidates, third parties may challenge the inventorship, ownership, validity, enforceability, or scope of such patents, which may result in such patents being narrowed or invalidated, or being held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. In addition, no assurances can be given that third parties will not create new products or methods that achieve similar results without infringing upon our patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If the patent applications we hold with respect to our programs or product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize future products. Several patent applications covering our product candidates have been filed recently. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents, or whether any issued patents will be found invalid or unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop.

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. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate. Furthermore, if third parties have filed such patent applications before enactment of the Leahy-Smith Act on March 16, 2013, an interference proceeding in the United States can be initiated by a third party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. In addition, patents have a limited lifespan. In the United States, the expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for the patent covering a product, we may be open to competition from generic competing products.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. In addition, the issuance of a patent does not give us

the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our product candidate, if approved, or practicing our own patented technology. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is either not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. 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, agreements or security measures may be breached, and we may not have adequate remedies for any breach. Once disclosed, we are likely to lose trade secret protection.

Although we require all of our employees and consultants to assign their inventions to us, to the extent that employees or consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Further, although we require that all of our employees, consultants, collaborators, advisors, and any third parties who have access to our proprietary know-how, information, or technology enter into confidentiality agreements, we cannot provide any assurances that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently discover our trade secrets or develop substantially equivalent information and techniques. Any of these parties may breach these agreements and we may not have adequate remedies for any specific breach. Misappropriation or unauthorized disclosure of our trade secrets or other confidential proprietary information could impair our competitive position and may have a material adverse effect on our business. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. Additionally, if the steps taken to maintain our trade secrets or other confidential proprietary information are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret or other confidential proprietary information.

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.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement, or allegations of infringement, of the patents and other proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexamination, and inter partes review proceedings before the United States Patent and Trademark Office, or USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. Many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to composition of matter, drug delivery, methods of manufacture, or methods for treatment related to the use or manufacture of our product candidates. We cannot guarantee that our technologies, products, compositions, and their uses do not or will not infringe third party patent or other intellectual property rights. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. After issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent, and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. If any third-party patents were held by a court of competent jurisdiction to cover the

composition of matter of any of our product candidates, the manufacturing process of any of our product candidates, or the method of use for any of our product candidates, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, which may not be available or may not be available on commercially reasonable terms, or until such patents expire.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates and/or harm our reputation and financial results. Defense of these claims, regardless of their merit, could involve substantial litigation expense and could be a substantial diversion of management and employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products, in the case of claims concerning registered trademarks, rename our product candidates, or obtain one or more licenses from third parties, which may require substantial time and monetary expenditure, and which might be impossible or technically infeasible. 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.

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

Competitors may infringe our patents, trademarks, copyrights, or other intellectual property. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. To counter infringement or unauthorized use, we may be required to file infringement claims on a country-by-country basis, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. There can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Any claims we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both.

In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid, is unenforceable and/or is not infringed, or may construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, interpreted narrowly, or held unenforceable, could put our patent applications at risk of not issuing, and could limit our ability to assert those patents against those parties or other competitors and curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, 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, which could materially harm our business and negatively affect our position in the marketplace.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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.

Recent patent reform legislation has increased the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, and may diminish the value of patents in general.

As is the case with other biotechnology companies, our commercial success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity and is therefore costly, time consuming, and inherently uncertain. Recent wide-ranging patent reform legislation in the United States, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase those uncertainties and costs.

The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted and may also affect patent litigation. Under the Leahy-Smith Act, 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. 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. The Leahy-Smith Act also enlarged the scope of disclosures that qualify as prior art, and it expanded the scope of procedures that a third party may use to challenge a U.S. patent, including post grant review and inter partes review procedures. 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. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, recent court rulings in cases such as Association for Molecular Pathology v. Myriad Genetics, Inc., BRCA1- &BRCA2-Based Hereditary Cancer Test Patent Litigation, and Promega Corp. v. Life Technologies Corp. have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO, and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

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

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

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

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.

If we initiated 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 candidate is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. 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, and equivalent proceedings in foreign jurisdictions (e.g., 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 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 one or more of our product candidates. Such a loss of patent protection could have a material adverse impact on our business. A defendant could also challenge our ownership of patents assigned to us. We cannot be certain that a third party would not challenge our rights to these patents and patent applications. Any legal proceeding or enforcement action can also be expensive and time-consuming.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.

The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. For patents that are eligible for extension of patent term, we expect to seek extensions of patent terms in the United States and, if available, in other countries. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional equivalent indications approved during the period of extension). We might not be granted an extension because of, for example, failure to apply within applicable periods, failure to apply prior to the expiration of relevant patents or otherwise, or failure to satisfy any of the numerous applicable requirements. Moreover, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to obtain approval of competing products following our patent expiration by referencing our clinical and pre-clinical data and launch their product earlier than might otherwise be the case. If this were to occur, it could have a material adverse effect on our ability to generate revenue.

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

Filing, prosecuting, and defending our intellectual property in countries throughout the world could be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. Therefore, we may choose not to pursue or maintain protection for certain intellectual property in certain jurisdictions. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent such competitors from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuit 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. In addition, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to “work” the invention in that country, or the third party has patented improvements) or limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent.

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

While we seek to protect the trademarks we use in the United States and in other countries, we may be unsuccessful in obtaining registrations and/or otherwise protecting these trademarks. If that were to happen, we may be prevented from using our names, brands, and trademarks unless we enter into appropriate royalty, license, or coexistence agreements, which may not be available or may not be available on commercially reasonable terms. Over the long term, if we are unable to establish name recognition based on our trademarks, trade names, service marks, and domain names, then we may not be able to compete effectively, resulting in a material adverse effect on our business. Our registered or unregistered trademarks or trade names may be challenged, infringed, diluted, or declared generic, or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. 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 to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trademarks and trade names similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks, then we may not be able to compete effectively and our business may be adversely affected. During trademark registration proceedings, we may receive rejections. 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. Effective trademark protection may not be available or may not be sought in every country in which our products are made available. Any name we propose to use for our products 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. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed product names, we may be required to expend significant additional resources in an effort to identify a usable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. 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.

Our proprietary rights may not adequately protect our technologies and product candidates, and 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 products that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own;
- others, including inventors or developers of our 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;
- we might not have been the first to conceive and reduce to practice the inventions covered by our patents or patent applications;
- we might not have been the first to file patent applications covering certain of our patents or patent applications;
- it is possible that our pending patent applications will not result in issued patents, or;
- that there are prior public disclosures that could invalidate our patents;
- our issued patents may not provide us with any commercially viable products or competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

•the Supreme Court of the United States, other U.S. federal courts, Congress, the USPTO, or similar foreign authorities may change the standards of patentability and any such changes could narrow or invalidate, or change the scope of, our or our collaboration partners' patents;

•patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time;

•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;

•ownership, validity, or enforceability of our 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.

Risks Related to Employee Matters

The May 2024 RIF was undertaken to significantly reduce our ongoing operating expenses but it may not result in our intended outcomes and may yield unintended consequences and additional costs.

In connection with the May 2024 RIF, we currently estimate that we will incur charges of approximately $3.9 to $4.1 million in connection with the reduction in force, primarily consisting of severance payments, employee benefits and related costs.

The reduction in force may result in unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended number of employees, decreased morale among our remaining employees, and the risk that we may not achieve the anticipated benefits of the reduction in force. In addition, while positions have been eliminated certain functions necessary to our operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. The reduction in workforce could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. If we are unable to realize the anticipated benefits from the reduction in force, or if we experience significant adverse consequences from the reduction in force, our business, financial condition, and results of operations may be materially adversely affected***.***

In the future, we may engage in acquisitions or strategic partnerships that could disrupt our business, cause dilution to our stockholders, reduce our financial resources, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

In the future, we may enter into transactions to acquire other businesses, products, or technologies or enter into strategic partnerships, including licensing. If we do identify suitable acquisition or partnership candidates, we may not be able to make such acquisitions or partnerships on favorable terms, or at all. Any acquisitions or partnerships we make may not strengthen our competitive position, and these transactions may be viewed negatively by employees, customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business or partnership that are not covered by the indemnification we may obtain from the seller or our partner. In addition, we may not be able to successfully integrate any acquired personnel, technologies, and operations into our existing business in an effective, timely, and non-disruptive manner. Acquisitions or partnerships may also divert management attention from day-to-day responsibilities, lead to a loss of key personnel, increase our expenses, and reduce our cash available for operations and other uses. We cannot predict the number, timing, or size of future acquisitions or partnerships or the effect that any such transactions might have on our operating results.

Risks Related to Our Common Stock

Our common stock may be delisted from The Nasdaq Global Market if we cannot regain compliance with Nasdaq's continued listing requirements, which could harm our business, the trading price of our common stock, our ability to raise additional capital and the liquidity of the market for our common stock.

Our common stock is currently listed on The Nasdaq Global Market. To maintain the listing of our common stock on The Nasdaq Global Market, we are required to meet certain listing requirements, including related to the price of our common stock. On July

19, 2024, we received a Notice from Nasdaq notifying us that for the last 30 consecutive business days, the bid price for our common stock, par value $0.001 per share, had closed below the $1.00 per share minimum bid price requirement for continued inclusion on The Nasdaq Global Market as set forth in Nasdaq Listing Rule 5450(a)(1) ("the Minimum Bid Price Requirement"). The Notice has no effect at this time on the listing of our common stock, which continues to trade on The Nasdaq Global Market under the symbol "LYRA."

In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we have a period of 180 calendar days, or until January 15, 2025 (the "Compliance Date") to regain compliance with the Minimum Bid Price Requirement. To regain compliance with the Minimum Bid Price Requirement, the closing bid price of the common stock must be at least $1.00 per share for a minimum of 10 consecutive business days prior to the Compliance Date.

In the event we do not regain compliance with the Minimum Bid Price Requirement by the Compliance Date, we may be eligible for a second 180 calendar day compliance period. To qualify, we must submit an application to transfer the listing of the common stock to The Nasdaq Capital Market, which requires us to meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement. We would also need to pay an application fee to Nasdaq and to provide written notice of its intention to cure the deficiency during the additional compliance period. As part of its review process, Nasdaq will make a determination of whether it believes we will be able to cure this deficiency. If the Company does not qualify for or fails to regain compliance during the additional compliance period, then Nasdaq will notify us of its determination to delist our common stock, at which point we would have an opportunity to appeal the delisting determination to a Nasdaq hearings panel. There can be no assurance that, if we decide to appeal any delisting determination, such appeal would be successful.

We intend to actively monitor the closing bid price of our common stock and may, if appropriate, consider implementing available options to regain compliance with the Minimum Bid Price Requirement. There can be no assurance that we will be able to regain compliance with the Minimum Bid Price Requirement or maintain compliance with any other listing requirements.

Delisting from The Nasdaq Global Market or any Nasdaq market could make trading our common stock more difficult for investors, potentially leading to declines in our share price and liquidity. In addition, without a Nasdaq market listing, stockholders may have a difficult time getting a quote for the sale or purchase of our common stock, the sale or purchase of our common stock would likely be made more difficult and the trading volume and liquidity of our common stock could decline. Delisting from Nasdaq could also result in negative publicity and could also make it more difficult for us to raise additional capital. The absence of such a listing may adversely affect the acceptance of our common stock as currency or the value accorded by other parties. If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on an over-the-counter quotation system, such as the OTCQB market, where an investor may find it more difficult to sell our common stock or obtain accurate quotations as to the market value of our common stock. We cannot assure you that our common stock, if delisted from Nasdaq, will be listed on another national securities exchange or quoted on an over-the counter quotation system.

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price may be volatile. The stock market in general and the market for smaller biotechnology 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, you may not be able to sell your common stock at or above your purchase price. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- actual or expected changes in our growth rate relative to our competitors;
- results of clinical trials of our product candidates or those of our competitors;
- developments related to our existing or any future collaborations;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- regulatory or legal developments in the United States and other countries;
- development of new product candidates that may address our markets and make our product candidates less attractive;

•changes in physician, hospital, or healthcare provider practices that may make our product candidates less useful or appealing;

•announcements by us, our partners, or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations, or capital commitments;

•developments or disputes concerning patent applications, issued patents, or other proprietary rights;

•the level of expenses related to any of our product candidates or clinical development programs;

•failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;

•the results of our efforts to discover, develop, acquire, or in-license additional product candidates or products;

•actual or expected changes in estimates as to financial results, development timelines, or recommendations by securities analysts;

•variations in our financial results or those of companies that are perceived to be similar to us;

•changes in the structure of healthcare payment or reimbursement systems;

•market conditions in the pharmaceutical and biotechnology sectors;

•short selling activities;

•general economic, industry, and market conditions; and

•the other factors described in this “Risk Factors” section and elsewhere in this Quarterly Report on Form 10-Q.

In addition, the trading prices for common stock of other biotechnology companies may become highly volatile as a result of geopolitical events such as the current conflict between Russia and Ukraine. The extent to which such events may impact our business, pre-clinical studies, and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Holders of approximately 60.1 million shares of our common stock have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 or until the rights terminate pursuant to the terms of the ninth amended and restated investor rights agreement between us and such holders. We have also registered all shares of common stock that we may issue under our equity compensation plans, which can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

We are an “emerging growth company,” and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and may remain an emerging growth company until December 31, 2025. However, if certain events occur prior to such date, including if we become a “large accelerated filer,” our annual gross revenues exceed $1.235 billion, or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to such date. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- 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; and

- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in our Annual Reports on Form 10-K and our Quarterly Reports on Form 10-Q including by providing only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we 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 reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline, even if our business is doing well.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property, or our stock performance, or if our target pre-clinical studies or clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We are a "smaller reporting company" and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are considered a "smaller reporting company." We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from disclosing certain executive compensation information and three years of financial statements. We are also exempt from the requirement to obtain an external audit on the effectiveness of internal control over financial reporting provided in Section 404(b) of the Sarbanes-Oxley Act. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may 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 prices may be more volatile.

Provisions in our restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of our Company, 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 restated certificate of incorporation and our amended and restated 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 market 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 include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our Board of Directors;

- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death, or removal of a director, which prevents stockholders from filling vacancies on our board of directors;

- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;

- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;

- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend, or repeal our bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors;

- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;

- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president, or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and

- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, 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.

Our restated certificate of incorporation designates specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving claims brought against us by stockholders; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act, the Exchange Act, the rules and regulations thereunder, or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our restated certificate of incorporation further provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our restated certificate of incorporation described above.

We believe these provisions benefit us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes and in the application of the Securities Act by federal judges, as applicable, efficient administration of cases on a more expedited schedule relative to other forums, and protection against the burdens of

multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees, and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees, or agents. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition, or results of operations.

General Risk Factors

We have incurred and expect to continue to incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we incur significant legal, accounting, and other expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and made some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our Board of Directors.

We continue to evaluate these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. We may discover significant deficiencies or material weaknesses, which we may not successfully remediate on a timely basis or at all. Any failure to remediate any significant deficiencies or material weaknesses identified by us or to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. The identification of one or more material weaknesses could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Because we do not anticipate paying any cash dividends on our common shares in the foreseeable future, capital appreciation, if any, would be your sole source of gain.

On March 20, 2012, we declared and paid a special cash dividend of $0.2630467 per share of our common stock, par value $0.001, which we refer to as the Special Dividend, which totaled approximately $42,115 in the aggregate. Other than the Special Dividend, we have never declared or paid any cash dividends on our common shares. We currently anticipate that we will retain future earnings for the development, and operation of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common shares would be your sole source of gain on an investment in our common shares for the foreseeable future.

Litigation could be costly and time-consuming and could result in additional liabilities.

We may from time to time be subject to legal proceedings and claims that arise in the ordinary course of business or otherwise, such as claims brought by us against, vendors or collaborators, and/or claims brought by our customers in connection with commercial disputes and employment claims made by our current or former employees. Claims may also be asserted by or on behalf of a variety of other parties, including government agencies, patients, or vendors of our customers, or stockholders.

Any litigation involving us may result in substantial costs, operationally restrict our business, and may divert management's attention and resources, which may seriously harm our business, overall financial condition, and results of operations. Insurance may not cover existing or future claims, be sufficient to fully compensate us for one or more of such claims, or continue to be available on terms acceptable to us. A claim brought against us that is uninsured or under insured could result in unanticipated costs, thereby adversely impacting our results of operations and resulting in a reduction in the trading price of our stock.

We could be subject to securities class action litigation.

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

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

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, and property, auto, workers' compensation, umbrella, and directors' and officers' insurance. Any additional product liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer.

Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If we obtain marketing approval for LYR-210, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the development and commercialization of any product candidates we develop. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Operating as a public company has made it more difficult and more expensive for us to obtain director and officer liability insurance, and in the future we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board of Directors, our board committees, or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect the Company's current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. The Company maintains the majority of its cash and cash equivalents in accounts with major U.S. institutions, and our deposits at certain of these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no

assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our current and projected business operations, our financial condition and results of operations.

Our ability to use our net operating losses and research and development credits to offset future taxable income may be subject to certain limitations.

As of December 31, 2023, we had net operating loss carryforwards, or NOLs, of $128.3 million for federal income tax purposes and $48.3 million for state income tax purposes, which may be available to offset our future taxable income, if any, and begin to expire at various dates through 2043. As of December 31, 2023, we also had federal and state research and development credit carryforwards of $5.3 million, which begin to expire at various dates through 2043. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, or IRC, as amended, or the Code, a corporation that undergoes an "ownership change," generally defined as a greater than 50% change by value in its equity ownership over a three-year period, is subject to limitations on its ability to utilize its pre-change NOLs and its research and development credit carryforwards to offset future taxable income. The Company had performed an IRC 382 study during the prior year which resulted in identifying three separate ownership changes that occurred on March 31, 2006, January 17, 2020, and April 13, 2022. We performed an update assessment to our 382 analysis in conjunction with the May 2023 financing noting no additional ownership change. For these reasons, in the event we experience a change of control, we may not be able to utilize a material portion of the NOLs or research and development credit carryforwards even if we attain profitability.

New tax legislation may impact our results of operations and financial condition.

The Inflation Reduction Act of 2022 introduced, among other changes, a 15% corporate minimum tax on certain United States corporations and a 1% excise tax on certain stock redemptions by United States corporations. The U.S. government may enact further significant changes to the taxation of business entities. The likelihood of these changes being enacted or implemented is unclear. We are currently unable to predict the ultimate impact of the Inflation Reduction Act or any such further changes on our business.

Unstable global, political or economic conditions may have serious adverse consequences on our business, financial condition and share price.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest and inflation rates, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. If the equity and credit markets continue to deteriorate, or the United States enters a recession, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. In addition, international terrorism and conflicts could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. Related sanctions, export controls or other actions have and may in the future be initiated by nations including the U.S., the EU or Russia (e.g., potential cyberattacks, disruption of energy flows, etc.), which could adversely affect our business and/or our supply chain, our CROs, CMOs and other third parties with which we conduct business. Any of the foregoing could harm our business, results of operations and price of our common stock may be adversely affected.

We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition, and prospects. If a natural disaster, power outage, or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities on which we rely, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. For example, following Hurricane Maria, shortages in production and delays in a number of medical supplies produced in Puerto Rico resulted, and any similar interruption due to a natural disaster affecting us or any of our third-party manufacturers could materially delay our operations.

International terrorism, political unrest, and wars, or other events such as the COVID-19 pandemic have previously and could in the future adversely impact our business and operations, including our clinical trials.

International terrorism, political unrest and wars could delay or disrupt our business activity, and if any conflict escalates or spills over to or otherwise impacts additional regions, it could heighten many of the other risk factors described in this Item 1A. In addition, the COVID-19 global pandemic and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, has fallen. If the COVID-19 pandemic resurges, our business and operations could be adversely affected again. Similarly, if another pandemic unfolds or if a geopolitical crisis escalates, our business and operations could be adversely affected.

We are subject to various risks associated with increased scrutiny of environmental, social, and governance matters.

Companies across industries are facing increasing scrutiny from a variety of stakeholders related to their environmental, social and governance ("ESG") practices, including regarding climate change and diversity & inclusion, among others. While we may, from time to time, engage in efforts to improve our ESG profile or respond to stakeholder expectations, such efforts may be costly and may not have the desired effect. Any negative perception of our ESG performance, whether or not accurate, could result in negative stakeholder sentiment, which may result in a reduction in interest in our stock or products, issues in attracting/retaining employees or business partners, or other adverse impacts on our business. There are also increasing regulatory obligations, disclosure-related and otherwise, on companies regarding ESG matters. For example, various policymakers, including the SEC and the State of California, have adopted or are considering adopting requirements for companies to provide significantly expanded disclosure on climate-related information, which may require us to incur additional costs and require attention from management, including in connection with internal controls on matters that have not previously been subject to such requirements. These and other stakeholder expectations may result in increased scrutiny that could increase any of the risks identified in this risk factor. Certain customers and suppliers may be subject to similar expectations, which may augment or create additional risks, including risks that may not be known to us.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

(a) Disclosure in lieu of reporting on a Current Report on Form 8-K.

None.

(b) Material changes to the procedures by which security holders may recommended nominees to the board of directors.

None.

(c) Insider trading arrangements and policies.

During the three months ended June 30, 2024, no director or officer of the Company, as defined in Rule 16a-1(f) of the Exchange Act, adopted or terminated a "Rule 10b5-1 trading arrangement" intended to satisfy the affirmative defense of Rule 10b5-1(c) or "non-Rule 10b5-1 trading arrangement" as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits.

Exhibit Number	Description	Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
3.1	Restated Certificate of Incorporation of the Registrant, dated May 5, 2020 and the Certificate of Amendment to the Restated Certificate of Incorporation of the Registrant, dated June 13, 2024.	8-K	3.1	June 18, 2024	001-39273
3.2	Amended and Restated Bylaws of the Registrant	8-K	3.1	December 18, 2023	001-39273
4.1	Specimen Stock Certificate evidencing the shares of Common Stock of the Registrant	S-1	4.2	April 27, 2020	333-236962
31.1*	Certification of Principal Executive 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				
31.2*	Certification of 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 Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
32.2+	Certification of 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 Date File (embedded within the Inline XBRL document)				

* Filed herewith.

+ Furnished herewith.

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.

LYRA THERAPEUTICS, INC.

Date: August 14, 2024

By: /s/ Maria Palasis, Ph.D.
Maria Palasis, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 14, 2024

By: /s/ Jason Cavalier
Jason Cavalier
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION 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

I, Maria Palasis, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of Lyra Therapeutics, Inc.;

2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(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.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2024

By: /s/ Maria Palasis, Ph.D.
Maria Palasis, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION 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

I, Jason Cavalier, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of Lyra Therapeutics, Inc.;

2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(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.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2024

By: /s/ Jason Cavalier
Jason Cavalier
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Lyra Therapeutics, Inc. (the "Company") for the period ended June 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1)the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: August 14, 2024

By: /s/ Maria Palasis, Ph.D.
Maria Palasis, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Lyra Therapeutics, Inc. (the "Company") for the period ended June 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1)the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: August 14, 2024

By: /s/ Jason Cavalier
Jason Cavalier
Chief Financial Officer
(Principal Financial and Accounting Officer)