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, 2021

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, 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 2, 2021, the registrant had 13,001,105 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. 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 facts contained in this Quarterly Report on Form 10-Q are forward looking statements, including but not limited to statements regarding:

- our plans to develop and commercialize our product candidates;
- the timing of our ongoing or planned clinical trials for LYR-210, LYR-220, and any future product candidates;
- the timing of and our ability to obtain and maintain regulatory approvals for LYR-210, LYR-220, and any future product candidates;
- the clinical utility of our product candidates;
- our commercialization, marketing, and manufacturing capabilities and strategy;
- our expectations about the willingness of healthcare professionals to use LYR-210, LYR-220, and any future product candidates;
- our expectations regarding the development and commercialization of LYR-210 pursuant to the terms of the LianBio License Agreement;
- our intellectual property position;
- our competitive position and developments and projections relating to our competitors or our industry;
- our ability to identify, recruit, and retain key personnel;
- the impact of laws and regulations;
- risks associated with the COVID-19 pandemic, 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 plans to identify additional product candidates with significant commercial potential that are consistent with our commercial objectives;
- our estimates and statements regarding our future revenue, future results of operations, and financial position;
- our business strategy;
- our research and development costs; and
- the plans and objectives of management for future operations.

These statements 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. 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. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances, or otherwise.

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:

- we have a limited operating history and a history of escalating operating losses, which may make it difficult to evaluate the prospects for our future viability;
- we have incurred significant losses since inception and expect to incur significant additional losses for the foreseeable future, and we may never achieve profitability;
- 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;
- our business is highly dependent on the success of our most advanced product candidate, LYR-210, which will require significant additional clinical testing before we can seek regulatory approval and potentially launch commercial sales, and 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;
- managing our obligations under our license and other strategic agreements may divert management time and attention, 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;
- we have entered into a collaboration agreement, and may enter into other collaboration agreements, 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;
- clinical trials required for our 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;
- 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, and the 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;
- even if either LYR-210 or LYR-220 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 will rely on third parties for the manufacture of materials for our research programs, pre-clinical studies and clinical trials and we do not have long-term contracts with any of these parties, which 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 rely on third parties to conduct our pre-clinical studies and clinical trials, and 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;

- 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;
- if we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers or other significant personnel or experience increases in our compensation costs, our business may materially suffer; and
- the pandemic caused by COVID-19 could adversely impact our business and operations, including our clinical trials.

Table of Contents

Item 1. Financial Statements.

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

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 69,046	$ 74,593
Prepaid expenses and other current assets	1,027	1,324
Total current assets	70,073	75,917
Property and equipment, net	3,853	2,165
Operating lease right-of-use assets	1,834	2,301
Restricted cash	329	329
Other assets	243	118
Total assets	$ 76,332	$ 80,830
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,899	$ 922
Accrued expenses and other current liabilities	2,976	2,977
Operating lease liabilities	1,029	985
Total current liabilities	5,904	4,884
Operating lease liabilities, net of current portion	929	1,454
Deferred revenue	12,000	—
Total liabilities	18,833	6,338
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.001 par value; 200,000,000 shares authorized at June 30, 2021 and December 31, 2020; 13,001,105 and 12,932,377 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	13	13
Additional paid-in capital	226,211	224,363
Accumulated deficit	(168,725)	(149,884)
Total stockholders' equity	57,499	74,492
Total liabilities and stockholders' equity	$ 76,332	$ 80,830

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,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 7,505	$ 2,103	$ 12,275	$ 5,067
General and administrative	3,560	2,442	6,621	3,726
Total operating expenses	11,065	4,545	18,896	8,793
Loss from operations	(11,065)	(4,545)	(18,896)	(8,793)
Other income:				
Interest income	26	5	55	21
Total other income	26	5	55	21
Net loss	$ (11,039)	$ (4,540)	$ (18,841)	$ (8,772)
Comprehensive loss	$ (11,039)	$ (4,540)	$ (18,841)	$ (8,772)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.85)	$ (0.56)	$ (1.45)	$ (2.11)
Weighted-average common shares outstanding—basic and diluted	12,991,837	8,182,725	12,968,820	4,206,793

See accompanying notes to unaudited condensed consolidated financial statements.

LYRA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(unaudited)
(in thousands, except share amounts)

Three Months Ended June 30,

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders' Equity (Deficit)
	Shares	Value	Shares	Amount	Capital	Deficit	
Balance at March 31, 2020	287,426,285	$ 160,197	230,860	$ —	$ 5,208	$ (131,989)	$ (126,781)
Accretion of convertible preferred stock to redemption value	—	30	—	—	(30)	—	(30)
Conversion of redeemable convertible preferred stock to common stock upon closing of initial public offering	(287,426,285)	(160,227)	8,335,248	8	160,219	—	160,227
Issuance of common stock from initial public offering, net of issuance costs of $7,072	—	—	4,025,000	4	57,324	—	57,328
Vesting of restricted common stock	—	—	19,661	—	—	—	—
Issuance of common stock upon exercise of warrants	—	—	313,794	1	(1)	—	—
Stock-based compensation	—	—	—	—	619	—	619
Net loss	—	—	—	—	—	(4,540)	(4,540)
Balance at June 30, 2020	—	$ —	12,924,563	$ 13	$ 223,339	$ (136,529)	$ 86,823
Balance at March 31, 2021	—	$ —	12,962,768	$ 13	$ 225,224	$ (157,686)	$ 67,551
Exercise of common stock options	—	—	38,337	—	331	—	331
Stock-based compensation	—	—	—	—	656	—	656
Net loss	—	—	—	—	—	(11,039)	(11,039)
Balance at June 30, 2021	—	$ —	13,001,105	$ 13	$ 226,211	$ (168,725)	$ 57,499

Six Months Ended June 30,

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders' Equity
	Shares	Value	Shares	Amount	Capital	Deficit	(Deficit)
Balance at December 31, 2019	209,119,674	$ 130,666	230,860	$ —	$ 4,419	$ (127,757)	$ (123,338)
Issuance of Series C redeemable convertible preferred stock, net of issuance costs of $201	78,306,611	29,446	—	—	—	—	—
Accretion of convertible preferred stock to redemption value	—	115	—	—	(115)	—	(115)
Issuance of common stock warrants in conjunction with sale of Series C redeemable convertible preferred stock	—	—	—	—	740	—	740
Conversion of redeemable convertible preferred stock to common stock upon closing of initial public offering	(287,426,285)	(160,227)	8,335,248	8	160,219	—	160,227
Issuance of common stock from initial public offering, net of issuance costs of $7,072	—	—	4,025,000	4	57,324	—	57,328
Vesting of restricted common stock	—	—	19,661	—	—	—	—
Issuance of common stock upon exercise of warrants	—	—	313,794	1	(1)	—	—
Stock-based compensation	—	—	—	—	753	—	753
Net loss	—	—	—	—	—	(8,772)	(8,772)
Balance at June 30, 2020	—	$ —	12,924,563	$ 13	$ 223,339	$ (136,529)	$ 86,823
Balance at December 31, 2020	—	$ —	12,932,377	$ 13	$ 224,363	$ (149,884)	$ 74,492
Exercise of common stock options	—	—	68,728	—	593	—	593
Stock-based compensation	—	—	—	—	1,255	—	1,255
Net loss	—	—	—	—	—	(18,841)	(18,841)
Balance at June 30, 2021	—	$ —	13,001,105	$ 13	$ 226,211	$ (168,725)	$ 57,499

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,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (18,841)	$ (8,772)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,255	753
Depreciation expense	373	21
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	297	(2,400)
Operating lease right-of-use assets	467	440
Accounts payable	743	138
Accrued expenses and other current liabilities	(22)	(1,237)
Operating lease liabilities	(481)	(438)
Deferred revenue	12,000	—
Net cash used in operating activities	(4,209)	(11,495)
Cash flows from investing activities:		
Purchases of property and equipment	(1,785)	(85)
Net cash used in investing activities	(1,785)	(85)
Cash flows from financing activities:		
Proceeds from the sale of Series C redeemable convertible preferred stock	—	30,392
Payment of offering costs related to sale of Series C redeemable convertible preferred stock	—	(205)
Proceeds from initial public offering, net of underwriting discounts	—	59,892
Payment of initial public offering costs	—	(1,708)
Payment of deferred offering expenses	(146)	—
Proceeds from exercise of stock options	593	—
Net cash provided by financing activities	447	88,371
Net (decrease) increase in cash and cash equivalents	(5,547)	76,791
Cash and cash equivalents and restricted cash, beginning of period	74,922	10,137
Cash and cash equivalents and restricted cash, end of period	$ 69,375	$ 86,928
Supplemental disclosure of non-cash financing and investing activities:		
Property and equipment purchases included in accounts payable	$ 363	$ 30
Conversion of redeemable convertible preferred stock	$ —	$ 160,227
Allocation of Series C redeemable convertible preferred stock to common stock warrant	$ —	$ 740
Series C redeemable convertible preferred stock stock issuance costs included in accounts payable and accrued expense	$ —	$ 1
Accretion of redeemable convertible preferred stock to redemption value	$ —	$ 115
Right-of-use asset obtained in exchange of operating lease obligations	$ —	$ 13
Deferred offering costs included in accounts payable and accrued expense	$ 97	$ 630

See accompanying notes to unaudited condensed consolidated financial statements.

1. Organization and Basis of Presentation

Lyra Therapeutics, Inc. (the "Company") is a clinical-stage therapeutics company focused on the development and commercialization of novel integrated drug and delivery solutions for the localized treatment of patients with ear, nose and throat ("ENT") diseases. The Company's proprietary technology platform, XTreo, is designed to precisely and consistently deliver medicines directly to the affected tissue for sustained periods with a single administration. The Company's initial product candidates, LYR-210 and LYR-220, are bioresorbable polymeric matrices designed to be administered in a brief, non-invasive, in-office procedure and intended to deliver up to six months of continuous drug therapy to the sinonasal passages for the treatment of chronic rhinosinusitis ("CRS"). The Company was incorporated as a Delaware corporation on November 21, 2005 and is located in Watertown, Massachusetts.

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.

Prior to our initial public offering ("IPO"), the Company has funded its operations with proceeds from sales of redeemable convertible preferred stock and funding from government contracts. The Company has incurred recurring net losses since inception and had net losses of approximately $18.8 million and $8.8 million for the six months ended June 30, 2021 and 2020, respectively. In addition, the Company has an accumulated deficit of approximately $168.7 million at June 30, 2021. The Company expects to continue to generate operating losses for the foreseeable future. At June 30, 2021, the Company had approximately $69.0 million of cash and cash equivalents.

On May 5, 2020, the Company completed its IPO, in which the Company issued and sold 4,025,000 shares of its common stock, including 525,000 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $16.00 per share, for aggregate gross proceeds of $64.4 million. The Company received approximately $57.3 million in net proceeds after deducting underwriting discounts and offering expenses paid by the Company.

The Company believes that its cash and cash equivalents as of June 30, 2021 will be sufficient to fund the Company's operating plan for a period of at least one year from the issuance date of the condensed consolidated financial statements. The Company will need additional financing to support its continuing operations and pursue its growth strategy. Until such time as the Company can generate significant revenue from product sales, if ever, it expects 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.

Upon the completion of the IPO of its common stock in May 2020, all outstanding redeemable convertible preferred stock of the Company converted into shares of common stock and all outstanding warrants to purchase common stock were automatically cashless exercised.

COVID-19 Pandemic and CARES Act

On January 30, 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the "COVID-19 outbreak") and the risks to the international community as the virus subsequently spread globally beyond its point of origin. On March 11, 2020, the WHO classified the COVID-19 outbreak as a pandemic, based on the rapid increase in exposure globally. The COVID-19 pandemic is affecting the United States and global economies and may affect the Company's operations and those of third parties on which the Company relies, including by causing disruptions in the supply of the Company's product candidates and the conduct of current and future clinical trials. In addition, the COVID-19 pandemic may affect the operations of the Food and Drug Administration and other health authorities, which could result in delays of reviews and approvals, including with respect to the Company's product candidates. In light of developments relating to the COVID-19 pandemic, the Company discontinued enrollment at 67 patients in its Phase 2 LANTERN clinical trial and did not enroll patients in the United States. Additionally, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce the Company's ability to access capital, which could negatively impact the Company's short-term and long-term liquidity. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change, including the length of time needed to vaccinate a significant segment of the global population and effectiveness of the vaccines with respect to the new variants of the virus. The Company does not yet know the full extent of potential delays or impacts on its business, financing or clinical trial activities or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on the Company's liquidity, capital resources, operations and business and those of the third parties on which the Company relies.

On March 27, 2020, President Trump signed into law the "Coronavirus Aid, Relief, and Economic Security (CARES) Act." The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations, increased limitations on qualified charitable contributions, and technical corrections to tax depreciation methods for qualified improvement property. The Company deferred the employer side social security payments. The CARES Act also appropriated funds for the SBA Paycheck Protection Program loans that are forgivable in certain situations to promote continued employment, as well as Economic Injury Disaster Loans to provide liquidity to small businesses harmed by COVID-19. On December 27, 2020, the Consolidated Appropriations Act, 2021 was signed into law in order to provide further stimulus and support to those affected by the COVID-19 pandemic. The Company has not and does not plan on obtaining funding from such loans. The Company does not believe the CARES Act or the Consolidated Appropriations Act, 2021 will have a material impact on its financial condition, results of operations, or liquidity.

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). 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").

The condensed consolidated financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of June 30, 2021 and the results of its operations and its cash flows for the three and six months ended June 30, 2021 and 2020. The results for the three and six months ended June 30, 2021 are not necessarily indicative of results to be expected for the year ending December 31, 2021, any other interim periods, or any future year or period. These condensed consolidated financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2020, and the notes thereto, which are included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 9, 2021.

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, 2020, included in the Company's Annual Report on Form 10-K filed with the SEC on March 9, 2021. Since the date of those financial statements, there have been no changes to its significant accounting policies except as noted below.

Use of Estimates

The preparation of the Company's condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and reported amounts of expenses during the reporting period. On an ongoing basis, the Company's management evaluates its estimates, which include but are not limited to management's judgments of accrued expenses, fair value of common stock, valuation of share-based awards, warrants to purchase common stock and deferred income taxes. Due to the uncertainty inherent in such estimates, actual results may differ from these estimates.

The Company utilizes significant estimates and assumptions in determining the fair value of its common stock. The Company has utilized various valuation methodologies to estimate the fair value of its common stock. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to the Company's common stock at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

Restricted Cash

The Company had restricted cash of approximately $0.3 million as of June 30, 2021 and December 31, 2020, which was held in certificates of deposit at the Company's financial institution to secure the Company's letter of credit for its facility lease.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains all its cash and cash equivalents at a single accredited financial institution, in amounts that exceed federally insured limits.

The Company has no significant off-balance sheet risk such as foreign exchange contracts, option contracts, or other foreign exchange hedging arrangements.

Revenue Recognition

Under ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

Once a contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations. The identification of material rights requires judgments related to the determination of the value of the underlying good or service relative to the option exercise price. The exercise of a material right is accounted for as a contract modification for accounting purposes.

The Company assesses whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct) and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract). In assessing whether a promised good or service is distinct, the Company considers factors such as the research, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. The Company also considers the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

The transaction price is then determined and allocated to the identified performance obligations in proportion to their standalone selling prices ("SSP") on a relative SSP basis. SSP is determined at contract inception and is not updated to reflect changes between contract inception and when the performance obligations are satisfied. Determining the SSP for performance obligations requires significant judgment. In developing the SSP for a performance obligation, the Company considers applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. The Company validates the SSP for performance obligations by evaluating whether changes in the key assumptions used to determine the SSP will have a significant effect on the allocation of arrangement consideration between multiple performance obligations.

If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The Company includes the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

If an arrangement includes development and regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

For arrangements with licenses of intellectual property that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if the timing of payments provides the Company with a significant benefit of financing. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less. The Company assessed its revenue generating arrangement in order to determine whether a significant financing component exists and concluded that a significant financing component does not exist.

The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied, either at a point in time or over time, and if over time recognition is based on the use of an output or input method.

Collaborative arrangement revenue

On May 31, 2021, the Company entered into a License and Collaboration Agreement ("LianBio License Agreement") with LianBio Inflammatory Limited ("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, the Company received an upfront payment of $12.0 million and 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, the Company 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 the Company 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 the Company's LYR-220 product candidate.

To date, the Company has not recognized any collaboration revenue from the LianBio License Agreement. The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* ("ASC 808"), which includes determining whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities, or ASC 606. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to ASC 606.

Royalty and other revenue

The LianBio License Agreement includes an out-licensing component that is within the scope of ASC 606. The terms of the LianBio License Agreement include the license of functional intellectual property, given the functionality of the intellectual property is not expected to change substantially as a result of the licensor's ongoing activities, and includes payment of the following: non-refundable up-front license fee; development and regulatory milestone payments and milestone payments based on the level of sales; and royalties on net sales of licensed products. If considered a separate performance obligation, nonrefundable up-front license fees are recognized as revenue at a point in time when the licensed intellectual property is made available for the customer's use and benefit, which is generally at the inception of the arrangement. 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. The Company recognizes royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

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 computed diluted net loss per common share after giving consideration to all potentially dilutive common shares, including options to purchase common stock, warrants to purchase common stock and redeemable convertible preferred stock, outstanding during the period determined using the treasury-stock and if-converted methods, except where the effect of including such securities would be antidilutive. Because the Company has reported net losses since inception, these potential common shares have been anti-dilutive and basic and diluted loss per share have been the same.

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Numerator:				
Net loss	$ (11,039)	$ (4,540)	$ (18,841)	$ (8,772)
Accretion of redeemable convertible preferred stock	—	(30)	—	(115)
Net loss attributable to common stockholders	$ (11,039)	$ (4,570)	$ (18,841)	$ (8,887)
Denominator:				
Weighted-average common shares—basic and diluted	12,991,837	8,182,725	12,968,820	4,206,793
Net loss per share attributable to common stockholders—basic and diluted	$ (0.85)	$ (0.56)	$ (1.45)	$ (2.11)

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 retroactively adjusted):

	Six Months Ended June 30,	
	2021	2020
Stock options	1,764,499	1,347,394
Total	1,764,499	1,347,394

Recently Adopted 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.

In May 2014, the FASB issued Accounting Standards Update (“ASU”) 606, which supersedes the revenue recognition requirements in ASC Topic 605, *Revenue Recognition*, and creates a new topic, ASC 606. In 2015 and 2016, the FASB issued additional ASUs related to ASC 606 that delayed the effective date of the guidance and clarified various aspects of the new revenue guidance, including principal versus agent considerations, identification performance obligations and licensing, and other improvements and practical expedients. The Company adopted ASU 606 on January 1, 2021. The Company had no revenue prior to the LianBio License Agreement, therefore the adoption of ASC 606 had no impact on the Company’s consolidated financial position, results of operations or cash flows.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* (“ASU No. 2019-12”), which makes a number of changes meant to add or clarify guidance on accounting for income taxes. The Company adopted ASU 2019-12 on January 1, 2021. The adoption of ASU 2019-12 did not have a material impact on the Company’s consolidated financial position, results of operations or cash flows.

3. Fair Value Measurements

The Company did not have financial assets and liabilities measured at fair value at June 30, 2021 and December 31, 2020.

There have been no changes to the valuation methods used during the three and six months ended June 30, 2021 and 2020. There were no transfers within the fair value hierarchy during the three and six months ended June 30, 2021 and 2020.

The carrying values of the Company's accounts payable and accrued expenses approximate their fair values due to the short-term nature of these liabilities.

In connection with the Company's sale of Series C redeemable convertible preferred stock ("Series C Preferred Stock") in January 2020, the Company issued to investors warrants for the purchase of common stock ("Warrants"). The proceeds from the issuance of the Series C Preferred Stock were allocated between the Series C Preferred Stock and Warrants based on their relative fair values at the time of issuance.

4. Property and Equipment

Property and equipment consist of the following at June 30, 2021 and December 31, 2020 (in thousands):

	June 30, 2021	December 31, 2020
Property and equipment:		
Laboratory equipment	$ 4,845	$ 3,277
Computer software and equipment	668	650
Office furniture and fixtures	301	301
Leasehold improvements	677	317
Construction in progress	613	498
	$ 7,104	$ 5,043
Accumulated depreciation	(3,251)	(2,878)
Property and equipment, net	$ 3,853	$ 2,165

The Company recognized approximately $0.3 million and $13,000 of depreciation expense for the three months ended June 30, 2021 and 2020, respectively, and $0.4 million and $21,000 of depreciation expense for the six months ended June 30, 2021 and 2020, respectively.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	June 30, 2021	December 31, 2020
Payroll and employee related expenses	$ 1,805	$ 1,892
Third-party research and development expenses	532	381
Professional and consulting fees	573	555
Other	66	149
Total accrued expenses and other current liabilities	$ 2,976	$ 2,977

6. Preferred and Common Stock

On May 5, 2020, the Company filed a restated certificate of incorporation which authorizes its Board of Directors to issue up to 200,000,000 shares of common stock, par value $0.001 per share and 10,000,000 shares of undesignated preferred stock, par value $0.001 per share.

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's Board of Directors approved a one-for-34.483 reverse stock split of its issued and outstanding common stock and stock options and a proportional adjustment to the existing conversion ratios for the Company's redeemable convertible preferred stock pursuant to an amendment to the Company's amended and restated certificate of incorporation effective as of April 27, 2020. Accordingly, all common stock shares, per share amounts, and additional paid in capital amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split.

In May 2020, the Company completed its IPO in which the Company issued and sold 4,025,000 shares of its common stock, including 525,000 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $16.00 per share, for aggregate gross proceeds of $64.4 million. The Company received approximately $57.3 million in net proceeds after deducting underwriting discounts and offering expenses paid by the Company. In connection with this financing, all outstanding shares of redeemable convertible preferred stock converted into 8,335,248 shares of the Company's common stock, all outstanding Warrants were automatically cashless exercised resulting in the issuance of 313,794 shares of the Company's stock and the issuance to one of our directors, in lieu of compensation payable by the Company under a consulting agreement, of 19,661 fully vested shares of the Company's common stock.

The Company currently has an effective shelf registration statement on Form S-3 (No. 333-256020) filed with the SEC on May 11, 2021 ("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 $250.0 million in the aggregate. As of June 30, 2021, the Company has not sold any securities under the Form S-3.

On May 11, 2021, the Company entered into an Open Market Sales Agreement ("2021 ATM Agreement") with Jefferies LLC ("Jefferies") to sell shares of its common stock, from time to time, with aggregate gross sales proceeds of up to $50.0 million, through an at-the-market equity offering program under which Jefferies will act as the Company's sales agent. As of June 30, 2021, the Company has received no proceeds from the sale of shares of common stock pursuant to the 2021 ATM Agreement.

The Company has reserved for future issuances the following shares of common stock as of June 30, 2021:

	As of June 30, 2021
Stock options	3,337,220
Employee stock purchase plan	214,661
Total	3,551,881

Warrants

In conjunction with the issuance of the Series C Preferred Stock, the Company issued Warrants to purchase 681,256 shares of common stock at an exercise price of $8.63 per share.

The Company classified the Warrants as equity in the condensed consolidated balance sheets in accordance with the guidance in ASC 815, *Derivatives and Hedging*. The Company allocated the net proceeds from the issuance of the Series C Preferred Stock based on the relative fair values of the Series C Preferred Stock and Warrants, which resulted in approximately $0.7 million of the net proceeds being allocated to the Warrants.

Upon the completion of the IPO of its common stock in May 2020, all outstanding Warrants were automatically cashless exercised resulting in the issuance of 313,794 shares of the Company's common stock.

7. Stock-Based Compensation Expense

The Company adopted the 2016 Equity Incentive Plan ("2016 Plan") in February 2016 and amended it in June 2017 and June 2018. Upon adoption of the 2016 Plan, no further grants were made under the 2005 Equity Incentive Plan ("2005 Plan").

In April 2020, the Company's Board of Directors adopted the Company's 2020 Incentive Award Plan ("2020 Plan", and together with the 2016 Plan and 2005 Plan, the "Plans"), and upon effectiveness of the 2020 Plan, the Company ceased granting equity-based awards under the 2016 Plan. The 2020 Plan provides for grant of incentive stock options and nonqualified stock options, stock appreciation rights, restricted stock, dividend equivalents, restricted stock units, performance awards and other share and cash-based awards to employees and consultants and members of the Board of Directors of the Company and its subsidiaries.

The initial number of shares of the Company's common stock that may be issued under the 2020 Plan is 2,100,000 shares plus the number of shares of the Company's common stock underlying outstanding awards under the 2005 Plan and 2016 Plan as of the effective date of the 2020 Plan that expire, lapse or are terminated, exchanged for cash, surrendered, repurchased, canceled or forfeited following the effective date of the 2020 Plan. The number of shares available under the 2020 Plan will automatically increase on January 1st of each year from 2021 to 2030 by the lesser of (i) 4% of the number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (ii) a smaller number of shares determined by the Company's Board of Directors. However, no more than 8,800,000 shares may be issued under the 2020 Plan pursuant to the exercise of incentive stock options. On January 1, 2021, the shares available for grant under the 2020 Plan was automatically increased by 517,295. As of June 30, 2021, the Company had 1,572,721 shares available for issuance under the 2020 Plan.

All stock option grants are nonqualified stock options except option grants to employees and officers intended to qualify as incentive stock options under the Internal Revenue Code of 1986, as amended. Stock options may not be granted at less than the fair market value of the Company's common stock on the date of grant. Vesting periods of awards are determined by the Board of Directors or its compensation committee. Vesting periods of awards granted to date range from vesting upon grant to vesting over a four-year period. Vesting conditions are generally based on continued service. Additionally, the Company has granted certain awards which vest upon the achievement of certain financing and revenue milestones. Stock options granted under the Plans expire no more than 10 years from the date of grant.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 146	$ 15	$ 288	$ 55
General and administrative	510	604	967	698
Total	$ 656	$ 619	$ 1,255	$ 753

The Company did not record any stock-based compensation associated with milestone-based awards in the three and six months ended June 30, 2021 and 2020.

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, with the following weighted-average assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Risk-free interest rate	0.9%	0.4%	0.7%	0.6%
Expected dividend yield	—%	—%	—%	—%
Expected term (in years)	5.7	6.0	6.0	6.0
Expected volatility	84.7%	80.6%	85.3%	80.1%

A summary of the stock option activity under the Plans for the six months ended June 30, 2021 was as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding December 31, 2020	1,428,886	$ 10.41	7.7	$ 5,165
Granted	439,700	10.27		
Exercised	(68,728)	8.63		
Cancelled	(35,359)	11.39		
Outstanding at June 30, 2021	1,764,499	$ 10.42	8.0	$ 2,979
Exercisable at June 30, 2021	719,441	$ 9.53	6.7	$ 2,048
Vested and expected to vest at June 30, 2021	1,764,499	$ 10.42	8.0	$ 2,979

The weighted-average fair value of options granted to employees, directors and non-employees during the three months ended June 30, 2021 and 2020 was $5.49 and $10.71, respectively, and $7.28 and $9.88 for the six months ended June 30, 2021 and 2020, respectively.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised during the three months ended June 30, 2021 and 2020 was approximately $72,000 and $0, respectively, and $0.2 million and $0 during the six months ended June 30, 2021 and 2020, respectively.

As of June 30, 2021, total unrecognized stock-based compensation expense relating to unvested stock options was approximately $7.9 million. This amount is expected to be recognized over a weighted-average period of 3.0 years. Additionally, as of June 30, 2021, there was approximately $36,000 of unrecognized stock-based compensation related to a stock option award related to the achievement of a revenue-based milestone. As the Company believes the achievement of the revenue-based milestone is currently not probable, it has not recorded any stock-based compensation related to this award. The Company will continue to assess the probability of achieving the revenue-based milestone at each reporting period.

2020 Employee Stock Purchase Plan

In April 2020, the Company's Board of Directors adopted the Company's 2020 Employee Stock Purchase Plan ("2020 ESPP"). The 2020 ESPP is structured as a qualified employee stock purchase plan under Section 423 of the Internal Revenue Code of 1986, as amended, and is not subject to the provisions of the Employee Retirement Income Security Act of 1974. The Company initially reserved 150,000 shares of common stock for issuance under the 2020 ESPP. In addition, the number of shares available for issuance under the 2020 ESPP will be annually increased on January 1st of each year from 2021 to 2030 by the lesser of (i) 0.5% of the number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares as is determined by the Company's Board of Directors, provided that no more than 987,500 shares of common stock may be issued under the 2020 ESPP. On January 1, 2021, the shares available for grant under the 2020 ESPP was automatically increased by 64,661. The 2020 ESPP permits eligible participants to purchase common stock through payroll deductions of up to a specified percentage of their eligible compensation. On the first trading day of each offering period, each participant will automatically be granted an option to purchase shares of the Company's common stock. The option will expire at the end of the applicable offering period, and will be exercised at that time to the extent of the payroll deductions accumulated during the offering period, subject to the limits set forth in the 2020 ESPP. The purchase price of the shares, in the absence of a contrary designation, will be 85% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the purchase date. As of June 30, 2021, no shares have been issued under the 2020 ESPP.

8. Income Taxes

During the three and six months ended June 30, 2021 and 2020, the Company recorded a full valuation allowance on federal and state deferred tax assets since management does not forecast the Company to be in a taxable position in the near future.

9. Leases

In August 2007, the Company entered into an operating lease, as amended, for approximately 22,343 square feet of office and laboratory space in Watertown, Massachusetts. In November 2017, the Company amended its lease ("2017 Amendment") and extended the lease term through April 2023. Initial base rent under the 2017 Amendment was approximately $1.0 million per year. The 2017 Amendment includes annual rent escalations over the term of the operating lease. 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 of certificate of deposits, 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.

In addition to the lease discussed above, the Company is party to an April 2020 lease for office equipment that expires in June 2024. The equipment lease is accounted for as an operating lease.

Embedded Leases

In April 2021, the Company entered into a clinical supply agreement with a contract manufacturing organization ("CMO") for clinical production of the Company's product candidates at an existing facility and a facility under construction. The Company concluded that this clinical supply agreement contains embedded operating leases as the clean rooms in the existing facility and the new facility are designated for the Company's exclusive use during the term of the agreement and the clinical supply agreement contains fixed commitments and variable costs related to production and material costs in excess of the fixed commitment specified in the agreement. The Company determined that it did not control the new facility during construction and, thus, the lease did not fall in the scope of "build-to-suit" accounting. The term of the clinical supply agreement is five years and will automatically renew for additional successive terms of one year unless either party gives notice of nonrenewal.

The lease period for the existing facility is less than 12 months and the Company has elected to apply the practical expedient in ASC Topic 842, *Leases* ("ASC 842"), to not recognize a lease liability or right-of-use asset but instead, recognize lease payments as an expense on a straight-line basis over the lease term and variable lease payments that do not depend on an index or rate, as an expense in the period in which the variable lease costs are incurred based on performance or usage in accordance with the clinical supply agreement.

At the inception of the new facility lease, the Company determined the fixed commitment specified in the purchase order issued under the clinical supply agreement was not material and did not recognize a lease liability and right-of-use asset. The lease costs under this purchase order will be recognized as expense in the period in which the lease costs are incurred based on performance or usage in accordance with the purchase order. In the future, the Company will purchase product in batches from the CMO in quantities to be set forth on purchase orders submitted to the CMO, within a certain time period, prior to the requested date of delivery. The quantities of product ordered on each purchase order are binding obligations to purchase from the CMO and considered fixed commitments and the Company will recognize the appropriate lease liability and right-of-use asset at that time.

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,	
	2021	2020	2021	2020
Lease Cost:				
Operating lease cost	$ 264	$ 264	$ 528	$ 527
Variable lease cost	1,243	177	1,362	370
Total lease cost	$ 1,507	$ 441	$ 1,890	$ 897

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 and variable lease costs associated with the Company's CMO embedded lease arrangement. During the three and six months ended June 30, 2021, the Company recorded as research and development expense approximately $1.1 million of operating lease costs related to the CMO embedded lease.

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

	As of June 30, 2021
Weighted-average remaining lease term (in years)	1.8
Weighted-average discount rate	5.5%

Maturity of the Company's operating lease liabilities in accordance with ASC 842 as of June 30, 2021 were as follows (in thousands):

Year ending December 31,	
Remainder of 2021	$ 553
2022	1,127
2023	382
2024	2
Total maturities	2,064
Less: Amount representing interest	(106)
Present value of operating lease liability	1,958
Less: Current portion of operating lease liability	(1,029)
Total operating lease liability, net of current portion	$ 929

10. Collaboration Agreement

On May 31, 2021, the Company entered into the LianBio License Agreement 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 Agreement, the Company received an upfront payment of $12.0 million and 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, the Company 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 the Company will retain all rights to LYR-210 in all other geographies. As part of the LianBio Agreement, LianBio will also have the first right to obtain development and commercial rights in the licensed territories to the Company's LYR-220 product candidate.

At the commencement of the arrangement, one combined unit of accounting was identified, which includes the license to develop and commercialize LYR-210, manufacturing activities related to the supply of LYR-210, and a non-exclusive license to manufacture LYR-210 and obligation to transfer manufacturing technology in the case of a supply failure. The Company determined that these performance obligations 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.

The Company analyzed the combined unit of accounting to assess whether it falls within the scope of Topic 808, *Collaborative Arrangements* ("ASC 808"), and will reassess this throughout the life of the arrangement based on changes in the roles and responsibilities of the parties. Based on the terms of the arrangement as outlined above, for the collaboration research performed prior to submitting for regulatory approval in the licensed territories, both parties are deemed to be active participants in the collaboration. Both parties are performing research and development activities and will share in these costs through submission to regulatory authorities. Additionally, the Company and LianBio are exposed to significant risks and rewards dependent on the commercial success of LYR-210. As such, the collaboration arrangement is deemed to be within the scope of ASC 808.

Consistent with its collaboration accounting policy, the Company will recognize the upfront payment of $12.0 million in future periods as it satisfies its performance obligations.

The Company 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.

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 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 therapeutics company focused on the development and commercialization of novel integrated drug and delivery solutions for the localized treatment of patients with ear, nose and throat diseases. Our proprietary technology platform, XTreo, is designed to precisely and consistently deliver medicines directly to the affected tissue for sustained periods with a single administration. Our initial product candidates, LYR-210 and LYR-220, are bioresorbable polymeric matrices designed to be administered in a brief, non-invasive, in-office procedure and intended to deliver up to six months of continuous drug therapy to the sinonasal passages for the treatment of chronic rhinosinusitis, or CRS. The therapeutic embedded within LYR-210 and LYR-220 is mometasone furoate, 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. We are advancing LYR-210 as a potential preferred alternative to surgery in our Phase 2 randomized, sham procedure-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 cleared 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 global pandemic we discontinued enrollment at 67 patients in our Phase 2 LANTERN clinical trial and did not enroll patients in the United States.

On December 7, 2020, we reported positive top-line results from our Phase 2 LANTERN clinical trial, including that the 7,500 µg dose of LYR-210 achieved statistically significant improvement in the composite four cardinal symptoms score, or 4CSS, in favor of the treatment arm as measured by the change from baseline at weeks 16, 20, and 24. However, although a strong treatment effect was observed at week 4, LYR-210 did not achieve the primary endpoint of change from baseline in 4CSS at week 4 at either the 7,500 µg dose or 2,500 µg dose. We believe this was due primarily to the discontinuation of enrollment related to the COVID-19 global pandemic. As a result of the decrease in the number of patients enrolled from planned (99 evaluable) to actually enrolled (67), a greater magnitude of change from baseline in 4CSS at week 4 and/or a smaller standard deviation associated with the change from baseline was required in order to achieve statistical significance for the primary endpoint at week 4. LYR-210 was observed to be safe and well-tolerated at all doses in the trial, and no treatment-related serious adverse events were reported.

In addition, although we collected certain pharmacokinetic data from all patients in our Phase 2 LANTERN clinical trial starting at week 4, our protocol contemplated utilizing a subset of U.S. patients to collect certain additional pharmacokinetic data in order to support the NDA for LYR-210. However, because we were unable to enroll patients in the United States due to the COVID-19 pandemic, we were unable to collect these additional pharmacokinetic, or PK, data as planned. As a result, in September 2020, we initiated a separate characterization study in the United States to collect these additional data. The PK study was a 56-day open label, multi-center, U.S. study of the PK and safety of LYR-210 in adult subjects with chronic rhinosinusitis. The primary objective of the study was to establish the PK profile of LYR-210. The study enrolled 24 patients, half of whom received LYR-210 2500 µg and the other half received LYR-210 7500 µg. The study indicated that both doses were safe and well tolerated, with the mean maximum plasma concentration, or Cmax, observed with the 7500 ug dose well below the Cmax established for FDA-approved formulations of mometasone furoate, or MF. MF blood plasma levels observed during the PK study support LYR-210's ability to deliver consistent and steady dosing over the entire treatment period.

In our Phase 1 clinical trial, LYR-210 met its primary safety endpoint, and we observed that patients generally experienced significant, rapid, clinically meaningful, and durable improvement in SNOT-22 scores, an established patient symptom severity scale, through week 25, which was the end of the trial. Secondary findings from our Phase 1 clinical trial showed that LYR-210 demonstrated significant reduction of sinonasal Type 2 inflammation in surgically-naïve patients with CRS. The reduction of Type 2 inflammation suggests a correlation with rhinologic symptom improvement in CRS and could be a potential measure of LYR-210's local anti-inflammatory effects at the site of inflammation in the sinonasal passages.

We are also developing LYR-220 for use in CRS patients who have an enlarged nasal cavity due to sinus surgery but continue to require treatment to manage CRS symptoms and, subject to the impact of COVID-19 on our business, we intend to initiate a Phase 2 clinical trial for LYR-220 by the end of 2021. Beyond CRS, we believe our XTreo platform has potential applications in other disease areas, which we are actively exploring to further broaden its therapeutic potential.

We were incorporated as a Delaware corporation on November 21, 2005, and our headquarters is located in Watertown, Massachusetts. 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 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 initial public offering, or 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.

Prior to our IPO, we funded our operations primarily through private placements of redeemable convertible preferred stock and funding from government contracts. From inception through June 30, 2021, we have raised an aggregate of $248.8 million to fund our operations, of which $162.1 million were gross proceeds from sales of our redeemable convertible preferred stock, $57.3 million were net proceeds from our IPO, $16.8 million were gross proceeds from government contracts and $12.0 million were gross proceeds from our license and collaboration agreement.

We have incurred significant net operating losses in every year since our 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 were $11.0 million and $4.5 million for the three months ended June 30, 2021 and 2020, respectively, and $18.8 million and $8.8 million for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, we had an accumulated deficit of $168.7 million. We anticipate that our expenses will increase significantly as we:

- conduct additional clinical trials of our most advanced product candidate, LYR-210, including one or more planned pivotal Phase 3 clinical trials of LYR-210;
- advance the development of LYR-220;
- continue to discover and develop additional product candidates;
- establish manufacturing and supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain marketing approval;

- seek regulatory and marketing approvals for product candidates that successfully complete 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;
- hire additional staff, including clinical, scientific, technical, regulatory, operational, financial commercial, and support personnel, to execute our business plan; and
- add clinical, scientific, operational, financial, and management information systems and personnel to support our product development and potential future commercialization efforts, and to enable us to operate as a public company.

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. Additionally, we currently use contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, to carry out our clinical development activities. 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 and pursue our growth strategy. 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 candidates, 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.

COVID-19 Pandemic and CARES Act

On January 30, 2020, the World Health Organization, or WHO, announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China, or the COVID-19 outbreak, and the risks to the international community as the virus subsequently spread globally beyond its point of origin. On March 11, 2020, the WHO classified the COVID-19 outbreak as a pandemic, based on the rapid increase in exposure globally. The COVID-19 pandemic is affecting the United States and global economies and may affect our operations and those of third parties on which we rely, including by causing disruptions in the supply of our product candidates and the conduct of current and future clinical trials. In addition, the COVID-19 pandemic may affect the operations of the FDA and other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates. Additionally, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change, including the length of time needed to vaccinate a significant segment of the global population and effectiveness of the vaccines with respect to the new variants of the virus. We do not yet know the full extent of potential delays or impacts on our business, financing, or clinical trial activities, or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on our liquidity, capital resources, operations, and business and those of the third parties on which we rely.

On March 27, 2020, President Trump signed into law the “Coronavirus Aid, Relief, and Economic Security (CARES) Act.” The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations, increased limitations on qualified charitable contributions, and technical corrections to tax depreciation methods for qualified improvement property. We deferred the employer side social security payments. The CARES Act also appropriated funds for the Small Business Administration Paycheck Protection Program loans that are forgivable in certain situations to promote continued employment, as well as Economic Injury Disaster Loans to provide liquidity to small businesses harmed by the COVID-19 pandemic. On December 27, 2020, the Consolidated Appropriations Act, 2021 was signed into law in order to provide further stimulus and support to those affected by the COVID-19 pandemic. We have not and do not plan on obtaining funding from

such loans. We do not believe the CARES Act or the Consolidated Appropriations Act, 2021 will have a material impact on our financial condition, results of operations, or liquidity.

As of June 30, 2021, we had cash and cash equivalents totaling $69.0 million. We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into 2023. 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, our platform, 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 and development 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.

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. To date, we have not recognized any collaboration revenue from our License and Collaboration Agreement, or LianBio License Agreement, with LianBio Inflammatory Limited, or LianBio.

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 our revenue for the next several years will be derived primarily from our collaboration agreement with LianBio as well as any additional collaborations that we may enter into in the future. We cannot provide assurance as to the timing of future milestone or royalty payments or that we will receive any of these payments at all.

Collaboration Agreement

On May 31, 2021, we entered into the LianBio License Agreement 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 and are 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.

At the commencement of the arrangement, one combined unit of accounting was identified, which includes the license to develop and commercialize LYR-210, manufacturing activities related to the supply of LYR-210, and a non-exclusive license to manufacture LYR-210 and obligation to transfer manufacturing technology in the case of a supply failure. We determined that these performance obligations 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.

We analyzed the combined unit of accounting to assess whether it falls within the scope of Topic 808, *Collaborative Arrangements*, or ASC 808, and will reassess this throughout the life of the arrangement based on changes in the roles and responsibilities of the parties. Based on the terms of the arrangement as outlined above, for the collaboration research performed prior to submitting for regulatory approval in the licensed territories, both parties are deemed to be active participants in the collaboration. Both parties are performing research and development activities and will share in these costs through submission to regulatory authorities. Additionally, we and LianBio are exposed to significant risks and rewards dependent on the commercial success of LYR-210. As such, the collaboration arrangement is deemed to be within the scope of ASC 808.

Consistent with our collaboration accounting policy, we will recognize the upfront payment of $12.0 million in future periods as we satisfy our performance obligations.

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.

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 preclinical studies and clinical trials, including fees paid to CMOs as well as other manufacturers that provide components of our product candidates for use in our preclinical and 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.

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 continue to increase for the foreseeable future as we initiate additional clinical trials, including one or more clinical trials for LYR-210 and LYR-220, scale our manufacturing processes, and continue to discover and develop additional product candidates.

The successful development of LYR-210, LYR-220, 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, LYR-220, and any potential future product candidates that are satisfactory to the FDA or any comparable foreign regulatory authority;
- approval of an IND for LYR-220 and 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 the COVID-19 global pandemic.

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, and public relations, accounting, auditing, tax services, and insurance costs.

We expect that our general and administrative expenses will increase in the future to support continued research and development activities and potential commercialization of our product candidates. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, attorneys, and accountants, among other expenses. Additionally, we will continue to incur increased expenses associated with being a public company, including costs of additional personnel, 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.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our 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, and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements during the reporting periods. 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.

Our critical accounting policies are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies" in our Annual Report on Form 10-K filed with the SEC on March 9, 2021 and the notes to the unaudited condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. During the six months ended June 30, 2021, there were no material changes to our critical accounting policies from those discussed in our Annual Report on Form 10-K except as otherwise described in Note 2, *Summary of Significant Accounting Policies*, in the Notes to Condensed Consolidated Financial Statements.

Recently Adopted Accounting Pronouncements

We have reviewed all recently issued standards and have determined that, other than as disclosed in Note 2 to 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, 2021 and 2020

The following table summarizes our results of operations for the three months ended June 30, 2021 and 2020 (in thousands):

	Three Months Ended June 30,		Dollar
	2021	2020	Change
Operating expenses:			
Research and development	$ 7,505	$ 2,103	$ 5,402
General and administrative	3,560	2,442	1,118
Total operating expenses	11,065	4,545	6,520
Loss from operations	(11,065)	(4,545)	(6,520)
Other income:			
Interest income	26	5	21
Total other income	26	5	21
Net loss	$ (11,039)	$ (4,540)	$ (6,499)

Research and Development Expenses

Research and development expenses increased by $5.4 million to $7.5 million for the three months ended June 30, 2021 from $2.1 million for three months ended June 30, 2020.

The increase in research and development expenses for the three months ended June 30, 2021 was primarily attributable to an increase in product development and manufacturing expenses of $2.4 million as we continue to increase our manufacturing capacity and produce our first product at our CMO; an increase in employee related costs of $1.0 million as we increased research and development headcount; an increase in clinical expenses of $0.8 million as we completed our separate characterization study to collect additional pharmacokinetic data, completed the final data analysis of our LANTERN clinical and prepare for a LYR-220 clinical trial; and an increase in consulting expenses of $0.7 million.

General and Administrative Expenses

General and administrative expenses increased by $1.1 million to $3.6 million for the three months ended June 30, 2021 from $2.4 million for the three months ended June 30, 2020.

The increase in general and administrative expenses for the three months ended June 30, 2021 was primarily attributable to an increase in professional and consulting expenses of $0.7 million; and an increase in costs associated with being a public company of $0.4 million.

Interest Income

Interest income increased by $21,000 to $26,000 for the three months ended June 30, 2021 from $5,000 for the three months ended June 30, 2020. The increase was attributable to investing a greater proportion of our cash and cash equivalent balances in interest bearing investments during the three months ended June 30, 2021 compared to the due to the three months ended June 30, 2020.

Comparison of the Six Months Ended June 30, 2021 and 2020

The following table summarizes our results of operations for the six months ended June 30, 2021 and 2020 (in thousands):

	Six Months Ended June 30,		Dollar
	2021	2020	Change
Operating expenses:			
Research and development	$ 12,275	$ 5,067	$ 7,208
General and administrative	6,621	3,726	2,895
Total operating expenses	18,896	8,793	10,103
Loss from operations	(18,896)	(8,793)	(10,103)
Other income:			
Interest income	55	21	34
Total other income	55	21	34
Net loss	$ (18,841)	$ (8,772)	$ (10,069)

Research and Development Expenses

Research and development expenses increased by $7.2 million to $12.3 million for the six months ended June 30, 2021 from $5.1 million for the six months ended June 30, 2020.

The increase in research and development expenses for the six months ended June 30, 2021 was primarily attributable to an increase in product development and manufacturing expenses of $3.1 million as we continue to increase our manufacturing capacity and produce our first product at our CMO; an increase in employee related costs of $1.7 million as we increased research and development headcount, including an increase of $0.2 million of stock-based compensation; an increase in consulting expenses of $1.0 million; an increase in clinical expenses of $0.9 million as we completed our separate characterization study to collect additional pharmacokinetic data, completed the final data analysis of our LANTERN clinical and prepare for a LYR-220 clinical trial; and an increase in depreciation expense of $0.4 million as a result of our investment in manufacturing infrastructure.

General and Administrative Expenses

General and administrative expenses increased by $2.9 million to $6.6 million for the six months ended June 30, 2021 from $3.7 million for the six months ended June 30, 2020.

The increase in general and administrative expenses for the six months ended June 30, 2021 was primarily attributable to an increase in costs associated with being a public company of $1.4 million, in particular an increase in the cost of directors and officers insurance of $0.7 million; an increase in professional and consulting expenses of $1.0 million; and an increase in employee related costs of $0.5 million, including an increase of $0.3 million of stock-based compensation.

Interest Income

Interest income increased by $34,000 to $55,000 for the six months ended June 30, 2021 from $21,000 for the six months ended June 30, 2020. The increase was attributable to higher average cash and cash equivalent balances partially offset by lower interest rates for the six months ended June 30, 2021 due to changes in market conditions.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations from inception through June 30, 2021 primarily with gross proceeds of $162.1 million from sales of our redeemable convertible preferred stock, net proceeds of $57.3 million from our IPO, $16.8 million from government contracts and $12.0 were gross proceeds from our license and collaboration agreement. The following table provides information regarding our total cash and cash equivalents at June 30, 2021 and December 31, 2020 (in thousands):

	As of June 30, 2021	As of December 31, 2020
Cash and cash equivalents	$ 69,046	$ 74,593

We currently have an effective shelf registration statement on Form S-3 (No. 333-256020) filed with the SEC on May 11, 2021, or the Form S-3, under which we 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 $250.0 million in the aggregate. As of June 30, 2021, we have not sold any securities under the Form S-3.

On May 11, 2021, we entered into an Open Market Sales Agreement, or 2021 ATM Agreement, with Jefferies LLC, or Jefferies, to sell shares of our common stock, from time to time, with aggregate gross sales proceeds of up to $50.0 million, through an at-the-market equity offering program under which Jefferies will act as our sales agent. As of June 30, 2021, we had received no proceeds from the sale of shares of common stock pursuant to the 2021 ATM Agreement.

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2021 and 2020 (in thousands):

	Six Months Ended June 30,	
	2021	2020
Net cash used in operating activities	$ (4,209)	$ (11,495)
Net cash used in investing activities	(1,785)	(85)
Net cash provided by financing activities	447	88,371
Net (decrease) increase in cash and cash equivalents	$ (5,547)	$ 76,791

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 $4.2 million for the six months ended June 30, 2021 compared to $11.5 million for the six months ended June 30, 2020. The decrease in cash used in operating activities of $7.3 million was primarily attributable to increases in cash provided by operating activities resulting from:

- $12.0 million upfront payment under the LianBio License Agreement;
- $0.5 million increase in stock-based compensation
- $0.4 million increase in depreciation expense; and
- $4.5 million increase in changes in the components of working capital.

The increase in cash provided by operating activities was offset by a $10.0 million increase in net loss.

Net Cash Used in Investing Activities

Net cash used in investing activities was $1.8 million for the six months ended June 30, 2021 compared to $85,000 for the six months ended June 30, 2020. The increase in cash used in investing activities of $1.7 million was attributable to an increase in cash used for the purchase of property and equipment, primarily for manufacturing our product candidates.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $0.4 million for the six months ended June 30, 2021 compared to $88.4 million for the six months ended June 30, 2020. The decrease in cash provided by financing activities of $87.9 million in the six months ended June 30, 2021 was primarily attributable to the net proceeds from our IPO and the sale of our Series C redeemable convertible preferred stock in the six months ended June 30, 2020.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development for, begin the manufacturing scale up process for, initiate later stage clinical trials for, and seek marketing approval for, our product candidates. In addition, if 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.

We expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into 2023. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the costs of conducting future clinical trials of LYR-210;
- the costs of manufacturing additional material for one or more pivotal Phase 3 clinical trials of LYR-210 and potential future clinical studies we might conduct for our other product candidates;
- the costs of scaling up our manufacturing process and supply chain capacity to provide sufficient quantities of LYR-210 for the potential commercialization of LYR-210 if our clinical development program is successful and we obtain marketing approval;
- the advancement of LYR-220;

- the scope, progress, results, and costs of discovery, preclinical 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 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;
- our headcount growth and associated costs as we expand our business operations, our research and development activities, and our manufacturing scale up;
- the costs of operating as a public company; and
- the cost of potential business interruptions resulting from the COVID-19 pandemic.

Identifying potential product candidates and conducting preclinical 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.

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 have access to additional funds to be earned in connection with our LianBio License Agreement, if development activities are successful under that agreement. 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.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012, or 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 $1.07 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, 2021.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 included or incorporated by reference 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 Financial Position and Need for Additional Capital

We have a limited operating history and a history of escalating operating losses, which may make it difficult to evaluate the prospects for our future viability.

We are a clinical-stage therapeutics company established in November 2005. Our operations to date have been limited to financing and staffing our company, developing our technology, and identifying and developing our product candidates. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. We have not yet demonstrated an ability to obtain marketing approval, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing, obtaining marketing approval for, and commercializing CRS treatments.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown obstacles. We will eventually need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

As we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any particular quarterly or annual period as indications of future operating performance.

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 $11.0 million and $4.5 million for the three months ended June 30, 2021 and 2020, respectively, and $18.8 million and $8.8 million for the six months ended June 30, 2021 and 2020, 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 addition, we expect to continue to incur significant additional operating losses for the foreseeable future as we seek to advance product candidates through pre-clinical and clinical development, expand our research and development activities, develop new product candidates, complete pre-clinical studies and clinical trials, seek regulatory approval, and, if we receive FDA approval, commercialize our products. 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 ENT disease 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 and as we:

- continue additional clinical trials of our most advanced product candidate, LYR-210, including the characterization study for LYR-210 initiated in September 2020 to collect pharmacokinetic data and one or more planned pivotal Phase 3 clinical trials of LYR-210;
- advance the development of LYR-220;
- continue to discover and develop additional product candidates;
- establish manufacturing and supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain marketing approval;
- seek regulatory and marketing approvals for product candidates that successfully complete 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;
- hire additional staff, including clinical, scientific, technical, regulatory, operational, financial, commercial, and support personnel, to execute our business plan;
- add clinical, scientific operational, financial, and management information systems and personnel to support our product development and potential future commercialization efforts, and as to enable us to operate as a public reporting company;
- 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;
- expand internationally;
- make royalty, milestone, or other payments under any future in-license agreements;
- implement additional internal 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 securing of manufacturing supply, capacity, and expertise, the use of external vendors, the building of a 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 manufacturing, sales, and 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.

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. 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.

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. 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. 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, obtain approval for, and commercialize our product candidates, including LYR-210, for which we plan to commence one or more pivotal Phase 3 clinical trials. We will also require substantial funds to further develop, obtain approval for, and commercialize our other product candidate, LYR-220, which is in pre-clinical development.

Based on our current operating plan, we believe that our current cash and cash equivalents will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into 2023. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. Because the length of time and activities associated with successful development of LYR-210 and LYR-220 is highly uncertain, we are unable to estimate the actual funds we will require for development, approval, and any approved marketing and commercialization activities. 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 the COVID-19 pandemic or other causes;
- the timing of, and the costs involved in, obtaining regulatory approvals for LYR-210 and LYR-220;
- 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;
- the cost of establishing sales, marketing, and distribution capabilities for our product candidates in regions where we choose to commercialize our products; and
- the initiation, progress, timing, and results of our commercialization of LYR-210 and LYR-220, if approved for commercial sale.

Depending on our business performance, the economic climate, and market conditions, we may be unable to raise additional funds through any sources. Market volatility resulting from the COVID-19 pandemic or other causes could also adversely impact our ability to access capital as and when needed. If we are unable to obtain adequate funding on a timely basis, we may be required to curtail or discontinue one or more of our development programs for LYR-210 or LYR-220, or to reduce our operations. If we raise additional funds by issuing equity securities, our then-existing stockholders will experience dilution and the terms of any new equity securities may have preference over those of our existing common stock.

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

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.

Our product candidates are in various stages of development.

We are a therapeutics company focused on the development and commercialization of novel integrated drug and drug delivery solutions for the localized treatment of patients with ENT diseases. Our product candidates are at stages of pre-clinical or clinical development, and favorable results in pre-clinical or 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, our product candidates may fail to be safe and effective in current or future clinical trials or pre-clinical studies, or we may have inadequate financial or other resources to pursue discovery and development efforts for new product candidates. Our product candidates will require significant additional development, clinical trials, regulatory authorizations, and additional investment by us before they can be commercialized.

Our business is highly dependent on the success of our most advanced product candidate, LYR-210, which will require significant additional clinical testing before we can seek regulatory approval and potentially launch commercial sales. 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 require additional 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 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, 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 or our other product candidates 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 global 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. There can be no assurance that we will be able to design a Phase 3 clinical trial for LYR-210 with a primary endpoint we desire, and in any event there can be no assurance that we will achieve the primary endpoint or any other endpoints in any Phase 3 clinical trial we commence for LYR-210.

Moreover, while we leveraged remote electronic data collection to enable us to complete the clinical assessments and generate sufficient information in our Phase 2 LANTERN clinical trial to commence designing our Phase 3 clinical trial, there can be no assurance that the COVID-19 pandemic or other delays or disruptions will not hinder our electronic data collection or our ability to collect data or measurements requiring sinus imaging to assess reduction in inflammation and phlebotomy to assess pharmacokinetics/pharmacodynamics. 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. The characterization study was a 56-day open label, multi-center, U.S. study of the PK and safety of LYR-210 in adult subjects with chronic rhinosinusitis. The primary objective of the study was to establish the PK profile of LYR-210. The study enrolled 24 patients, half of whom received LYR-210 2500 µg and the other half received LYR-210 7500 µg. The study indicated that both doses were safe and well tolerated, with the mean maximum plasma concentration, or Cmax, observed with the 7500 ug dose well below the Cmax established for FDA-approved formulations of mometasone furoate, or MF. MF blood plasma levels observed during the PK study support LYR-210's ability to deliver consistent and steady dosing over the entire treatment period. There can be no assurance that any future trial we may conduct will not be affected or further affected by the COVID-19 pandemic or other delays and disruptions.

If the required regulatory approvals for LYR-210 are not obtained or are significantly delayed, including as a result of the COVID-19 pandemic, or any approved products are not commercially successful, our business, financial condition, and results of operations may be materially harmed.

LYR-210 is our most advanced product candidate, and if we experience regulatory or developmental issues with respect to LYR-210, our development plans and business could be significantly harmed. Moreover, if we experience similar regulatory or developmental issues with our other pipeline product candidates, 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 have entered into a License and Collaboration Agreement with LianBio Inflammatory Limited on May 31, 2021, or the LianBio License Agreement. The LianBio License Agreement grants an exclusive license to develop and commercialize the Company's product candidate LYR-210, an anti-inflammatory, intra-nasal drug matrix designed to treat chronic rhinosinusitis Disease 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 Lyra's product candidate LYR-220, an anti-inflammatory, intra-nasal, drug matrix in development for the treatment of chronic rhinosinusitis patients who have undergone a prior sinus surgery but continue to have persistent disease in the Territory. 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.

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 carveouts. We also made certain covenants to grant an exclusive option to LianBio for the development and commercialization of our product candidate, 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 III clinical trial for LR-210 and seek regulatory approval for the same 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 have entered into a collaboration, and may enter into 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, in May 2021, we entered into 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 drugs, 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 not be successful in our efforts to identify and successfully commercialize additional product candidates.

Part of our strategy involves identifying novel product candidates. The process by which we identify product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- competitors may develop alternatives that render our potential product candidates obsolete or less attractive;
- potential product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- potential product candidates may, on further study, be shown to have harmful side effects, toxicities, or other characteristics that indicate that they are unlikely to be products that will receive marketing approval or achieve market acceptance;
- potential product candidates may not be effective in treating their targeted diseases or symptoms;
- the market for a potential product candidate may change so that the continued development of that product candidate is no longer reasonable;
- a potential product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- the regulatory pathway for a potential product candidate is highly complex and difficult to navigate successfully or economically.

In addition, we may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful, or to license or purchase a marketed product that does not meet our financial expectations. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such product candidates through collaboration, licensing, or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. If we are unable to identify and successfully commercialize additional suitable product candidates, this would adversely impact our business strategy and our financial position.

We may 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 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 plan to commence one or more pivotal Phase 3 clinical trials for our most advanced product candidate, LYR-210. Our other product candidate, LYR-220, is in pre-clinical development. It is impossible to predict when or if either of our product candidates will prove effective and safe in humans or if we will receive regulatory approval for any of our product candidates, and the risk of failure through the development process is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must 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 the COVID-19 pandemic.

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 may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- any 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. For example, our Phase 2 LANTERN clinical study for LYR-210 did not meet its primary endpoint and the FDA may not find such result to be sufficient to advance to a Phase 3 pivotal study. 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, LYR-220, 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, LYR-220, or any future product candidate could be harmed, and our ability to generate revenues from LYR-210, LYR-220, 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.

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.

Both of our current product candidates are in clinical or pre-clinical development stages. Notwithstanding the data obtained to date with respect to LYR-210 and LYR-220 in CRS, LYR-210 and LYR-220 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 the COVID-19 pandemic, or other problems, our developmental plans and business could be significantly harmed. For example, our Phase 2 LANTERN clinical trial for LYR-210 failed to meet its primary endpoint which may delay our overall commercialization efforts.

If the development of LYR-210, LYR-220, or any other future product candidate is unsuccessful, our ability to generate revenues will be 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 biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. 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. For example, our Phase 2 LANTERN clinical trial for LYR-210 failed to meet its primary endpoint and we may be required to conduct additional trials to evaluate the efficacy of this product candidate beyond those trials we currently anticipate.

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. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. 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 certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates may likely 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 our current product candidates, LYR-210 and LYR-220, and we may seek FDA approval for future product candidates, 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, specifically in Australia, Austria, Czech Republic, New Zealand, and Poland, and we may in the future choose to conduct other clinical trials outside the United States for LYR-210, LYR-220, 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 good clinical practice, or 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 and LYR-220 are drug-device combinations, which may result in additional regulatory and other risks.

LYR-210 and LYR-220 are drug-device combination products. We may experience delays in obtaining regulatory approval of these product candidates given the increased complexity of the review process when approval of a drug and a delivery device is sought under a single marketing application. Both LYR-210 and LYR-220 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 or LYR-220, 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 and LYR-220.

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 the COVID-19 pandemic, 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, LYR-220, 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, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products through April 2020, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic, 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 the ongoing 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, LYR-220, 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. For more information, see "Business—LYR-210 for the Treatment of CRS—Overview of Our Clinical Development."

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 who had a serious adverse event of Acarodermatitis in our Phase 2 LANTERN clinical trial, which was deemed to be not related to treatment.

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, or DSMB, 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 currently train and expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition, and prospects significantly.

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.

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

As product candidates proceed through pre-clinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

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 due to liability. If we obtain marketing approval for LYR-210 and/or LYR-220, 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.

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; (iii) data privacy, security, fraud and abuse, and other healthcare laws and regulations; or (iv) laws that require the reporting of true, complete, and accurate financial information and data. 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 hurricanes), terrorism, war, 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, LYR-220, 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 the COVID-19 pandemic. Although, to our knowledge, we have not experienced any material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost, or stolen. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, 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 and interpretations of existing healthcare statutes and regulations are frequently adopted.

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, with the temporary suspension from May 1, 2020 through December 31, 2020, 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 current good manufacturing practice, or 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 control.

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, manufacturers, or manufacturing processes, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such products;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- 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, LYR-220, 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 or commercialized in a timely manner, which could negatively impact our business.

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products through April 2020, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic, including providing guidance regarding the conduct of clinical trials. If a prolonged government shutdown occurs, or 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. 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. Beginning in 2022, such obligations will 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.

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 our partners may be subject to diverse laws and regulations relating to data privacy and security, including, in the United States, HIPAA 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. For example, on June 28, 2018, California enacted the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020. 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 data breaches that is expected to increase data breach litigation. Complying with these numerous, complex, and often changing regulations is expensive and difficult, and 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 sensitive or confidential patient or consumer information, whether by us or another third-party, could adversely affect our business, financial condition, and results of operations, including but not limited to: 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 went into effect on May 25, 2018. 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; in July 2020, the Court of Justice of the European Union limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the EU-US Privacy Shield and imposing further restrictions on use of the standard contractual clauses, 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 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, and the expiry of the transition period, companies will 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. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk.

We cannot assure you that our third-party service providers with access to our or our customers', suppliers', trial patients', and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible 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 and thus are not subject to its requirements or penalties. 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 or third-party CMOs, 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. 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, the production efforts of our third-party manufacturers or 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. 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 drugs. 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.

Significant competition exists in the treatment of CRS. We will need to compete with all currently available or future therapies within the indications where our development is focused. LYR-210, if approved and commercialized, will face significant competition. The main classes of marketed products that are available for the treatment of CRS include nasal saline irrigation, intranasal corticosteroidal sprays and antibiotics, as well as surgical intervention. In addition, one company is currently marketing, and several companies are also currently developing, biologic monoclonal antibodies, or mAbs, for the treatment of nasal polyps. If these biologic mAbs are successfully developed and approved for marketing, they could represent competition for LYR-220 for the segment of patients that have polyps.

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: Hoffman-La Roche, GlaxoSmithKline, AnaptysBio, Regeneron, OptiNose, and Intersect ENT.

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.

Further, the status of reimbursement codes for any of our product candidates, if approved, could also affect reimbursement. J-Codes and Q-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 or Q-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 or Q-Code will be granted. To the extent separate coverage or reimbursement is available for any product candidate, if approved, and a specific J-Code or Q-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. We cannot assure you that any data that we or others generate, including from any pivotal Phase 3 clinical study we may pursue for LYR-210, will be consistent with that observed in the Phase 1 clinical trial of LYR-210 and Phase 2 LANTERN clinical trial, nor that results will be maintained beyond the time points studied. 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 either LYR-210 or LYR-220 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 either LYR-210 or LYR-220 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, we may not generate significant product revenues or become profitable. The degree of market acceptance of LYR-210 or LYR-220, 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 platform;
- the perception by members of the healthcare community, including physicians, or patients that the process of administering LYR-210 or LYR-220 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 insert 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 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 through third-party manufacturers, 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 and LYR-220, our products may fail to gain market acceptance, and our business will be harmed.

Our initial product candidates, LYR-210 and LYR-220, are bioresorbable polymeric matrices designed to be administered in a brief, non-invasive, in-office procedure by an ENT physician under endoscopic visualization via a single-use applicator. While we believe ENT physicians will be able to administer our product candidates, 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 and LYR-220 receive 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 a FESS procedure in an operating room, healthcare economics are subject to change. If the use of our products were to cease being more cost-effective than FESS due to changes in reimbursement economics, our products may fail to gain market acceptance, our future growth would be limited, and our business may be adversely affected.

If we are unable to establish sales, marketing, and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing LYR-210 or LYR-220, if approved, and we may not be able to generate any revenue.

We do not have any infrastructure for the sales, marketing, or distribution of our products, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so.

We expect to build our own focused sales, distribution, and marketing infrastructure to market LYR-210 and LYR-220 in the United States, if approved. There are significant expenses and risks involved with establishing our own sales, marketing, and distribution capabilities, including our ability to hire, retain, and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing, and distribution capabilities could delay any product launch, which would adversely impact the commercialization of LYR-210. Additionally, if the commercial launch of LYR-210 or LYR-220 for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

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

We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of LYR-210, LYR-220, 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 or LYR-220, we may be forced to delay the potential commercialization of LYR-210 or LYR-220 or reduce the scope of our sales or marketing activities for LYR-210 or LYR-220. 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 LYR-220 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 or LYR-220 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.

Our future growth 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;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training and the need for language translations;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

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;
- undertaking pre-clinical testing and clinical trials;
- obtaining NDA approval by the FDA and comparable foreign regulatory approvals of product candidates;
- formulating and manufacturing products; and
- launching, marketing, and selling products.

If 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 either LYR-210 or LYR-220 is approved for commercialization, we intend to selectively 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.

Certain legal and political risks are also inherent in foreign operations. For example, it may be more difficult for us to enforce our agreements or collect receivables through foreign legal systems. There is a risk that foreign governments may nationalize private enterprises in certain countries where we may operate. In certain countries or regions, terrorist activities and the response to such activities may threaten our operations more than in the United States. Social and cultural norms in certain countries may not support compliance with our corporate policies including those that require compliance with substantive laws and regulations. Also, changes in general economic and political conditions in countries where we may operate are a risk to our financial performance and future growth. Additionally, the need to identify financially and commercially strong partners for commercialization outside the United States who will comply with the high manufacturing and legal and regulatory compliance standards we require is a risk to our financial performance. As we operate our business globally, our success will depend, in part, on our ability to anticipate and effectively manage these and other related risks. There can be no assurance that the consequences of these and other factors relating to our international operations will not have an adverse effect on our business, financial condition or results of operations.

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 our product candidates, including LYR-210 and LYR-220, 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 LYR-220, or from the degradation or dislodgment of the LYR-210 or LYR-220 polymeric matrix 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:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend the related litigation and related litigation;
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize LYR-210 or LYR-220 or any other product candidate;
- product recalls, withdrawals or labeling, marketing, or promotional restrictions;
- decreased demand for LYR-210 or LYR-220 or any other product candidate, if approved for commercial sale; and
- loss of revenue.

Risks Related to Our Dependence on Third Parties

We rely on third parties for the manufacture of materials for our research programs, pre-clinical studies, and clinical trials and we do not have long-term contracts with any of these parties. This 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 currently rely on third parties for the manufacture of our product candidates and related raw materials for future pre-clinical and clinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. We purchase certain required materials for pre-clinical and clinical drug supply on a purchase order basis. In addition, we have engaged a third-party contract manufacturer to complete the manufacturing for the anticipated LYR-210 Phase 3 clinical trials. 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 third-party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of drug products and other laws and regulations. If these third-party manufacturers cannot successfully manufacture 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 have no control over the ability of 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 entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications;
- failure to manufacture our product according to our schedule or at all;
- 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 the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of our products and product candidates will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its 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, and we expect to rely on third parties to conduct any future clinical trials and pre-clinical studies for our product candidates, including LYR-220. 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 additional CROs, investigators, and other third parties involves 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. The COVID-19 pandemic and government measures taken in response have also 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, LYR-220, 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, LYR-220, or our future product candidates successfully, if at all.

We may seek collaborative relationships for the development and commercialization of LYR-210, LYR-220, or any future product candidates. Failure to obtain a collaborative relationship for LYR-210, LYR-220, 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. The process of establishing and maintaining collaborative relationships is difficult, time-consuming, and involves significant uncertainty, such as:

- a collaboration partner may shift its priorities and resources away from our product candidates due to a change in business strategies, or a merger, acquisition, sale, or downsizing;
- a collaboration partner may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control, or other reasons;
- a collaboration partner may cease development in therapeutic areas which are the subject of our strategic collaboration;
- a collaboration partner may not devote sufficient capital or resources towards our product candidates;
- a collaboration partner may change the success criteria for a product candidate, thereby delaying or ceasing development of such candidate;
- a significant delay in initiation of certain development activities by a collaboration partner will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities;
- a collaboration partner could develop a product that competes, either directly or indirectly, with our product candidate;
- a collaboration partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution, or sale of a product;
- a collaboration partner with manufacturing responsibilities may encounter regulatory, resource, or quality issues and be unable to meet demand requirements;
- a collaboration partner may terminate a strategic alliance;
- a dispute may arise between us and a partner concerning the research, development, or commercialization of a product candidate resulting in a delay in milestones, royalty payments, or termination of an alliance and possibly resulting in costly litigation or arbitration which may divert management attention and resources; and
- a partner may use our products or technology in such a way as to invite litigation from a third party.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing, or commercialization efforts related to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense, or find alternative sources of capital. Moreover, any collaborative partners we enter into agreements with in the future may shift their priorities and resources away from our product candidates or seek to renegotiate or terminate their relationships with us.

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

We may not be able to negotiate 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 or LYR-220, 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 or LYR-220. If we obtain regulatory approval for LYR-210 or LYR-220, 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 or LYR-220. We also do not have long-term supply agreements with any of our component 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. Manufacturing 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 LYR-220 or, if we obtain regulatory approval for LYR-210 or LYR-220, to commercialize them.

We may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances, or partnerships with third-parties that may not result in the development of commercially viable products or the generation of significant future revenues.

In the ordinary course of our business, we may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances, partnerships, or other arrangements to develop new products and to pursue new markets. Proposing, negotiating, and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances, or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology, or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms, or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenues and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our future collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with any current or future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we may have limited control over the amount and timing of resources that any current or future collaborators devote to our or their future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements will be contractual in nature and will generally be terminable under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain, and enforce such licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. If our licensors do not adequately protect such licensed intellectual property, competitors may be able to use such intellectual property and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our products and product candidates, and delay or render impossible our achievement of profitability. Further, entering into such license agreements could impose various diligence, commercialization, royalty, or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects.

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, LYR-220, 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 successfully 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 biopharmaceutical companies, our commercial success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical 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 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 all 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;
- it is possible 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 and Managing Growth

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

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of product candidate development, regulatory affairs, and sales, marketing and distribution. As of June 30, 2021, we had 45 full-time employees. To manage our growth activities, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. As we expand our organization, we may have difficulty identifying, hiring, and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate, and integrate additional employees, consultants, and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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

If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers, or other significant personnel, or experience increases in our compensation costs, our business may materially suffer.

We are highly dependent on our management and directors, including our chief executive officer, Maria Palasis, Ph.D., among others. Due to the specialized knowledge each of our officers and key employees possesses with respect to our product candidates and our operations, the loss of service of any of our officers or directors could delay or prevent the successful enrollment and completion of our clinical trials. We do not carry key person life insurance on our officers or directors. Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time.

In addition, our future success and growth will depend in part on the continued service of our directors, employees, and management personnel and our ability to identify, hire, and retain additional personnel. If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of, and commercialize product candidates successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain, or motivate these additional key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to develop and commercialize product candidates will be limited.

Many of our employees have become or will soon become vested in a substantial amount of our common stock or a number of common stock options. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock. Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees.

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 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.

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.

The global pandemic caused by COVID-19 could adversely impact our business and operations, including our clinical trials.

In December 2019, a disease caused by a novel strain of the coronavirus, COVID-19, was identified in Wuhan, China, and on March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic. This virus has subsequently spread to a number of countries where we have planned or ongoing clinical trials and activities, including the United States, Australia, Austria, Czech Republic, New Zealand, and Poland, and continues to spread globally. The global pandemic and government measures taken in response have also 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, such as travel, has fallen.

In light of developments relating to the COVID-19 pandemic and the focus of healthcare providers and hospitals on fighting the virus, and consistent with the FDA's updated industry guidance for conducting clinical trials issued on March 18, 2020, we discontinued enrollment at 67 patients in our Phase 2 LANTERN clinical trial and we did not open any sites in the United States. Ultimately, LYR-210 did not achieve the primary endpoint in our Phase 2 LANTERN clinical trial, we believe due primarily 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), a greater magnitude of change from baseline in 4CSS at week 4 and/or a smaller standard deviation associated with the change from baseline was required in order to achieve statistical significance for the primary endpoint at week 4.

Moreover, although we leveraged remote electronic data collection to enable us to complete certain clinical assessments and generate sufficient information to commence designing our Phase 3 clinical trial, 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, 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. Furthermore, in response to the spread of COVID-19, we have closed our executive offices with our administrative employees continuing their work outside of our offices.

As a result of the COVID-19 pandemic, we may experience further disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling patients in our planned clinical trials;
- further delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by foreign, federal, or state governments, employers, and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages, and disruptions in delivery systems;
- interruptions in planned pre-clinical studies due to restricted or limited operations at our laboratory facility;
- limitations on employee resources that would otherwise be focused on the conduct of our pre-clinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- refusal of the FDA to accept data from clinical trials in these affected geographies; and
- interruption or delays to our sourced discovery and clinical activities.

Additionally, certain third parties, including manufacturers, medical institutions, clinical investigators, CROs, and consultants with whom we conduct business are similarly adjusting their operations and assessing their capacity in light of the COVID-19 pandemic. If these third parties continue to experience shutdowns or business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. For example, as a result of the COVID-19 pandemic, there could be delays in the manufacturing supply chain for mometasone furoate, which could delay or otherwise impact the manufacturing of LYR-210. It is also likely that the disproportionate impact of COVID-19 on hospitals and clinical sites will have an impact on recruitment and retention for our planned clinical trials.

The COVID-19 pandemic continues to evolve. The extent to which the outbreak impacts our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of COVID-19, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, and the effectiveness of actions taken and vaccines and other treatments developed in the United States and other countries to contain and treat COVID-19. The COVID-19 pandemic resulted in a widespread health crisis that adversely affected the economies and financial markets worldwide, resulting in an economic downturn that could continue to significantly impact our business, financial condition, and results of operations. To the extent the COVID-19 pandemic adversely affects our business, financial condition, and results of operations, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

Litigation against us could be costly and time-consuming to defend 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 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 underinsured could result in unanticipated costs, thereby adversely impacting our results of operations and resulting in a reduction in the trading price of our stock.

Risks Related to Our Common Stock

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 biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the 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;
- 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 recruitment or departure of key personnel;
- 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 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 biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. The COVID-19 outbreak continues to evolve. The extent to which the outbreak 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.

Our current executive officers, directors, and principal stockholders, if they choose to act together, will continue to have the ability to control or significantly influence all matters submitted to stockholders for approval.

Based on the number of shares of common stock outstanding as of June 30, 2021, our current executive officers, directors, and stockholders who own more than 5% of our outstanding common stock and their respective affiliates will, in the aggregate, hold shares representing approximately 60.9% of our outstanding voting stock. As a result, if these stockholders choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors, the composition of our management, and approval of any merger, consolidation, or sale of all or substantially all of our assets.

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 5.4 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 stockholders’ 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 $1.07 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:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this Quarterly Report on Form 10-Q;
- 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 Report on Form 10-K filed with the SEC on March 9, 2021. In particular, in that Annual Report on Form 10-K, we have provided 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 providing selected financial data and executive compensation information. 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 increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we have incurred significant legal, accounting, and other expenses that we did not incur as a private company. 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 need to 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 are evaluating 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 will be 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. If we identify one or more material weaknesses, it 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, operation, and expansion 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.

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 biopharmaceutical 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 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, 2020, we had net operating loss carryforwards, or NOLs, of $135.4 million for federal income tax purposes and $116.0 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 2037. As of December 31, 2020, we also had federal and state research and development credit carryforwards of $5.6 million, which begin to expire at various dates through 2035. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, 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. Our existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes. Future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. 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.

The impact of the Tax Cuts and Jobs Act on our financial results is not entirely clear and could differ materially from the financial statements provided herein.

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act, or TCJA, that significantly reformed the Code. The TCJA, among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; limitation of the tax deduction for interest expense; limitation of the deduction for NOLs and elimination of NOL carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such tax losses may be carried forward indefinitely); and modifying or repealing many business deductions and credits. The financial statements contained herein reflect the effects of the TCJA based on current guidance. However, there remain uncertainties and ambiguities in the application of certain provisions of the TCJA, and, as a result, we made certain judgments and assumptions in the interpretation thereof. The U.S. Treasury Department and the Internal Revenue Service may issue further guidance on how the provisions of the TCJA will be applied or otherwise administered that differs from our current interpretation. In addition, the TCJA could be subject to potential amendments and technical corrections, any of which could materially lessen or increase certain adverse impacts of the legislation on us.

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

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

In the quarter ended June 30, 2021, we did not repurchase any shares of our common stock.

Use of Proceeds from Initial Public Offering of Common Stock

On May 5, 2020, we completed the sale of 4,025,000 shares of our common stock, including 525,000 shares pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $16.00 per share. The offer and sale of the shares in our initial public offering, or IPO, was registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-236962), which was declared effective by the SEC on April 30, 2020 (the "Registration Statement").

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus for our IPO dated April 30, 2020 and filed pursuant to Rule 424(b)(4) under the Securities Act on May 1, 2020. We invested the funds received in cash equivalents and other short-term investments in accordance with our investment policy.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

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	8-K	3.1	May 5, 2020	001-39273
3.2	Amended and Restated Bylaws of the Registrant	8-K	3.2	May 5, 2020	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
10.1*†	License and Collaboration Agreement dated May 31, 2021, by and between the Registrant and LianBio Inflammatory Limited and LianBio.				
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.

† Certain portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

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 9, 2021

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

Date: August 9, 2021

By: /s/ R. Don Elsey
R. Don. Elsey
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

Certain information marked as [***] has been excluded from this exhibit because it is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

LICENSE AND COLLABORATION AGREEMENT

THIS LICENSE AND COLLABORATION AGREEMENT (this "Agreement"), entered into as of May 31, 2021 (the "Effective Date"), is entered into by and among LianBio Inflammatory Limited, a company limited by shares organized and existing under the laws of Hong Kong Special Administrative Region of the People's Republic of China ("Lian") LianBio, a corporation organized under the laws of the Cayman Islands ("LianBio") (for purposes of Sections 2.9(a) (By Lian) and 14.17 (LianBio Guarantee)) and Lyra Therapeutics, Inc., a Delaware corporation ("Lyra").

INTRODUCTION

WHEREAS, Lian wishes to obtain from Lyra and Lyra wishes to grant to Lian certain rights and licenses under intellectual property owned or controlled by Lyra to Develop, have Manufactured, and Commercialize the Licensed Product in the Field in the Territory (each as defined below), subject to the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless the context clearly indicates otherwise, the following terms used in this Agreement will have the meanings set forth in this Article 1 (Definitions):

1.1 "Accounting Standards" means, with respect to a Person, as applicable, (a) generally accepted accounting principles ("GAAP") as practiced in the United States or (b) the International Financial Reporting Standards issued by the International Financial Reporting Standards Foundation and the International Accounting Standards Board, in each case, consistently applied.

1.2 "Acquired Party" has the meaning set forth in Section 2.9(c) (Business Combinations).

1.3 "Acquirer" means, collectively, the Third Party referenced in the definition of Change of Control and such Third Party's Affiliates, other than the applicable Party in the definition of Change of Control and such Party's Affiliates, determined as of immediately prior to the closing of such Change of Control.

1.4 "Action" means any claim, action, cause of action, or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), assessment, arbitration, investigation, hearing, charge, complaint, demand, notice or proceeding of, to, from, by or before any Governmental Authority.

1.5 "Adverse Event" or "AE" has the meaning set forth in the PRC Measures for the Administration of Reporting and Surveillance of Drug Adverse Events (effective as of July 1, 2011) or the equivalent applicable Laws in any relevant Region, and generally means any untoward medical occurrence associated with the use of a product in human subjects, whether or not considered related to such product. An AE does not necessarily have a causal relationship with a product, that is, an AE can be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of such product.

1.6 "Affiliate" means, with respect to any Person, any entity controlling, controlled by or under common control with such first Person, at the time that the determination of affiliation is made and for as long as such control exists. For purposes of this definition, "control" means (a) direct or indirect ownership of more than 50% of the stock or shares having the right to vote for the election of directors of such Person (or if the jurisdiction where such Person is domiciled prohibits foreign ownership of such entity, the maximum foreign ownership interest permitted under such Laws; provided, however, that such ownership interest provides actual control over such Person), (b) status as a general partner in any partnership, or (c) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Affiliates of a Party exclude Persons who are financial investors of such Party or under common control of such financial investors other than such Party and its subsidiary entities.

1.7 "Agreement" has the meaning set forth in the Preamble.

1.8 "Alliance Manager" has the meaning set forth in Section 5.7(a) (Appointment).

1.9 "Anti-Corruption Laws" means laws, regulations, or orders prohibiting the provision of a financial or other advantage for a corrupt purpose or otherwise in connection with the improper performance of a relevant function, including without limitation, the US Foreign Corrupt Practices Act (FCPA), the Anti-Unfair Competition Law of the PRC and the Criminal Law of the PRC, and similar laws governing corruption and bribery, whether public, commercial or both, to the extent applicable in the applicable territory.

1.10 "Assigned Invention" has the meaning set forth in Section 7.1(a) (Inventions).

1.11 "Bankruptcy Code" means Title 11 of the United States Code, Section 101, *et seq.*, as amended.

1.12 "Breaching Party" has the meaning set forth in Section 12.3(a) (Termination of Material Breach).

1.13 "Business Day" means any day, other than a Saturday or a Sunday, on which the banks in Boston, New York, Beijing, Hong Kong, and Cayman Islands are open for business.

1.14 "Calendar Quarter" means each of the three month periods ending on March 31, June 30, September 30, and December 31 of any Calendar Year; provided, however: (a) the first Calendar Quarter of the Term will extend from the Effective Date to the end of the Calendar Quarter in which the Effective Date occurs; and (b) the last Calendar Quarter will extend from the beginning of the Calendar Quarter in which this Agreement expires or terminates until the effective date of such expiration or termination.

1.15 "Calendar Year" means, for the first Calendar Year, the period beginning on the Effective Date and ending on December 31, 2021, and for each Calendar Year thereafter each 12-month period commencing on January 1, and ending on December 31, except that the last Calendar Year will commence on January 1 of the year in which this Agreement expires or terminates and end on the effective date of such expiration or termination.

1.16 "Change of Control" means, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than 50% of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the direct or indirect beneficial owner of more than 50% of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of

all or substantially all of such Party's and its controlled Affiliates' assets. Notwithstanding the foregoing, any transaction or series of transactions effected for the primary purpose of financing the operations of the applicable Party (including the issuance or sale of securities for financing purposes) or changing the form or jurisdiction of organization of such Party will not be deemed a "Change of Control" for purposes of this Agreement.

1.17 "Clinical Trial" means a trial in which human subjects or patients are dosed with a drug, whether approved or investigational.

1.18 "Clinical Supply Agreement" has the meaning set forth in Section 4.1 (Supply Agreement).

1.19 "CMC" means the Chemistry, Manufacturing, and Controls portion of any Regulatory Filing.

1.20 "CMC Data" means any data included in the CMC or in any supporting development reports thereto, in each case, with respect to any Licensed Product in any country in the world.

1.21 "Commercial Plan" has the meaning set forth in Section 4.4(b) (Commercial Plan).

1.22 "Commercial Supply Agreement" has the meaning set forth in Section 4.1 (Supply Agreement).

1.23 "Commercialization" means any and all activities related to the pre-marketing, launching, marketing, promotion (including advertising and detailing), labeling, bidding and listing, pricing and reimbursement, distribution, storage, handling, offering for sale, selling, having sold, importing and exporting for sale, having imported and exported for sale, distribution, having distributed, customer service and support, and post-marketing safety surveillance and reporting of a product (including the Licensed Product), but not including Development activities or Manufacturing. "Commercializing" or "Commercialize" will be construed accordingly.

1.24 "Commercially Reasonable Efforts" means, [***].

1.25 "Competing Product" means [***].

1.26 "Confidential Information" means (a) all trade secrets or confidential or proprietary information (including any tangible materials embodying any of the foregoing) of the disclosing Party or its Affiliates provided or disclosed (directly or indirectly) to the other Party or any of its Affiliates in connection with this Agreement or disclosed in connection with the Term Sheet, (b) "Confidential Information" (as defined in the Prior CDA) that was disclosed by or on behalf of a Party or any of its Affiliates to the other Party or an y of its Affiliates under the Prior CDA and (c) the terms and conditions of this Agreement (which shall be deemed the Confidential Information of both Parties); provided, however, that Confidential Information will not include information that:

(i) is published by a Third Party or otherwise is or hereafter becomes part of the public domain by public use, publication, general knowledge, or the like through no breach of this Agreement on the part of the receiving Party or its Affiliates;

(ii) is in the receiving Party's or its Affiliates' possession prior to disclosure by the disclosing Party hereunder, and not through a prior disclosure by the disclosing Party, without any obligation of confidentiality with respect to such information (as evidenced by the receiving Party's written records or other competent evidence);

(iii) is subsequently received by the receiving Party from a Third Party without restriction and without breach of any agreement between such Third Party and the disclosing Party; or

(iv) is independently developed by or for the receiving Party without reference to, or use or disclosure of, the disclosing Party's Confidential Information (as evidenced by the receiving Party's or such Affiliate's written records or other competent evidence).

1.27 "Contract Manufacturing Organization" or "CMO" means any Third Party contract manufacturing organization.

1.28 "Control" or "Controlled" means the possession by a Party of the legal authority or right (whether by ownership, license, or otherwise other than pursuant to this Agreement), (a) with respect to any tangible Know-How, to provide such tangible Know-How to the other Party on the terms set forth herein, or (b) with respect to Patent Rights, Regulatory Approvals, Regulatory Filings, intangible Know-How, or other Intellectual Property, to grant a license, sublicense, access, or right to use (as applicable) to the other Party under such Patent Rights, Regulatory Approvals, Regulatory Filings, intangible Know-How, or other Intellectual Property on the terms set forth herein, in each case ((a) and (b)), without (i) breaching or otherwise violating the terms of any arrangement or agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use, licenses, or sublicense or (ii) paying any consideration to any Third Party, except for any Know-How, Patent Right, Regulatory Filing, Regulatory Approval or other property right that a Party in-licenses and under which the other Party elects to take a sublicense and agrees to make any associated payments to the applicable Third Party to the extent directly and specifically attributable to such other Party's activities or exercise of its license to such Know-How, Patent Right, Regulatory Fling, Regulatory Approval or other property right, which will be considered under the Control of such Party, provided that any such payments made by Lian under such a sublicense will be subject to Section 6.3(c) (Third Party Payments). Notwithstanding anything in this Agreement to the contrary, a Party will be deemed not to Control any Patent Rights, Know-How, Regulatory Filing, Regulatory Approval, or other property right that are owned or in-licensed by an Acquirer except (A) with respect to any such Patent Rights, Know-How, Regulatory Filing, Regulatory Approval, or other property right arising from active participation by employees or consultants of the Acquirer in the Development, Manufacture, or Commercialization of Licensed Products in the Field after such Change of Control, or (B) to the extent that any such Patent Rights, Know-How, Regulatory Filing, Regulatory Approval, or other property right are actually included in or used in furtherance of the Development, Manufacture, or Commercialization of Licensed Products in the Field by the Acquirer after such Change of Control.

1.29 "Cost of Goods Sold" means a Party's actual costs for the Manufacture of Licensed Products (or any component, precursor, or intermediate thereof), calculated in accordance with a Party's internal accounting policies and principles (in accordance with its Accounting Standards, consistently applied). The Cost of Goods Sold for Manufacturing activities with respect to such Licensed Product (or any component, precursor, or intermediate thereof) includes costs for the following, in each case, directly allocable to the Manufacture of such Licensed Products:

(a) [***]t;

(b) [***];

(c) [***];

(d) [***];

(e) [***];

(f) [***];

(g) [***];

(h) [***]; and

(i) [***];

but excludes [***].

1.30 "Cover," "Covering," or "Covered" means, when referring to the Licensed Product: (a) with respect to an issued Patent Right, that, in the absence of a license granted to a Person under an issued claim included in such Patent Right, the manufacture, use, sale, offer for sale or import by such Person of a specified activity with respect to such Licensed Product would infringe such claim, or (b) with respect to an application for Patent Rights, that, in the absence of a license granted to a Person under a claim included in such application, the manufacture, use, sale, offer for sale or import by such Person of a specified activity with respect to such Licensed Product would infringe such claim if such patent application were to issue as a patent.

1.31 "CRO" means a Third Party contract research organization.

1.32 "CRS" means chronic rhinosinusitis.

1.33 "Deficient Site" has the meaning set forth in Section 3.4(b) (Clinical Trial Audits).

1.34 "Development" means all internal and external (a) Clinical Trials and activities in support of Clinical Trials (including non-clinical and preclinical activities), and (b) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials and to obtain, support, or maintain Regulatory Approval of a pharmaceutical or biologic product and interacting with Regulatory Authorities following receipt of Regulatory Approval in the applicable country or region for such pharmaceutical or biologic product regarding the foregoing, but excluding activities directed to Manufacturing or Commercialization. Development will include development and regulatory activities for additional indications for a pharmaceutical product after receipt of Regulatory Approval of such product (including label expansion), including Clinical Trials initiated following receipt of Regulatory Approval or any Clinical Trial to be conducted after receipt of Regulatory Approval that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved indication (such as post-marketing studies, observational studies, implementation and management of registries and analysis thereof, in each case, if required by any Regulatory Authority in any region in the Territory to support or maintain Regulatory Approval for a pharmaceutical or biologic product in such region). "Develop," "Developing," and "Developed" will be construed accordingly.

1.35 "Development Milestone Event" has the meaning set forth in Section 6.1(b) (Development Milestone Payment).

1.36 "Development Milestone Payment" has the meaning set forth in Section 6.1(b) (Development Milestone Payment).

1.37 "Development Plans" means the Territory-Specific Development Plan and the Global Development Plan, collectively.

1.38 "Dollars" or "US$" means United States dollars.

1.39 "Drug Matrix" has the meaning set forth in Section 1.79 (LYR-210 Product).

1.40 "Effective Date" has the meaning set forth in the Preamble.

1.41 "Export Control Laws" means all applicable U.S. laws and regulations relating to (a) sanctions and embargoes imposed by the Office of Foreign Assets Control of the U.S. Department of Treasury or (b) the export or re-export of commodities, technologies, or services, including the Export Administration Act of 1979, 24 U.S.C. §§ 2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-1706, the Trading with the Enemy Act, 50 U.S.C. §§ 1 et. seq., the Arms Export Control Act, 22 U.S.C. §§ 2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986 (as amended).

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

1.43 "Field" means all palliative and therapeutic uses or indications in humans.

1.44 "First Commercial Sale" means with respect to the Licensed Product in any Region in the Territory, the first sale for monetary value for use or consumption by the end user of such Licensed Product in such Region after Marketing Authorization for such Licensed Product has been obtained in such Region. First Commercial Sale excludes any sale or transfer of Licensed Product (a) to or between Lian, its Affiliates or its or their Sublicensees for further sale by such entity (but includes the subsequent sale by such entity to a Third Party that is not a Selling Party) or (b) as *bona fide* samples, as charitable donations, or for Clinical Trial or other Development purposes, any expanded access program, any compassionate sales or use program (including named patient program or single patient program), or any indigent program, in each case, where the Licensed Product is supplied at or below cost.

1.45 "Force Majeure" has the meaning set forth in Section 14.9 (Force Majeure).

1.46 "GCP" or "Good Clinical Practice" means all applicable then-current standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable, (a) as set forth in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products, (b) the Declaration of Helsinki (2013) as last amended at the 64th World Medical Association in October 2013 and any further amendments or clarifications thereto, (c) as set forth in the PRC Good Clinical Practice for Pharmaceuticals effective as of September 1, 2003 and its subsequent amendments, (d) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), and (e) the equivalent applicable Laws in any relevant Region, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.47 "Generic Product" means, with respect to a particular Licensed Product in a Region, any product that (a) (i) contains the same or similar active pharmaceutical ingredient(s) as such Licensed Product and (ii) qualifies as a generic or is bioequivalent to and exchangeable with the Licensed Product, as determined by the applicable Regulatory Authority under the applicable Laws in such Region, (b) has received Regulatory Approval for use in such Region from the relevant Regulatory Authority in such Region, where such Regulatory Approval relied on or incorporated the Regulatory Approval for such Licensed Product in such Region or any clinical data contained in such Regulatory Approval, (c) during the Royalty Term is not owned or licensed by Lian under this Agreement; and (d) is sold in the same Region as the relevant Licensed Product by a Third Party that is not a Sublicensee or Affiliate of Lian and that did not purchase such product in a chain of distribution that included Lian or its Affiliates or its or their Sublicensees.

1.48 "Global Development Plan" has the meaning set forth in Section 3.3(b) (Global Development Plan).

1.49 "Global Phase III Trial" means the second of two planned global registrational Phase III Trials for the Licensed Product, as referenced in the Territory-Specific Development Plan as "Ph3-II".

1.50 "GLP" or "Good Laboratory Practice" means all applicable then-current standards for laboratory activities for pharmaceuticals, as set forth in the FDA's Good Laboratory Practice regulations as defined in 21 C.F.R. Part 58, the PRC Good Clinical Practice effective as of September 1, 2003, or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development (OECD), and such standards of good laboratory practice as are required by the equivalent applicable Laws in the relevant Region and other organizations and governmental agencies in countries in which the Licensed Product is intended to be sold by the Party that is subject to such standards.

1.51 "GMP" or "Good Manufacturing Practice" means all applicable then-current standards for Manufacturing, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. §§ 201, 211, 600 and 610 and all applicable FDA guidelines and requirements, (b) European Directive 2003/94/EC for medicines and investigational medicines for human use and the applicable guidelines stated in the Eudralex guidelines, (c) Pharmaceutical Good Manufacturing Practice of the PRC effective as of March 1, 2011 and its appendices, (d) the principles detailed in the applicable ICH guidelines, (e) the conduct of an inspection by a Qualified Person (as defined therein) and the execution by such Qualified Person of an appropriate certification of inspection and (f) the equivalent applicable Laws in any relevant Region, each as may be amended and applicable from time to time.

1.52 "Governmental Authority" means any multinational, federal, national, state, provincial, local or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal, official or officer, exercising executive, judicial, legislative, police, regulatory, administrative, or taxing authority or functions of any nature pertaining to government.

1.53 "ICH" means the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.54 "IND" means (a) an Investigational New Drug Application as defined in the United States Federal Food, Drug, and Cosmetic Act, as amended, and regulations promulgated thereunder, or any successor application or procedure required to initiate clinical testing of a drug in humans in the United States, (b) a clinical trial application filed with the NMPA to commence human clinical trials in the PRC, or (c) any equivalent application to the applicable Regulatory Authority, the filing of which is required to initiate clinical testing of a drug or device in humans in such Region.

1.55 "Indemnified Party" means a Person entitled to indemnification under Article 10 (Indemnification; Damages).

1.56 "Indemnifying Party" means a Party from whom indemnification is sought under Article 10 (Indemnification; Damages).

1.57 "Indication" means each separate and distinct disease, disorder, illness, health condition, or interruption, cessation or disruption of a bodily function, system, tissue type or organ, for which a separate Clinical Trial is performed and a separate Regulatory Approval Application (or a supplement to an existing Regulatory Approval Application) is required to be filed to obtain

Regulatory Approval. By way of example, CRS and allergic rhinitis constitute separate "Indications".

1.58 "Infringement" has the meaning set forth in Section 7.3(a) (Notice).

1.59 "Infringement Action" has the meaning set forth in Section 7.3(b) (Lian First Right).

1.60 "Infringement Claim" has the meaning set forth in Section 7.4 (Claimed Infringement).

1.61 "Intellectual Property" means all Patent Rights, rights to Inventions, copyrights, design rights, trademarks, trade secrets, Know-How, materials, and all other intellectual property rights (whether registered or unregistered), and all applications and rights to apply for any of the foregoing anywhere in the world.

1.62 "Invention" has the meaning set forth in Section 7.1(a) (Inventions).

1.63 "Joint Know-How" means Know-How developed or invented jointly by a Party's or its Affiliates', licensees', Sublicensees', or subcontractors' employees, agents, or independent contractors, or any persons contractually required to assign or license such Know-How to such Party or any Affiliate of such Party, on the one hand, and the other Party's or its Affiliates', licensees', Sublicensees', or subcontractors' employees, agents, or independent contractors, or any Persons contractually required to assign or license such Know-How to such Party or any Affiliate of such Party, on the other hand, in the performance of activities under this Agreement during the Term.

1.64 "Joint Patent Right" means any Patent Right claiming any Invention conceived jointly by a Party's or its Affiliates', licensees, Sublicensees, or subcontractors' employees, agents or independent contractors, or any persons contractually required to assign or license such Invention to such Party or any Affiliate of such Party, on the one hand, and the other Party's or its Affiliates', licensees', Sublicensees', or subcontractors' employees, agents, or independent contractors, or any Persons contractually required to assign or license such Invention to such Party or any Affiliate of such Party, on the other hand.

1.65 "JSC" has the meaning set forth in Section 5.1 (Formation; Purposes and Principles).

1.66 "Know-How" means all proprietary chemical and biological materials and other tangible materials, inventions, practices, methods, protocols, formulae, knowledge, know-how, trade secrets, processes, procedures, assays, skills, experience, techniques, information, data and results of experimentation and testing, including pharmacological, toxicological and pre-clinical and clinical test data and analytical and quality control data, whether patentable or otherwise.

1.67 "Law" or "Laws" means all laws, statutes, rules, codes, regulations, orders, decrees, judgments or ordinances of any Governmental Authority, or any license, permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law.

1.68 "Lian" has the meaning set forth in the Preamble.

1.69 "Lian Indemnified Party" has the meaning set forth in Section 10.1 (Indemnification by Lyra).

1.70 "Lian Obligations" has the meaning set forth in Section 14.17 (LianBio Guarantee).

1.71 "Lian Technology" means the Patent Rights and Know-How Controlled by Lian, its Affiliates or Sublicensees (including Product Inventions and Patent Rights that claim any such Product Inventions) as of the Effective Date or during the Term of this Agreement, that are actually

used by Lian, its Affiliates, or Sublicensees in the Development, Manufacture or Commercialization of the Licensed Product in the Field.

1.72 "LianBio" has the meaning set forth in the Preamble.

1.73 "Licensed Know-How" means any and all Know-How Controlled by Lyra or any of its Affiliates as of the Effective Date or during the Term that is necessary or reasonably useful for the Development, Manufacture, or Commercialization of the Licensed Product in the Field, including any Assigned Inventions, but excluding any Joint Know-How. The Licensed Know-How as of the Effective Date includes the Know-How listed in Schedule 1.73 (Licensed Know-How).

1.74 "Licensed Mark(s)" means any mark(s) that Lyra or its Affiliates registers with a Governmental Authority in any Region in the Territory to be used in connection with the Commercialization of a Licensed Product.

1.75 "Licensed Patent Rights" means any and all Patent Rights Controlled by Lyra or any of its Affiliates as of the Effective Date or during the Term that (a) Cover the Licensed Know-How or (b) are otherwise necessary or reasonably useful for the Development, Manufacture, or Commercialization of the Licensed Product in the Field in the Territory. The Licensed Patent Rights as of the Effective Date are listed in Schedule 1.75 (Licensed Patents). The Licensed Patent Rights exclude any Joint Patent Rights.

1.76 "Licensed Product" means (a) LYR-210 Product and (b) any improvements or updates thereto made by or on behalf of Lyra or its Affiliates using [***].

1.77 "Licensed Technology" means collectively Licensed Patent Rights, Licensed Know-How and Lyra or its Affiliates' interests in the Joint Know-How and Joint Patent Rights.

1.78 "Losses" means damages, losses, liabilities, costs (including costs of investigation, defense), fines, penalties, taxes, expenses, or amounts paid in settlement (in each case, including reasonable attorneys' and experts' fees and expenses), in each case, resulting from an Action.

1.79 "LYR-210 Product" means Lyra's proprietary therapeutic combination product referred to by Lyra as "LYR-210", comprised of [***] (the "Drug Matrix") [***], as further described on Schedule 1.79 (LYR-210 Product) attached hereto.

1.80 "LYR-220 Product" means Lyra's proprietary therapeutic combination product referred to by Lyra as "LYR-220", comprised of a [***], as further described on Schedule 1.80 (LYR-220 Product), [***].

1.81 "Lyra" has the meaning set forth in the Preamble.

1.82 "Lyra Indemnified Party" has the meaning set forth in Section 10.2 (Indemnification by Lian).

1.83 "Manufacture" means all activities directed to manufacturing, processing, packaging, labeling, filling, finishing, assembly, quality assurance, quality control, testing, and release, shipping, or storage of any pharmaceutical product (or any components or delivery systems thereof), including process development, qualification, and validation, scale-up, pre-clinical, clinical, and commercial manufacture and analytic development, product characterization, and stability testing, but excluding activities directed to Development or Commercialization. "Manufacturing" or "Manufactured" will be construed accordingly.

1.84 "Marketing Authorization" means the grant of all necessary final or conditional permits, registrations, authorizations, licenses, and approvals (or waivers) required for the

Commercialization of the Licensed Product for use in the Field and in the Territory, including any Regulatory Approval for sale or marketing, and, where applicable, Pricing and Reimbursement Approvals.

1.85 "Milestone Payments" means Development Milestone Payments and Sales Milestone Payments.

1.86 "Net Sales" means, with respect to a Licensed Product in a Region for any period, the total amounts invoiced for sales of such Licensed Product in such Region for such period by Lian or any of its Affiliates or its or their Sublicensees (for the purpose of this definition, "Sublicensees" will not include any distributors or wholesalers) (each of the foregoing Persons, a "Selling Party") to Third Parties that are not Selling Parties in the Territory, in *bona fide* arm's length transactions, less the following deductions calculated in accordance with the Accounting Standards, related specifically to such Licensed Product and actually taken, paid, accrued, allowed, included, or allocated by the Selling Party in accordance with the Selling Party's Accounting Standards, consistently applied, and not otherwise recovered by or reimbursed to the Selling Party, as set forth below (collectively, "Permitted Deductions"):

(a) [***];

(b) [***];

(c) [***];

(d) [***];

(e) [***]; and

(f) [***].

No amount for which deduction is permitted pursuant to the above shall be deducted more than once. In addition, to the extent any amounts deducted pursuant to the above are subsequently recovered by or reimbursed to the Selling Party, such recovered amounts shall be [***]; provided that, [***].

Net Sales will be calculated only once for the first *bona fide* arm's length sale of the Licensed Product to a Third Party that is not a Selling Party. Net Sales does not [***], in each case, where the Licensed Product is [***].

Subject to the above, Net Sales will be calculated in accordance with the standard internal policies and procedures of the Selling Party, if any, and copies of such policies and procedures will be furnished to Lyra upon request.

1.87 "NMPA" means the National Medical Product Administrations of the PRC, or its successor.

1.88 "Non-Breaching Party" has the meaning set forth in Section 12.3(a) (Termination by Material Breach).

1.89 "Party" means either Lyra or Lian; "Parties" means Lyra and Lian, collectively.

1.90 "Party Vote" has the meaning set forth in Section 5.5 (Decision-Making; Escalation to Senior Officers).

1.91 "Patent Challenge" has the meaning set forth in Section 12.3(d) (Patent Challenge).

1.92 "Patent Rights" means the rights and interests in and to (a) all patents and patent applications (including provisional applications), including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, re-issues, additions, renewals, extensions,

confirmations, registrations, any other pre- or post-grant forms of any of the foregoing, (b) any confirmation patent or registration patent or patent of addition, utility models, patent term extensions, and supplemental protection certificates or requests for continued examinations, foreign counterparts, and the like of any of the foregoing, and (c) any and all patents that have issued or in the future issue from the foregoing patent applications, including author certificates, utility models, petty patents, innovation patents and design patents and certificates of invention.

1.93 "Permitted Deductions" has the meaning set forth in Section 1.86 (Net Sales).

1.94 "Person" means any natural person, corporation, general partnership, limited partnership, joint venture, proprietorship or other business organization or a Governmental Authority.

1.95 "Pharmacovigilance Agreement" has the meaning set forth in Section 3.10 (Pharmacovigilance).

1.96 "Phase III Trial" means a Clinical Trial of an investigational product in subjects that incorporates accepted endpoints for confirmation of statistical significance of efficacy and safety with the aim to generate data and results that can be submitted to obtain Regulatory Approval as described in 21 C.F.R. 312.21(c), or a comparable Clinical Trial prescribed by the relevant Regulatory Authority in a country other than the United States.

1.97 "PRC" means the People's Republic of China, which for the purposes of this Agreement, excludes Hong Kong, Macau and Taiwan.

1.98 "Preclinical Development" means all internal and external non-clinical or preclinical activities related to pharmaceutical products, including non-clinical testing and research, toxicology testing and studies, preclinical studies.

1.99 "Pricing and Reimbursement Approval" means, with respect to the Licensed Product, the governmental approval, agreement, determination, or decision establishing the price or level of reimbursement for such Licensed Product in a given Region in the Territory prior to the sale of such Licensed Product in such Region in the Field in the Territory.

1.100 "Prior CDA" means the Mutual Confidential Disclosure Agreement, executed on February 25, 2019, by and between LianBio and Lyra.

1.101 "Product Inventions" means any Inventions, other than Assigned Inventions, that are necessary or reasonably useful for the Development, Manufacture, or Commercialization of the Licensed Product in the Field.

1.102 "Prosecution" or "Prosecute" means, with respect to a particular Patent Right, all activities associated with the preparation, filing, prosecution, and maintenance of such Patent Right, as well as supplemental examinations, re-examinations, reissues, supplementary protection certificates and the like with respect to such Patent Right, together with the conduct of interferences, derivation proceedings, *inter partes* review, post-grant review, the defense of oppositions, and other similar proceedings with respect to such Patent Right.

1.103 "Region" means each of the PRC, Hong Kong, Macau, Taiwan, Singapore, South Korea, and Thailand.

1.104 "Regulatory Approval" means the final or conditional approval of the applicable Regulatory Authority necessary for the marketing and sale of a Licensed Product in the Field in a country(ies) or Region(s), excluding separate Pricing and Reimbursement Approval that may be applicable in a Region.

1.105 "Regulatory Approval Application" means an application to seek regular or expedited Regulatory Approval of the Licensed Product for sale or marketing in any country(ies) or Region(s) in the Territory, as defined in the applicable Laws and filed with the Regulatory Authority of such country(ies) or Region(s).

1.106 "Regulatory Authority" means any multinational, federal, national, state, provincial, or local regulatory agency, department, bureau, or other Governmental Authority with authority over the clinical development, Manufacture, marketing or sale of the Licensed Product in a Region, including the NMPA.

1.107 "Regulatory Exclusivity" means, with respect to a Licensed Product in a Region, the period of time during which: (a) a Party or its Affiliates or its or their Sublicensees has been granted the exclusive legal right by a Regulatory Authority in such Region to market and sell such Licensed Product; or (b) the data and information submitted by a Party or its Affiliates or its or their sublicensees to the relevant Regulatory Authority in such Region for purposes of obtaining Regulatory Approval of such Licensed Product in such Region may not be disclosed, referenced, or relied upon in any way by a Third Party or such Regulatory Authority (including by relying upon the Regulatory Authority's previous findings regarding the safety or effectiveness of the Licensed Product) to support the Regulatory Approval of any product of a Third Party in such Region.

1.108 "Regulatory Filing" means any documentation comprising or relating to or supporting any filing or application with any Regulatory Authority with respect to the Licensed Product, including any documents submitted to any Regulatory Authority, including INDs, Regulatory Approval Applications, and all correspondence with any Regulatory Authority with respect to any Licensed Product (including minutes of any meetings, telephone conferences, or discussions with any Regulatory Authority).

1.109 "Reversion License" has the meaning set forth in Section 12.5(c)(i) (License Grant to Lyra).

1.110 "ROFR" has the meaning set forth in Section 2.10 (Right of First Refusal for LYR-220 Product).

1.111 "ROFR Terms" has the meaning set forth in Section 2.10 (Right of First Refusal for LYR-220 Product).

1.112 "Royalty Term" has the meaning set forth in Section 6.2(b) (Royalty Term).

1.113 "Rules" has the meaning set forth in Section 13.2 (Arbitration).

1.114 "Safety Data" means any Adverse Event information from Clinical Trials and all results from non-clinical safety studies, including toxicology and carcinogenicity data (if any), with respect to the Licensed Product required by one or more Regulatory Authorities to be collected or to be reported to such Regulatory Authorities under applicable Laws, but excluding any information related to the efficacy of the Licensed Product.

1.115 "Sales Milestone Event" has the meaning set forth in Section 6.1(c) (Sales Milestone Payments).

1.116 "Sales Milestone Payment" has the meaning set forth in Section 6.1(c) (Sales Milestone Payments).

1.117 "Securitization Transaction" has the meaning set forth in Section 14.1(b) (Securitization).

1.118 "Sell-Off Period" has the meaning set forth in Section 12.5(g)(ii) (Sell-Off Period).

1.119 "Selling Party" has the meaning set forth in Section 1.86 (Net Sales).

1.120 "Senior Officers" means the Chief Executive Officer of each Party. If the position of any of the Senior Officers identified in this definition no longer exists due to a corporate reorganization, corporate restructuring or the like that results in the elimination of the identified position, then the applicable title of the Senior Officer set forth herein will be replaced with the title of another executive officer with responsibilities and seniority comparable to the eliminated Senior Officer, and the relevant Party will promptly provide notice of such replacement title to the other Party.

1.121 "Sublicense" means a grant of rights from Lian to a Sublicensee or an Affiliate under any of the rights licensed to Lian by Lyra under Section 2.1 (License Grants; Right of Reference).

1.122 "Sublicensee" means a Third Party sublicensee to which a Party or its Affiliates has granted rights under this Agreement or a Third Party licensee of rights with respect to the Licensed Product, which rights are retained by a Party under this Agreement with respect to such Licensed Product, or any further sublicensee of such rights (regardless of the number of tiers, layers, or levels of sublicenses of such rights).

1.123 "Supply Agreements" has the meaning set forth in Section 4.1 (Supply Agreement).

1.124 "Supply Failure" means, for a given [***], that Lyra has failed to supply or cause to be supplied to Lian those quantities of Licensed Product ordered in accordance with the terms of the applicable Supply Agreement, and [***].

1.125 "Tax Withholdings" has the meaning set forth in Section 6.5 (Tax Withholding).

1.126 "Term" has the meaning set forth in Section 12.1 (Term).

1.127 "Term Sheet" means that certain non-binding (except with respect to confidentiality obligations therein) term sheet by and between Lian and Lyra, dated as of March 4, 2021.

1.128 "Territory" means the PRC, Hong Kong, Macau, Taiwan, Singapore, South Korea, and Thailand.

1.129 "Territory-Specific Development Plan" has the meaning set forth in Section 3.3(a) (Territory-Specific Development Plan).

1.130 "Third Party" means any Person other than a Party or any of its Affiliates.

1.131 "Third Party Claim" has the meaning set forth in Section 10.3(a) (Notice).

1.132 "Third Party Losses" means Losses resulting from an Action by a Third Party.

1.133 "Trademark" means all registered and unregistered trademarks, service marks, trade dress, trade names, logos, insignias, domain names, symbols, designs, and combinations thereof.

1.134 "Two-Invoice Policy" means the policy described in "the Opinion on the Implementation of the 'Two-Invoices' System in the Procurement of Pharmaceutical Products by Public Medical Institutions (trial)" (Guoyigaibanfa [2016] No. 4), officially released on 9 January 2017 and in any other applicable Laws that mandates public hospitals or any other purchaser of drugs in mainland China to purchase drugs from the distributor that purchases the drugs directly from the drug manufacturer, limiting the total number of invoices to two.

1.135 "United States" or "U.S." or "US" means the United States and its territories, possessions and commonwealths.

1.136 "Valid Claim" means either: (a) a claim of an issued and unexpired patent included within the Licensed Patent Rights that (i) has not been irrevocably or unappealably disclaimed or abandoned, or been held unenforceable, unpatentable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction; and (ii) has not been admitted to be invalid or unenforceable through reissue, disclaimer, or otherwise, or (b) a claim included in a patent application that has not been irretrievably cancelled, withdrawn, or abandoned, nor been pending for more than [***].

ARTICLE 2
LICENSE GRANTS

2.1 License Grants; Right of Reference.

(a) License Grants to Lian. Subject to the terms and conditions of this Agreement, Lyra hereby grants to Lian:

(i) an exclusive (even with respect to Lyra and its Affiliates, subject to this Section 2.1(a) (License Grants to Lian) and Section 2.5 (Lyra Right of Access and Reference)), sublicensable (solely as permitted under Section 2.2(a)) (Lian Right to Sublicense), non-transferable (except as provided Section 14.1 (Assignment)), royalty-bearing license under the Licensed Technology to Develop, and Commercialize and otherwise, use, offer for sale, sell, have sold, and import the Licensed Product in the Field in the Territory; and

(ii) a non-exclusive, non-transferable (except as provided Section 14.1 (Assignment)), sublicensable (solely as permitted under Section 2.2(a)) (Lian Right to Sublicense) worldwide license under the Licensed Technology to Manufacture the Licensed Product solely for (1) Development solely for purposes of obtaining Regulatory Approval of the Licensed Product in the Field in the Territory; and (2) Commercialization of the Licensed Product in the Field in the Territory, provided that Lian will not practice under the license granted in this Section 2.1(a)(ii) unless and until the occurrence of (A[***] or (B) [***], following the completion of the technology transfer described in Section 4.3 (Manufacturing Technology Transfer), subject to the terms set forth in Section 4.3 (Manufacturing Technology Transfer).

(b) Lian Right of Access and Reference. Lyra hereby grants Lian and its Affiliates and Sublicensees access to, and a right of reference with respect to, (i) the Regulatory Filings, Regulatory Approvals, Marketing Authorizations, and (ii) all data generated by or on behalf of Lyra or its Affiliates or licensees relating to the Licensed Product, including clinical and preclinical data (including any such data generated from any Clinical Trial performed by or on behalf of Lyra or its Affiliates), Safety Data, and CMC Data, in each case, contained or referenced in any such Regulatory Filings, Regulatory Approvals or Marketing Authorizations, in each case ((i) and (ii)), Controlled by Lyra or its Affiliates as of the Effective Date or at any time during the Term and to the extent reasonably useful or necessary for Developing, seeking, and securing Regulatory Approval and Marketing Authorization for the Development, Manufacture, or Commercialization of the Licensed Product in the Field in the Territory. The foregoing rights include the right for Lian and, to the extent permitted under this Agreement, its Affiliates and Sublicensees, to make copies of and reproduce such documentation and information for the sole purposes set forth in this Section 2.1(b) (Lian Right of Access and Reference). Lyra will promptly provide to Lian all data generated by or on behalf of it or its Affiliates from any Clinical Trial or other non-clinical or pre-clinical study, in each case, for a Licensed Product that is necessary or reasonably useful to Lian or its Affiliates or Sublicensees for securing Regulatory

Approval and Marketing Authorization for the Development, Manufacture, or Commercialization of the Licensed Product in Field and in the Territory.

2.2 Sublicensing and Subcontracting.

(a) Lian Right to Sublicense. Lian will have the right to grant Sublicenses (through multiple tiers) to (i) its Affiliates and to independent contractors engaged pursuant to Section 2.3 (Performance by Independent Contractors) of any and all rights granted to Lian by Lyra pursuant to Section 2.1 (License Grants; Right of Reference) [***], and (ii) to Third Parties, [***], subject to the requirements of Section 2.2(b) (Sublicense Requirements); provided that any such sublicense to an Affiliate will terminate if such sublicensee ceases to be an Affiliate of Lian.

(b) Sublicense Requirements. Each Sublicense granted by Lian to a Third Party pursuant to Section 2.2(a) (Lian Right to Sublicense) will be in writing and will be consistent with the relevant terms and conditions set forth in this Agreement. Any sublicense granted to a Third Party under this Section 2.2 (Sublicensing and Subcontracting) must [***], and provided that [***]. Lian shall keep Lyra informed through the JSC of each sublicense granted to an Affiliate or Third Party, specifying the name of the Sublicensee and the material terms (including duration) of the sublicense. No Sublicense will diminish, reduce or eliminate any obligation of either Party under this Agreement. Lian will be liable for any act or omission of its Sublicensees as if such Sublicensees were Lian hereunder and Lyra will have the right to proceed directly against Lian without any obligation to first proceed against such Sublicensee. Without limiting the foregoing, each Sublicense granted by Lian or its Affiliates to a Sublicensee will contain (i) confidentiality and non-use provisions at least as restrictive or protective as those set forth in Section 8.1 (Confidential Information) with respect to Lyra's Confidential Information, (ii) if such Sublicense contains a right to Commercialize Licensed Products, such Sublicense will also contain the following provisions: (A) a requirement that the Sublicensee submit applicable sales or other reports to Lian to the extent necessary or relevant to the reports required to be made or records required to be maintained by Lian under this Agreement, and (B) audit requirements in favor of Lian consistent with those set forth in Section 6.4 (Audits), (iii) invention ownership and assignment provisions consistent with and no less restrictive than those set forth in Section 7.1 (Ownership of Intellectual Property), and (iv) if possible under applicable Law, Lian will use reasonable efforts to include in such Sublicense assignment and transfer of possession of, or a right to reference (which right of reference shall be sublicensable (through multiple tiers)) to, all Regulatory Filings and Regulatory Approvals Controlled by such Sublicensee pertaining to any Licensed Product Developed or Commercialized by such Sublicensee (which assignment or right of reference may also be provided to Lian); provided that, if despite using reasonable efforts Lian is unable to obtain such assignment and transfer of, or a right of reference to, such Regulatory Filings and Regulatory Approvals, then Lian will include in such Sublicense that upon termination of such Sublicense, Lian obtains such assignment and transfer of, or a right of reference to, such Regulatory Filings and Regulatory Approvals. Lian will provide Lyra with a copy of any such Sublicense agreement it enters into with a Third Party (other than Third Party subcontractors), within [***]days after the execution thereof, provided that [***].

(c) Sublicense Survival. Upon the termination of this Agreement by Lyra pursuant to Sections 12.3(a) (Termination for Material Breach), 12.3(c) (Termination for Bankruptcy), 12.3(d) (Patent Challenge), or 12.3(e) (Termination for Cessation of Development or Commercialization), at the written request of any Sublicensee (other than Third Party subcontractors) who is not then in breach of its sublicense agreement, Lyra agrees to enter into a direct license agreement with such Sublicensee under the

same terms and conditions of this Agreement (except for Section 6.1(a)) (Upfront Payment), effective upon the date that notice of such written request. If Lian terminates this Agreement pursuant to Section 12.3(b) (Termination by Lian for Convenience), then Lyra agrees to consider in good faith any request from any Sublicensee (other than Third Party subcontractors) to enter into a direct license agreement with such Sublicensee.

2.3 Performance by Independent Contractors. Lian may contract or delegate any portion of its obligations hereunder to a contractor subject to the terms and condition of Section 14.8 (Affiliates, Sublicensees, and Contractors); provided that Lian [***]. Lyra is responsible for the compliance of its Affiliates and contractors with the terms and conditions of this Agreement, and any act or omission of an Affiliate or contractor that would be a breach of this Agreement if performed by Lyra will be deemed to be a breach by Lyra under this Agreement. For clarity, Lian shall have no right to contract or delegate its obligations hereunder to any Affiliate of Lian or any contractor, CMO or other Third Party, in each case, under terms permitting the performance of any activities related to any Licensed Product outside the Territory, including any Manufacture (for any purpose) of any Licensed Product outside the Territory.

2.4 License Grant to Lyra. Lian hereby grants to Lyra and its Affiliates a non-exclusive, sublicensable (through multiple tiers), royalty-free, fully paid up, perpetual, and irrevocable license under any Product Inventions invented or otherwise developed or generated during the Term by or on behalf of Lian (including its Affiliates, or any of its or their employees, Sublicensees, independent contractors, or agents) to (a) Develop, Manufacture, and Commercialize and otherwise, make, have made, use, offer for sale, sell, have sold, and import the Licensed Product in the Field outside the Territory and (b) with prior written notice to Lian, conduct Preclinical Development and Development in the Territory (subject to the same restrictions with respect to Lyra's retained rights under the Licensed Technology in the third sentence in Section 2.7 (No Implied Licenses; Reservation of Rights)) for the purposes of Preclinical Developing, Developing, and Commercializing the Licensed Product outside of the Territory.

2.5 Lyra Right of Access and Reference. Lian hereby grants Lyra and its Affiliates and Sublicensees access to, and a right of reference with respect to, (a) the Regulatory Filings, Regulatory Approvals, Marketing Authorizations and (b) all data generated by or on behalf of Lian or its Affiliates or Sublicensees relating to the Licensed Product, including clinical and preclinical data (including any such data generated from any Clinical Trial performed by or on behalf of Lian or its Affiliates), Safety Data, and CMC Data, in each case, contained or referenced in any such Regulatory Filings, Regulatory Approvals or Marketing Authorizations, in each case ((a) and (b)), Controlled by Lian or its Affiliates as of the Effective Date or at any time during the Term and to the extent reasonably useful or necessary for Developing, seeking, and securing Regulatory Approval and Marketing Authorization for the Development, Manufacture, or Commercialization of the Licensed Product in the Field in or outside the Territory. The foregoing rights include the right for Lyra and, to the extent permitted under this Agreement, its Affiliates and Sublicensees, to make copies of and reproduce such documentation and information for the sole purposes set forth in this Section 2.5 (Lyra Right of Access and Reference). Without limiting the foregoing, Lian shall use reasonable efforts to [***]. Lian will promptly provide to Lyra all data generated by or on behalf of it or its Affiliates from any Clinical Trial for a Licensed Product that is necessary or reasonably useful to Lyra or its Affiliates or Sublicensees for securing Regulatory Approval and Marketing Authorization for the Development, Manufacture, or Commercialization of the Licensed Product in Field outside the Territory.

2.6 Rights in Bankruptcy.

(a) All rights and licenses now or hereafter granted by Lyra to Lian under or pursuant to this Agreement, including, for the avoidance of doubt, the licenses granted to Lian pursuant to Section 2.1 (License Grants; Right of Reference) are, for all purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined in the Bankruptcy Code. Upon any filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, upon the appointment of a receiver or trustee over all or substantially all property, or upon an assignment of a substantial portion of the assets for the benefit of creditors by Lyra, Lyra agrees that Lian, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code, to the extent applicable. Without limiting the generality of the foregoing, Lyra and Lian intend and agree that any sale of Lyra's assets that are necessary for the rights and licenses granted by Lyra to Lian under or pursuant to this Agreement (including, for the avoidance of doubt, the licenses granted to Lian pursuant to Section 2.1 (License Grants; Right of Reference)) under Section 363 of the Bankruptcy Code shall be subject to Lian's rights under Section 365(n), that Lian cannot be compelled to accept a money satisfaction of its interests in the Intellectual Property licensed pursuant to this Agreement, and that any such sale therefore may not be made to a purchaser "free and clear" of Lian's rights under this Agreement and Section 365(n) without the express, contemporaneous consent of Lian. Lyra will, during the Term, create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all Intellectual Property licensed by Lyra under this Agreement. Lyra acknowledges and agrees that "embodiments" of Intellectual Property within the meaning of Section 365(n) include laboratory notebooks, product samples and inventory, research studies and data, all Regulatory Approvals (and all applications for Regulatory Approval) and rights of reference therein, the Licensed Know-How, Licensed Patent Rights, and all information related to the Licensed Know-How or Licensed Patent Rights. If (i) a case under the Bankruptcy Code is commenced by or against Lyra, (ii) this Agreement is rejected in such case as provided in the Bankruptcy Code and (iii) Lian elects to retain its rights hereunder as provided in Section 365(n) of the Bankruptcy Code, Lyra (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) will: (A) provide Lian with all such Intellectual Property (including all embodiments thereof) held by Lyra and such successors and assigns, or otherwise available to them, immediately upon Lian's written request. Whenever Lyra or any of its successors or assigns provides to Lian any of the Intellectual Property licensed hereunder (or any embodiment thereof) pursuant to this Section 2.6(a) (Rights in Bankruptcy), Lian will have the right to perform Lyra's obligations hereunder with respect to such Intellectual Property, but neither such provision nor such performance by Lian will release Lyra from liability resulting from rejection of the license or the failure to perform such obligations, except to the extent such release is provided under Section 365(n) or by operation of another provision of the Bankruptcy Code; and (B) not interfere with Lian's rights under this Agreement, or any agreement supplemental

hereto, to such Intellectual Property (including such embodiments), including any right to obtain such Intellectual Property (or such embodiments) from another entity, to the extent provided in Section 365(n) of the Bankruptcy Code. Following Lian's exercise of its election under Section 365(n) of the Bankruptcy Code to retain its rights under this Agreement, Lian shall comply with and perform its obligations pursuant to Sections 365(n)(2)(B) and (2)(C) of the Bankruptcy Code.

(b) All rights, powers and remedies of Lian provided in this Section 2.6 (Rights in Bankruptcy) are in addition to and not in substitution for any other rights, powers, and remedies now or hereafter existing at law or in equity (including the Bankruptcy Code) in the event of the commencement of a case under the Bankruptcy Code with respect to Lyra. The Parties intend the following rights to extend to the maximum extent permitted by applicable Law, and to be enforceable to the extent permitted under the

Bankruptcy Code, including under Bankruptcy Code Section 365(n): (i) the right of access to any Intellectual Property (and all embodiments thereof) of Lyra or any Third Party that is licensed or sublicensed to Lian under this Agreement; and (ii) the right to contract directly with any Third Party to complete the contracted work.

2.7 No Implied Licenses; Reservation of Rights. No rights, other than those expressly set forth in this Agreement, are granted to either Party under this Agreement, and no additional rights will be deemed granted to either Party by implication, estoppel, or otherwise, with respect to any intellectual property rights. All rights not expressly granted by either Party or its Affiliates to the other Party under this Agreement are reserved. Notwithstanding anything to the contrary set forth in this Agreement, Lyra reserves the right (on behalf of itself, its Affiliates and its licensees, other than Lian and its Sublicensees) under the Licensed Technology, with the right to grant licenses and sublicenses through multiple tiers, to (a) conduct or have conducted Preclinical Development, Development, and Manufacturing of the Licensed Product anywhere in the world (including the Territory) for the purposes of Preclinical Developing, Developing and Commercializing the Licensed Product outside the Territory, provided that (i) Lyra will provide prior written notice to Lian of any Preclinical Development of the Licensed Product by or on behalf of Lyra within the Territory and (ii) any clinical Development of the Licensed Product by or on behalf of Lyra within the Territory will be subject to Lian's prior written consent, not to be unreasonably withheld, and (b) perform, and have performed, its obligations under any Development Plan. Neither Party nor any of its Affiliates will use or practice under any Patent Rights licensed or provided to such Party or any of its Affiliates outside the scope of or otherwise not in compliance with the rights and licenses granted to such Party and its Affiliates under this Agreement.

2.8 Transfer of Licensed Know-How. [***], Lyra will disclose and make available to Lian the Licensed Know-How that exists as of the Effective Date. Lyra may make such Licensed Know-How available in such reasonable form as Lyra determines and is reasonably acceptable to Lian, including in the form such Licensed Know-How is maintained by Lyra. In addition, Lyra will provide periodic updates throughout the Term to Lian of any Know-How that Lyra or its Affiliates comes to Control that constitutes Licensed Know-How, and Lyra will (a) make available to Lian all such Licensed Know-How not previously provided to Lian hereunder, and (b) for a period of [***] after the initial Licensed Know-How transfer, provide Lian with reasonable assistance to facilitate the successful transfer of such Licensed Know-How; provided that [***].

2.9 Non-Compete.

(a) By Lian. During the Term and subject to the terms of this Agreement, neither LianBio will, nor any of LianBio's Affiliates will, nor Lian, nor any of its Affiliates will, directly or indirectly, Commercialize any Competing Product anywhere in the Territory, nor collaborate with, enable, or otherwise authorize, license, or grant any right to any Third Party to Commercialize any Competing Product anywhere in the Territory, in each case, in the field of [***]. Notwithstanding the foregoing, this Section 2.9(a) (By Lian) shall no longer apply to LianBio nor any of its Affiliates in the event that LianBio is no longer an Affiliate of Lian.

(b) By Lyra. Subject to the terms of this Agreement, prior to [***] neither Lyra will, nor any of its Affiliates will, directly or indirectly, Commercialize any Competing Product anywhere in the Territory, nor collaborate with, enable, or otherwise authorize, license, or grant any right to any Third Party to Commercialize any Competing Product anywhere in the Territory, in each case, in the field of [***].

(c) [***].

(d) [***].

2.10 Right of First Refusal for LYR-220 Product. If, at any time prior to the [***] anniversary of the Effective Date, Lyra decides to grant to a Third Party a license to Develop or Commercialize the LYR-220 Product in the Territory, and the material terms of which have been substantially agreed by Lyra, as reflected in a term sheet, letter of intent or other written documentation ("ROFR Terms") then, prior to entering into any agreement with respect to any such license in the Territory, Lyra will provide written notice to Lian of such potential transaction, including [***]. Lian will have a right of first refusal ("ROFR") with respect to obtaining such license in the Territory on the ROFR Terms, exercisable no later than [***] after Lian's receipt of such notice. If Lian provides written notice to Lyra of its exercise of such right of first refusal within the applicable period, then Lian will have [***] from the date of Lyra's receipt of such notice to negotiate and execute an amendment to this Agreement adding the LYR-220 Product to this Agreement [***]. [***]. If Lyra and Lian fail to reach a definitive agreement with respect to the Development or Commercialize of the LYR-220 Product in the Territory, then Lyra or any of its Affiliates will be free to enter into a definitive agreement with any Third Party with respect to the Development or Commercialization of LYR-220 Product in the Territory [***], provided that, if Lyra does not enter into such a definitive agreement with a Third Party, then [***]. Notwithstanding the foregoing, the obligations set forth in this Section 2.10 (Right of First Refusal for LYR-220 Product) will not apply to (a) a transaction that is a Change of Control of Lyra, (b) any agreement between Lyra or its Affiliates and any academic, government, or not-for-profit Third Party, and (c) any agreement between Lyra or its Affiliates and any CRO, CMO, or other Third Party under which such Third Party performs contract services on behalf of Lyra or its Affiliates that would grant such Third Party any license relating to the LYR-220 Product in all or any portion of the Territory.

ARTICLE 3
DEVELOPMENT

3.1 Development Responsibilities in General.

(a) Development Diligence. Lian (directly, or through their respective Affiliates, Sublicensees and contractors) will use Commercially Reasonable Efforts to Develop and seek Regulatory Approval for the Licensed Product in the Territory, and Lyra (directly, or through its respective Affiliates, Sublicensees and contractors) will use Commercially Reasonable Efforts to (i) complete the planned Global Phase III Trial for the Licensed Product (subject to Lian's compliance with its diligence obligations in this Section 3.1(a) (Development Diligence) with respect to such Global Phase III Trial), and (ii) seek and obtain Regulatory Approval for the Licensed Product in the U.S. Without limiting the foregoing and subject to Lyra's compliance with its diligence obligations in the foregoing sub-clauses (i) and (ii) (but not, for clarity, dependent upon the prior completion of the activities in the foregoing sub-clauses (i) and (ii)), Lian will [***] engage Clinical Trial sites in the Territory and enroll up to [***] of the total number of Clinical Trial subjects in the planned Global Phase III Trial for the Licensed Product to be conducted by Lyra and Lian; provided that, [***].

(b) Development Responsibilities. Subject to the terms and conditions of this Agreement, including this Article 3 (Development) and Section 5.5 (Decision-Making; Escalation to Senior Officers), Lian will have sole authority to, at its own costs and expense, Develop the Licensed Product for the purpose of obtaining Regulatory Approval in the Field in the Territory. Lian will be responsible for the day-to-day implementation of any Development activities for which it (or any of its Affiliates) is assigned responsibility under this Agreement (including under the Development Plans) and will keep Lyra reasonably informed as to the progress of such activities in accordance with Section 3.5(b) (Reporting).

3.2 Development Activities.

(a) Regulatory Guidance. Promptly (and in any event within [***] months) following the Effective Date, Lian will seek NMPA guidance as to the classification of the Licensed Product as either a drug or device.

(i) Drug Classification. If the NMPA provides guidance that the Licensed Product will be classified as a drug, then, [***].

(ii) Device Classification. If the NMPA provides guidance that the Licensed Product will be classified as a device, then, [***].

(b) Development in the Territory. Subject to the terms and conditions of this Agreement, Lian will lead Development activities for the Licensed Product in the Territory as required to obtain, support and maintain the Regulatory Approval of the Licensed Product for CRS in the Territory. Lian will have the right to determine after considering in good faith Lyra's suggestions from which Regions all patients in any Clinical Trial for the Licensed Product conducted in the Territory are enrolled, provided that such sites selected by Lian for the Regions do not [***] under the Global Development Plan, and otherwise, the Parties will agree upon (i) [***]; provided however, if the NMPA requires or recommends additional study endpoints, a different study design, or other study protocol changes for the Phase III Trial that are not consistent with the study endpoints, study design, or study protocol contemplated by the IND in the U.S., and Lyra reasonably determines that accommodating such modifications in the Global Phase III Trial would materially delay Regulatory Approval of the Licensed Product in the U.S., then Lyra shall have the right to [***], and (ii) [***]. Notwithstanding anything to the contrary herein, if Lian does not provide its Clinical Trial data from the Global Phase III Trial in the PRC to Lyra prior to the date set forth in the Global Development Date for the U.S. data read-out for the Global Phase III Trial (which such date will be discussed and approved by the JSC), then Lyra shall have the right, [***].

3.3 Development Plans.

(a) Territory-Specific Development Plan. All Development of the Licensed Product in the Territory will be conducted pursuant to a written a plan (the "Territory-Specific Development Plan"), the initial draft of which will be prepared by Lian and submitted to the JSC within [***] after the Effective Date [***]. The Territory-Specific Development Plan will contain in reasonable detail (i) [***], (ii) [***], and (iii) [***]. Lian will update the Territory-Specific Development Plan not less than [***], and either Party may propose modifications to the Territory-Specific Development Plan at any time, including with respect to the inclusion of any additional Indication (subject to Section 3.2(b) (Development in the Territory)), subject in each case [***]. [***], each update to the Territory-Specific Development Plan will become effective and supersede the then-current Territory-Specific Development Plan. In the event of any proposed change to the Territory-Specific Development Plan as a result of any interaction with any Regulatory Authority, the JSC will meet as promptly as practicable to review and discuss any such proposed changes and determine an appropriate revision (if any) to the Territory-Specific Development Plan. If Lian is delayed in performing (or fails to perform) an obligation assigned to Lian in the Territory-Specific Development Plan as a result of Lyra's failure to timely perform any of its obligations under this Agreement, then the timelines for the performance of Lian's obligations under the Territory-Specific Development Plan will be extended commensurate with the delay caused by Lyra.

(b) Global Development Plan. Lyra's global Development of the Licensed Product outside of the Territory and, [***], clinical Development within the Territory will be conducted pursuant to a written plan (the "Global Development Plan"). [***], Lyra will provide to the JSC for its review and discussion the initial Global Development Plan. The Global Development Plan will include an outline of all major Development activities for the Licensed Product to be conducted throughout the world by Lyra. From time to time, Lyra may propose updates to the then-current Global Development Plan for the Licensed Products, to the JSC to review and discuss and, solely to the extent relating to activities to be conducted by Lian in the Territory, to determine whether to approve such activities.

3.4 Clinical Trial Audits.

(a) Upon reasonable notification by Lyra and [***] based on an audit scope agreed upon by the Parties, [***] may conduct an audit, to the extent permitted under Lian's applicable agreements, of Lian's Sublicensees, subcontractors and all Clinical Trial sites engaged by Lian or its Affiliates or Sublicensees to perform Lian's obligations under any Development Plans to ensure that the applicable Clinical Trials are conducted in compliance with such Development Plans, GCP, and applicable Law and meet Lyra's Clinical Trial standards provided by Lyra from time to time during the Term. Lian will use Commercially Reasonable Efforts to obtain such audit rights from its Sublicensees, subcontractors and Clinical Trial sites engaged by Lian or its Affiliates and Sublicensees to enable [***] to audit such Persons in accordance with this Section 3.4 (Clinical Trial Audits), provided that if Lian is unable to obtain such audit rights, Lian will obtain the right to conduct substantially equivalent audits itself and, [***]. No later than [***] days after preparing or receiving the audit report, Lyra will provide Lian with a written summary of Lyra's findings of any deficiencies or other areas of remediation that Lyra identifies during any such audit. Lian will [***] remediate any deficiencies identified in an audit report [***] within [***] days (or a reasonably longer, mutually agreed period (not to exceed [***] days) depending upon the deficiencies) following Lian's receipt of such report, [***]. [***].

(b) If either Party reasonably determines that any deficiencies with respect to a Global Phase III Clinical Trial site identified pursuant to Section 3.4 (Clinical Trial Audits) (each, a "Deficient Site") may cause a Regulatory Authority to reject or otherwise deem deficient the Clinical Trial data from the conduct of any such Global Phase III Clinical Trial at such Deficient Site, or if the any such deficiencies are not remediated within the time period for remediation specified in Section 3.4(a), then such Party will notify the other Party of such Deficient Site and the Parties will discuss, attempt to agree upon, and implement a remediation plan for such Deficient Site. If the Parties do not agree to such a remediation plan for a Deficient Site that is participating in a global Clinical Trial, then [***].

(c) Lian will provide Lyra with copies of all quality oversight or audit reports prepared in connection with any audit that Lian or its Affiliates or Sublicensees conduct of any Sublicensee, subcontractor, or Clinical Trial site that Lian or its Affiliates or Sublicensees have engaged or are evaluating to potentially engage to fulfill Lian's obligations under a Global Development Plan or a Territory-Specific Development Plan no later than [***] days after receiving or preparing any such report (as applicable), to the extent permitted under the applicable agreement and subject to redaction as Lian reasonably believes appropriate to protect confidential business information and other sensitive information as applicable. If Lyra believes in good faith that any such quality oversight or audit report may be necessary in connection with obtaining, supporting, or maintaining one or more Regulatory Approvals for a Licensed Product or for other communications with Regulatory Authorities outside of

the Territory, then upon Lyra's request, Lian will provide a certified translation thereof at Lyra's sole cost and expense.

(d) Compliance. Lian will conduct, and will ensure that all of its Affiliates, Sublicensees, and other Third Party subcontractors conduct, Development of the Licensed Product in the Field in the Territory in compliance with applicable Laws and, with respect to any such Development activities conducted as part of the Global Phase III Trial, in compliance with applicable FDA requirements to the extent necessary for the submission of data generated from such activities in Regulatory Filings.

3.5 Development Records and Reporting.

(a) Records. Lian will maintain complete and accurate records of Development activities conducted by Lian in furtherance of seeking Regulatory Approval for the Licensed Product in the Field in the Territory. Such records will be maintained in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and in accordance with applicable Laws.

(b) Reporting. Lian will provide a written report to the JSC for review and discussion, at least [***], in English, describing in reasonable detail Lian's activities and progress related to the pursuit of Regulatory Approval for the Licensed Product in the Field in the Territory. Lian will respond to the JSC's reasonable questions or requests for additional information relating to such activities in a timely manner. Any copies of Regulatory Submissions that Lian provides or presents to the JSC shall be in the local language, provided that Lian will also provide to the JSC summaries of such documentation in English.

3.6 Development Costs. Except as set forth in this Section 3.6 (Development Costs), each Party will bear 100% of the costs and expenses it incurs in connection with its respective Development activities. With respect to the Development activities in support of the Global Phase III Trial for the Licensed Product to be conducted by Lyra and Lian in the Territory, Lian will be responsible for: (a) [***], and (b) [***]. As reasonably requested by Lian, Lyra will provide training in English to Lian's Clinical Trial sites in the Territory. Lian will reimburse Lyra's reasonable (a) [***] and (b) [***].

3.7 Regulatory Submissions and Approvals; Communications; Meetings.

(a) Regulatory Filings and Approvals. Lian, or its relevant Affiliates or Sublicensees, will have the sole and exclusive right to file and hold all Regulatory Filings, and to apply for and maintain all Regulatory Approvals and Pricing and Reimbursement Approvals, in each case, for all Licensed Products in the Field in the Territory at Lian's cost and expense in the name of Lian or any of its Affiliates and Sublicensees. The Parties will use good faith efforts to cooperate to effectuate this Section 3.7(a) (Regulatory Filings and Approvals), and if, after the Parties' use of good faith efforts, Lian, or its Affiliate or Sublicensee [***]. Subject to the terms and conditions of this Agreement, Lian will be responsible, at its sole cost and expense, for all regulatory activities leading up to and including the obtaining of Regulatory Approvals and any Pricing and Reimbursement Approvals, as applicable, for Licensed Products in the Field from Regulatory Authorities or Governmental Authorities in the Territory. Lian will conduct such activities (and any and all regulatory activities delegated to Lian in this Agreement) (A) in its own name, if Lian is the legal and beneficial owner of the Regulatory Approvals for the Licensed Products in the Field in the Territory, [***].

(b) Regulatory Communications. Subject to applicable Law and this Section 3.7 (Regulatory Submissions and Approvals; Communications; Meetings), (i) Lian will

oversee, monitor, and manage all interactions and communications with Regulatory Authorities with respect to the Licensed Products in the Field in the Territory and (ii) Lian will have final decision-making authority regarding all regulatory activities for the Licensed Products in the Field in the Territory, including the labeling strategy and the content of Regulatory Filings for Licensed Products. Lian will promptly provide Lyra with copies of all material communications or correspondence with Regulatory Authorities with respect to the Licensed Product in the Field in the Territory that are received by Lian from any Regulatory Authority or submitted by Lian to any Regulatory Authority. Lian will provide proposed material submissions by Lian to any Regulatory Authority to Lyra for review and comment sufficiently in advance of submission. Lian shall not unreasonably refuse to incorporate any of Lyra's comments to such submissions.

(c) Regulatory Meetings. Until such time as Lian obtains Regulatory Approval for the Licensed Product in the Field in the Territory, to the extent legally permissible and practicable, Lian will provide Lyra with reasonable prior written notice of all substantive meetings with Regulatory Authorities in the Territory regarding the Licensed Product if permitted by applicable Law or the Regulatory Authority. Lyra will have the right to request to be present as an observer at or participant in all such meetings with Regulatory Authorities to the extent permitted under applicable Law[***], and Lian will use reasonable efforts to permit Lyra to be present at, or participate in, any such meetings, as applicable.

(d) Termination or Suspension of Clinical Trials. Notwithstanding any provision to the contrary set forth in this Agreement or the Pharmacovigilance Agreement, the Parties hereby agree that Lian may terminate or suspend any Clinical Trial relating to the Licensed Products in the Field in the Territory, and Lyra may terminate or suspend any Clinical Trial outside of the Territory, in each case, without the approval or consent of the JSC or the other Party and without violation or default under any provision set forth in this Agreement, if (i) a Regulatory Authority, institutional review board, or safety data review board for such Clinical Trial has required or recommended such termination or suspension or (ii) following review and discussion with the JSC, the Party seeking such termination believes in good faith that such termination or suspension is warranted because of observed safety risks to the study subjects. In either case, such Party will promptly notify the other Party in writing of such termination or suspension.

(e) Regulatory Investigation or Inquiry. If any Regulatory Authority (i) contacts Lian or its Affiliate with respect to the alleged improper Development, Manufacture, or Commercialization of any Licensed Product, (ii) conducts, or gives notice of its intent to conduct, an inspection at Lian's or its Affiliate's facilities used in the Development of the Licensed Product, or (iii) takes, or gives notice of its intent to take, any other regulatory action with respect to any activity of Lian or its Affiliate that could reasonably be expected to adversely affect any Development, Manufacture, or Commercialization activities with respect to the Licensed Product outside of the Territory, then Lian will promptly notify Lyra in writing of such contact, inspection or notice.

3.8 No Harmful Actions. Each Party will promptly notify the other Party of all material communications or correspondence with Regulatory Authorities with respect to any Licensed Product in such Party's territory that (a) are received by such Party or its Affiliates, Sublicensees, or other licensees (to the extent that such Party has the right to disclose such material communications or correspondence of other licensees and provided that such Party uses reasonable efforts to obtain such right from such other licensees) from any Regulatory Authority or submitted by such Party, its Affiliates or other licensees to any Regulatory

Authority and (b) would reasonably be expected to impact the other Party's Development, Manufacture, or Commercialization of the Licensed Products in the Field in the other Party's territory. If either Party believes that the other Party is taking or intends to take any action with respect to a Licensed Product in such other Party's territory that could have a material adverse impact upon the regulatory status of any Licensed Product in such Party's territory, then such Party will have the right to bring the matter to the attention of the JSC and the Parties will discuss in good faith the views and suggestions of the JSC to minimize the impact of such action with respect to a Licensed Product in the other Party's territory.

3.9 Development of the Licensed Products outside the Territory. Lyra retains the exclusive right and will be solely responsible and have sole discretion and control over the Development activities (including regulatory activities) of the Licensed Products anywhere in the world, other than in Territory. Lyra will, in its sole discretion, oversee, monitor and manage all interactions and communications with Regulatory Authorities with respect to such Licensed Products outside of the Territory. Lyra will have final decision-making authority regarding all regulatory activities, including the labeling strategy and the content of Regulatory Filings with respect to such Licensed Products outside of the Territory.

3.10 Pharmacovigilance. No later than [***] prior to (a) [***] or (b) [***], the Parties will negotiate in good faith and finalize the actions that the Parties will employ with respect to the Licensed Products to protect patients and promote their well-being in a written pharmacovigilance agreement (the "Pharmacovigilance Agreement"). These responsibilities will include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of Adverse Event reports and any other information concerning the safety of any Licensed Product, including recall and withdrawal responsibilities, processes, and procedures. Such guidelines and procedures will be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under applicable Law. Furthermore, such agreed procedure will be consistent with relevant ICH guidelines, except where such guidelines may conflict with existing local regulatory reporting safety reporting requirements, in which case local reporting requirement will prevail. Lian will be responsible for reporting quality complaints, Adverse Events, and safety data related to the Licensed Products in the Field to applicable Regulatory Authorities in the Territory, as well as responding to safety issues and to all requests of Regulatory Authorities relating to Licensed Products in the Field in the Territory. Lyra will be responsible for reporting quality complaints, Adverse Events, and safety data related to Licensed Product to applicable Regulatory Authorities outside the Territory, as well as responding to safety issues and to all requests of Regulatory Authorities relating to Licensed Product outside the Territory. The Pharmacovigilance Agreement will also provide for a worldwide safety database to be maintained by Lyra at its sole cost and expense, which worldwide safety database will be accessible by Lian and its Affiliates, Sublicensees, and contractors to the full extent necessary for Lian to exercise its rights under this Agreement, comply with its obligations under this Agreement, and comply with all applicable Law. Each Party will comply with its respective obligations under such Pharmacovigilance Agreement and will cause its Affiliates and Sublicensees and contractors to comply with such obligations.

ARTICLE 4
MANUFACTURE, SUPPLY, AND COMMERCIALIZATION

4.1 Supply Agreements. Within [***] following the JSC's approval of the Territory-Specific Development Plan, the Parties will negotiate in good faith and enter into a supply agreement for the Manufacture and supply of clinical quantities of Licensed Products by Lyra to Lian for use solely in connection with Clinical Trials and other Development of Licensed Products in the Field in the Territory (the "Clinical Supply Agreement") and, no later than [***] prior to the date Lian anticipates its First Commercial Sale of the Licensed Products in the Territory, a supply agreement for the Manufacture and supply of commercial quantities of Licensed

Products by Lyra to Lian for the commercial sale and distribution of Licensed Products in the Field in the Territory (the "Commercial Supply Agreement" and, together with the Clinical Supply Agreement, the "Supply Agreements"). Unless otherwise agreed or required by applicable Laws, the Supply Agreements will specify that Lyra will (or will cause its Affiliates to) Manufacture and supply, and Lian will purchase from Lyra, all of Lian's, its Affiliates' and Sublicensees' requirements for the Licensed Products for the Development or Commercialization (as applicable) in the Field in the Territory in their finished form and at a price equal to (a) under the Clinical Supply Agreement, [***] and (b) under the Commercial Supply Agreement, [***]; provided [***].

4.2 Two-Invoice Policy. The Parties agree that in the event, under the Two-Invoice Policy and tendering policies and applicable Laws in a given province in the PRC, neither Lian nor any of its Affiliates can, based on their existing qualifications, distribute the Licensed Products for such province directly or indirectly to its distributors for the PRC, then, the Parties will use reasonable efforts to discuss in good faith alternative arrangements for the distribution of the Licensed Product in such province that complies with the Two-Invoice Policy as implemented in such province and that maintains the economic interests of the Parties as agreed under this Agreement.

4.3 Manufacturing Technology Transfer. In the event [***], upon Lian's written notice to Lyra, (i) the Parties will discuss in good faith and prepare a technology transfer plan pursuant to which Lyra will (A) provide access, and transfer, to Lian or a CMO designated by Lian that is approved by Lyra (which approval may not be unreasonably withheld, conditioned, or delayed) the Licensed Know-How Controlled by Lyra or its Affiliates that is necessary or reasonably useful for Lian or such CMO to Manufacture the Licensed Product in the Field in the Territory, and (B) provide all other reasonably necessary assistance and services to Lian [***] to enable Lian or its designated CMO to Manufacture the Licensed Product in substantially the same manner as Lyra or its Affiliates or CMOs (as applicable) Manufactures the Licensed Product for Lian; (ii) following agreement on such plan, Lyra will perform and execute the technology transfer plan in accordance with its terms at Lian's cost and expense, and (iii) Lian will have the right to Manufacture or have Manufactured Licensed Products to satisfy the needs of Lian and its permitted Sublicensees and distributors in the Territory.

4.4 Commercialization.

(a) Commercialization Diligence. Upon receipt of Marketing Authorization for the Licensed Product in the Field in a given Region in the Territory, Lian (directly, or through its Affiliates, Sublicensees, or contractors) will use Commercially Reasonable Efforts to Commercialize the Licensed Product in the Field in such Region in the Territory. Lian will have sole decision-making authority and control over the Commercialization of the Licensed Product in the Field in the Territory. [***].

(b) Commercial Plan. All Commercialization of the Licensed Product in the Territory will be conducted pursuant to a Commercial Plan. No later than [***] prior to the [***], Lian will prepare a draft of a standard commercial plan for the Commercialization of the Licensed Product in the Field in such Region, including details with respect to (i) [***], (ii) [***], and (iii) [***] (the "Commercial Plan"). Such draft Commercial Plan and any material changes to the Commercial Plan, including proposed changes to the Commercial Plan as a result of any interaction with any Regulatory Authority, will be submitted to the JSC for review, discussion, and approval pursuant to Section 5.2 (Specific Responsibilities), subject to the decision-making and escalation procedures set forth in Section 5.5 (Decision-Making; Escalation to Senior Officers).

(c) Reporting Obligations. Lian will update the JSC at the JSC's regularly-scheduled meetings regarding Lian's significant Commercialization activities for the Licensed

Products in the Territory. Without limiting the foregoing, on [***] basis, beginning with the [***] following the first Regulatory Approval of a Licensed Product in the Field in the Territory (for the period ending December 31 of the prior Calendar Year), summarizing in reasonable detail Lian's material Commercialization activities for such Licensed Product performed to date (or updating such report for activities performed since the last such report was given hereunder, as applicable).

(d) Trademarks.

(i) Subject to review and discussion by the JSC, Lian will have the right to brand the Licensed Products in the Field in the Territory using Lian related Trademarks and any other Trademarks and trade names it determines appropriate for the Licensed Products, which branding may vary by Region or within a Region. Lian will own all rights in such Trademarks and register and maintain such Trademarks in the countries and regions within the Territory, where and how it determines appropriate.

(ii) Lian will also have the right to brand the Licensed Products in the Field and in the Territory using the Licensed Marks, and Lian will comply with Lyra's reasonable trademark usage guidelines and quality control guidelines in effect from time to time as provided by Lyra. Lyra will own and retain all rights to the Licensed Marks (together with all goodwill associated therewith) in the Territory, and will prepare, file, prosecute, and maintain all Licensed Marks in the Territory at its own expense; provided, however, Lyra will provide to Lian copies of all applications, submissions, communications, and correspondence intended to be sent to, sent to or received by Governmental Authorities or Third Parties in connection with such filing, prosecution, and maintenance of the Licensed Marks in the Territory so that Lian may review and comment thereon (which will be provided with sufficient advanced notice so that Lian may meaningfully review and comment, to the extent practicable), and will incorporate any reasonable comments provided by Lian with respect to such applications, submissions, communications, or correspondence. Subject to terms and conditions of this Agreement, Lyra will grant and hereby grants an exclusive, sublicensable (subject to Section 2.2) (Sublicensing and Subcontracting), fully paid-up, royalty free, non-transferrable (subject to Section 14.1 (Assignment)) license under the Licensed Marks for Lian to Commercialize the Licensed Products in the Field in the Territory.

(iii) Diversion. Subject to applicable Law, each Party hereby covenants and agrees that (A) it and its Affiliates will not, and it will contractually obligate (and use reasonable efforts to enforce such contractual obligation) its licensees, Sublicensees and contractors not to, directly or indirectly, actively promote, market, distribute, import, sell or have sold any Licensed Product, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like, in the other Party's territory, and (B) neither Party will engage, nor permit its Affiliates, Sublicensees, or contractors to engage, in any advertising or promotional activities relating to any Licensed Product for use directed primarily to customers or other buyers or users of such product located in any country, Region or jurisdiction in the other Party's territory, or solicit orders from any prospective purchaser located in any country, Region or jurisdiction in the other Party's territory. If Lyra or Lian or any of its Affiliates or sublicensees receives any order for Licensed Product for use from a prospective purchaser located in a country or jurisdiction outside such Party's territory, then such Party, its Affiliates or sublicensees shall immediately refer that order to the other Party and shall not accept any such orders. Neither Lyra

nor Lian shall, nor permit its Affiliates or sublicensees to, deliver or tender (or cause to be delivered or tendered) any Licensed Product for use in the other Party's territory.

(e) Marking. To the extent permitted by applicable Law, Lian shall use reasonable efforts to include on all packaging for each Licensed Product a designation (i) that the Licensed Product incorporates the Licensed Patent Rights, including the word "patent" or the abbreviation "pat." and either the relevant Licensed Patent Rights or a web address that is freely accessible to the public and that lists the relevant Licensed Patent Rights and (ii) if applicable, that the Licensed Product is Manufactured by Lyra, which designations must be in accordance with applicable Laws in the Territory. Lian shall use reasonable efforts to ensure that all Sublicensees and applicable subcontractors mark the Licensed Product accordingly.

(f) No Violation. Notwithstanding any provision to the contrary set forth herein, Lian (including its Affiliates, Sublicensees, and contractors) will not be obligated to undertake or continue any Commercialization activities with respect to Licensed Products if Lian (or its Affiliates, Sublicensees or contractors, as applicable) reasonably determines that performance of such Commercialization activity would violate applicable Laws or infringe any Third Party Patent Rights.

ARTICLE 5
GOVERNANCE; JOINT STEERING COMMITTEE

5.1 Formation; Purposes and Principles. [***], Lyra and Lian will form a joint steering committee (the "JSC") to provide oversight and to facilitate information sharing between the Parties with respect to the activities of the Parties under this Agreement.

5.2 Specific Responsibilities. In addition to its overall responsibility to provide strategic oversight and to facilitate information sharing between the Parties with respect to the activities of the Parties under this Agreement, the JSC will:

(a) coordinate and share information with respect to the Development and Commercialization of the Licensed Product by Lian in the Territory and by Lyra outside the Territory;

(b) coordinate and share information with respect to the Manufacture of the Licensed Products by Lyra, for so long as Lyra is supplying Licensed Products to Lian;

(c) keep each Party reasonably informed of the other Party's Development and Commercialization activities and interactions with Regulatory Authorities in the other Party's territory, by receiving updates from the Party conducting such activities to the extent that such activities materially impact or would reasonably be expected to materially impact the other Party's Development, Manufacture or Commercialization of the Licensed Products in the Territory;

(d) [***];

(e) keep Lyra informed of each sublicense granted, and each subcontract entered into, by Lian, as described in Section 2.2(a) (Sublicense Requirements) and Section 2.3 (Performance by Independent Contractors);

(f) [***];

(g) review and discuss the initial Global Development Plan, and each update thereto, as described in Section 3.3(b) (Global Development Plan);

(h) review, discuss, and determine whether to approve (i) any activities to be conducted by Lian in the Territory under the Global Development Plan, as described in Section 3.3(b) (Global Development Plan) and (ii) the date for the U.S. data read-out for the Global Phase III Trial under the Global Development Plan ;

(i) review and discuss the termination or suspension of any Clinical Trial relating to the Licensed Product in light of observed safety risks to the study subjects, as described in Section 3.7(d) (Termination or Suspension of Clinical Trials);

(j) review, discuss, and determine matters that may have a material adverse impact upon the regulatory status of the Licensed Products, as described in Section 3.8 (No Harmful Action);

(k) [***];

(l) [***];

(m) review and discuss the Trademarks and trade names used for the Licensed Products for each Region, as described in Section 4.4(d)(i) (Trademarks);

(n) review and discuss proposed publications that cover the results of Development or Commercialization of Licensed Products in the Field in the Territory for which a Party has concerns of a potential competitive advantage, and resolve such concerns, as described in Section 8.2(b) (Publicity); and

(o) perform such other functions as are assigned to it in this Agreement or as appropriate to further the purposes of this Agreement to the extent agreed to in writing by the Parties.

5.3 Membership. The JSC will be composed of a total of [***] representatives of each Party, which will be appointed by each of Lyra and Lian, respectively. Each individual appointed by a Party as a representative to the JSC will be an employee of such Party with sufficient seniority and decision-making authority within the applicable Party to provide meaningful input and make decisions arising within the scope of the JSC's responsibilities, and have knowledge and expertise in the Development and Commercialization of products similar to the Licensed Products under this Agreement. The JSC may change its size from time to time by consent of its members, provided that the JSC will consist at all times of an equal number of representatives of each Party, unless otherwise agreed by the Parties in writing. Each Party may replace any of its JSC representatives at any time upon written notice to the other Party, which notice may be given by e-mail, sent to the other Party's co-chairperson. The JSC will be co-chaired by one designated representative of each Party. The co-chairperson of the JSC will cast its Party's vote on the JSC and such designee will have the authority to make decisions on behalf of such Party. Each co-chairperson will alternate being responsible for each meeting for (a) calling and conducting meetings, (b) preparing and circulating an agenda in advance of each meeting; provided, however, that the applicable co-chairperson will include any agenda items proposed by either Party on such agenda, (c) preparing minutes of each meeting that reflect the material decisions made and action items identified at such meetings promptly thereafter, and (d) sending draft meeting minutes to each member of the JSC for review and approval within [***] days after each JSC meeting. Meeting minutes issued in accordance with clause (d) of this Section 5.3 (Membership) will be deemed approved unless [***] members of the JSC objects to the accuracy of such minutes within [***] Business Days of receipt. The Alliance Managers will work with the chairpersons to prepare and circulate agendas and to ensure the preparation and approval of minutes. Each JSC representative will be subject to

confidentiality obligations no less stringent than those in Article 8 (Confidentiality and Publicity).

5.4 Meetings; Reports. The JSC will hold meetings at least [***] per Calendar Quarter during the Term for so long as the JSC exists, unless the Parties agree in writing to a different frequency. No later than [***] Business Days prior to any meeting of the JSC (or such shorter time period as the Parties may agree), the applicable co-chairperson will prepare and circulate an agenda for such meeting. Either Party may also call a special meeting of the JSC by providing at least [***] Business Days prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, in which event such Party will work with the applicable co-chairperson of the JSC and the Alliance Managers to provide the members of the JSC no later than [***] Business Day prior to the special meeting with an agenda for the meeting and materials reasonably adequate to enable an informed decision on the matters to be considered. The JSC may meet in person or by audio or video conference as its representatives may agree. Other representatives of the Parties, their Affiliates, or Third Parties involved in the Development, Manufacture, or Commercialization of Licensed Products may be invited by the members of the JSC to attend meetings as non-voting observers if such representatives are subject to confidentiality obligations no less stringent than those set forth in Article 8 (Confidentiality and Publicity). No action taken at a meeting will be effective unless at least [***] of each Party (which [***] not such Party's Alliance Manager) is present or participating. Neither Party will unreasonably withhold attendance of at least one representative of such Party at any meeting of the JSC for which reasonable advance notice was provided.

5.5 Decision-Making; Escalation to Senior Officers. The Parties will endeavor in good faith and in compliance with this Agreement to reach unanimous agreement with respect to all matters within the JSC's authority. Each Party's representatives on the JSC will collectively have one vote, (the "Party Vote") and no action or decision will be taken by the JSC without unanimous Party Vote (*i.e.*, the affirmative Party Vote of each Party). If the JSC is not be able to reach agreement with respect to a matter at a duly called meeting of the JSC, then either Party may refer such matter to the Senior Officers for resolution, and the Senior Officers will attempt to resolve the matter in good faith. If the Senior Officers fail to resolve such matter within [***] Business Days after the date on which the matter is referred to the Senior Officers (unless a longer period is agreed to by the Parties), then Lian will have the final decision-making authority as to all matters relating to [***], except for (a) [***], (b) [***] (i) [***], (ii) [***], or (iii) [***] (A) [***] or (B) [***]; and (c) [***]. Lyra will have final decision-making authority over [***]. The status quo with respect to any matter that is not subject to a Party's final decision-making authority, and is not resolved at the JSC or by escalation to the Senior Officers as described above, will [***].

5.6 Limitations. Notwithstanding anything to the contrary, neither Party will have the final decision-making authority on amending or updating the Development Plans in any way that would materially alter the scope of the other Party's obligations hereunder, increase the other Party's financial obligations hereunder, or result in the disclosure of the Confidential Information of the other Party, in each case, without the other Party's prior written consent. Notwithstanding any provision of this Article 5 (Governance; Joint Steering Committee) to the contrary, the JSC will not have the authority to amend the terms or conditions of this Agreement.

5.7 Alliance Managers.

(a) Appointment. Each Party will appoint a person to oversee interactions between the Parties for all matters related to the Development and Commercialization of Licensed Products between meetings of the JSC (each, an "Alliance Manager"). The Alliance Managers will have the right to attend all meetings of the committees as non-voting participants and may bring to the attention of the JSC any matters or issues either

Alliance Manager reasonably believes should be discussed and will have such other responsibilities as the Parties may agree in writing. Each Party may replace its Alliance Manager at any time or may designate different Alliance Managers with respect to Development and Commercialization matters, respectively, by notice in writing to the other Party.

(b) Responsibility. The Alliance Managers will have the responsibility of creating and maintaining a constructive work environment within the JSC and between the Parties for all matters related to this Agreement. Without limiting the generality of the foregoing, each Alliance Manager will:

(i) provide a single point of communication within the Parties' respective organizations and between the Parties with respect to this Agreement;

(ii) coordinate cooperative efforts, internal communications and external communications between the Parties with respect to this Agreement; and

(iii) take such other steps as may be required to ensure that meetings of the JSC occur as set forth in this Agreement, that procedures are followed with respect to such meetings (including working with the co-chairpersons with respect to the giving of proper notice and the preparation and approval of minutes) and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

ARTICLE 6
FINANCIAL PROVISIONS

6.1 Upfront Payment; Milestone Payments.

(a) Upfront Payment. Subject to the terms and conditions of this Agreement, Lian will pay Lyra a non-refundable, non-creditable, and not subject to set-off payment in the amount of $12,000,000 U.S. Dollars, which upfront payment will be due and payable to Lyra within [***] Business Days following the Effective Date.

(b) Development Milestone Payment. During the Term, upon the achievement by or on behalf of a Party or its Affiliates or Sublicensees of any milestone event set forth below in Table 6.1(b) (Development Milestone Payments) (each, a "Development Milestone Event") for the Licensed Product, the achieving Party will notify the other Party promptly after the occurrence thereof, and Lian will pay Lyra a non-refundable, non-creditable, and not subject to set-off, milestone payment set forth in the table below (each, a "Development Milestone Payment") no later than [***] days after its achievement of such milestone event. Each of the milestone payments set forth below in Table 6.1(b) (Development Milestone Payment) is payable [***].

Table 6.1(b) (Development Milestone Payments)	
Development Milestone Event	**Development Milestone Payment (in Dollars)**
1.[***]	[***]
2.[***]	[***]
4.[***]	[***]
5.[***]	[***]
6.[***]	[***]
Total	[***]

(c) Sales Milestone Payments. During the Term, Lian will notify Lyra in writing of its achievement of each of the sales milestones below within [***] days after the [***] in which the cumulative Net Sales of all Licensed Products in the Territory first exceed the indicated Dollar value set forth below in Table 6.1(c) (Sales Milestone Events) (each, a "Sales Milestone Event"). Lian will pay to Lyra each of the non-refundable, non-creditable, and not subject to set-off, Sales Milestone Payments set forth below in Table 6.1(c) (Sales Milestone Events) within [***] days of providing notice of each Sales Milestone Event (each, a "Sales Milestone Payment"). Each of the milestone payments set forth in Table 6.1(c) (Sales Milestone Payments) is payable only upon the first achievement of such Sales Milestone Event and none of the Sales Milestone Payments will be payable more than once regardless of how many times such Sales Milestone Event is achieved. For clarity, the Sales Milestone Payments are additive, such that if more than one Sales Milestone Events are achieved in the same time period, then the Sales Milestone Payments for all such Sales Milestone Events shall be payable.

Table 6.1(c) (Sales Milestone Payments)	
Sales Milestone Event	**Sales Milestone Payment (in Dollars)**
1.[***]	[***]
2.[***]	[***]
3.[***]	[***]
4.[***]	[***]
Total	[***]

6.2 Royalties.

(a) Royalty Rate. Subject to the terms and conditions of this Agreement, during the Royalty Term, Lian will pay to Lyra a tiered royalty on the Net Sales of all Licensed Products in the Territory that is the product of the aggregate annual Net Sales of all Licensed Products in the Territory and the applicable royalty rate in the following Table 6.2 (Royalty Rates), subject to the provisions of Section 6.3 (Royalty Payment Adjustments).

Table 6.2 (Royalty Rates)

Portion of the Annual Net Sales of the Licensed Products in the Territory	Royalty Rate
1.[***]	[***]
2.[***]	[***]
3.[***]	[***]
4.[***]	[***]

(b) Royalty Term. Royalties will be due under this Section 6.2 (Royalties), on a Licensed Product-by-Licensed Product and Region-by-Region basis, during the period commencing upon the First Commercial Sale of such Licensed Product in such Region and ending upon the latest to occur of (i) the expiration of the last-to-expire Valid Claim of a Licensed Patent Right Covering the making, using, selling, offering for sale or importing of such Licensed Product in such Region, (ii) the expiry of the applicable Regulatory Exclusivity for such Licensed Product in such Region; or (iii) the [***] anniversary of the First Commercial Sale of such Licensed Product in such Region (such period, the "Royalty Term").

(c) Royalty Payments and Reports. [***]. Within [***] days following the end of each [***] following the First Commercial Sale of a Licensed Product, Lian shall furnish to Lyra a written report for the [***] showing [***]. Such written report shall include [***]. Lian shall pay Lyra the royalty due for such Calendar Quarter calculated in accordance with this Agreement within [***] days of delivery of the written report to Lyra.

6.3 Royalty Payment Adjustments. The following will apply to all royalties paid pursuant to Section 6.2(a) (Royalty Rate):

(a) Expiration of Valid Claims. On a Licensed Product-by-Licensed Product and Region by Region basis, if at any time during the Royalty Term in a given Region in the Territory, there is no Valid Claim of a Licensed Patent Right Covering the composition of matter of such Licensed Product that would be infringed by the sale of such Licensed Product in such Region, then the applicable royalty rate in effect with respect to such Licensed Product in such Region as specified in Section 6.2(a) (Royalty Rate) will be reduced by [***] for the remainder of the Royalty Term for such Licensed Product in such Region.

(b) Generic Entry. On a [***] basis, if, at any time during the Royalty Term subsequent to the first commercial sale of a Generic Product with respect to a Licensed Product in a Region, [***], then the applicable royalty rates in effect with respect to such Licensed Product in such Region as specified in Section 6.2(a) (Royalty Rate) will be reduced by [***] for [***] for such Licensed Product in such Region. For clarity, such reduction will be applied in each [***] for the remainder of the Royalty Term for such

Licensed Product in such Region in which (i) [***] and (ii) [***]. For purposes of this Section 6.3(b) (Generic Entry), a "first commercial sale" of a Generic Product in a Region means the first sale for monetary value in an arm's length transaction for use or consumption by an end user of such Generic Product in such Region after the marketing authorization of such Generic Product has been obtained in such Region.

(c) Third Party Payments. If Lian makes a payment under any agreement with a Third Party pursuant to which Lian obtains a license or sublicense under Patent Right(s) or Patent Right(s) together with Know-How owned or controlled by such Third Party in a given Region that is necessary or reasonably useful to Develop, Manufacture, or Commercialize one or more Licensed Products in such Region, then Lian may offset against [***] due to Lyra for such Licensed Product in such Region covered by such license an amount equal to [***] of the amounts paid to such Third Party under such agreement, subject to Section 6.4(d) (Cumulative Deductions).

(d) Cumulative Deductions. Notwithstanding the foregoing, in no event will the deductions set forth in Section 6.3(a) (Expiration of Valid Claims) through Section 6.3(c) (Third Party Payments) reduce the royalties otherwise payable to Lyra as specified in Section 6.2(a) (Royalty Rate) by more than [***]. To the extent the foregoing limitation limits the reduction Lian is permitted to take during a Calendar Quarter, Lian will be entitled to carryforward the amount of the reduction Lian was unable to take during such Calendar Quarter and apply such amounts to royalties payable to Lyra in future Calendar Quarters within the following three Calendar Years.

6.4 Audits. Each Party will maintain and will cause its Affiliates and all Sublicensees to maintain, complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of the calculation of royalties, Milestone Payments, Cost of Goods Sold calculations, and other payments under this Agreement. Upon reasonable prior notice, but not more than once per Calendar Year and not more than once with respect to any records, such records will be available during regular business hours for a period of [***] years from the end of the Calendar Year to which they pertain for examination at the expense of the requesting Party by an independent certified public accountant selected by the requesting Party and reasonably acceptable to the other Party, for the sole purpose of verifying the accuracy of the financial reports and correctness of the payments furnished by the other Party pursuant to this Agreement. Any such auditor will not disclose the other Party's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the other Party or the amount of payments due by the other Party under this Agreement. The accountant's report will be disclosed simultaneously to both Parties, and such report will be the Confidential Information of the audited Party and subject to the terms of Article 8 (Confidentiality and Publicity). Any amounts shown to be owed but unpaid will be paid within [***] days from the accountant's report. Any amounts shown to have been overpaid will be refunded within [***] days from the accountant's report. The requesting Party will bear the full cost of such audit unless such audit discloses an underpayment by the other Party of more than [***] of the amount due, in which case the other Party will bear the full cost of such audit. The audit rights in this Section 6.4 (Audits) will survive the Term for [***] following the effective date of any termination or expiration of this Agreement.

6.5 Tax Withholding. In the event any withholding, value added, or other tax (including any tax based on income to Lyra) ("Tax Withholdings") is required to be withheld and deducted from payments by Lian (or its Affiliate paying on behalf of Lian) pursuant to this Agreement under applicable Laws, notwithstanding any provision to the contrary set forth under this Agreement, Lian (or its Affiliate paying on behalf of Lian) will make such deduction and withholding [***]. Any amounts so withheld and deducted will be remitted by Lian (or its Affiliate paying on behalf of Lian) on a timely basis to the appropriate Governmental Authority for the account of Lyra and Lian (or its Affiliate paying on behalf of Lian) will provide Lyra reasonable evidence

of the remittance within [***] days thereof and for the purposes of this Agreement, Lian will be deemed to have fulfilled all of its payment obligations to Lyra with respect to such payments paid to the such Governmental Authority. Lian may satisfy its withholding, value added or other tax obligations under this Section 6.5 (Tax Withholding) through its Affiliates.

6.6 Currency of Payments. All amounts payable and calculations under this Agreement will be in Dollars. As applicable, Net Sales and any royalty reductions will be translated into Dollars using the average of the applicable daily foreign exchange rates published in the *Wall Street Journal* (or any other qualified source that is acceptable to both Lyra and Lian) for [***] in which such Net Sales occurred. All payments under this Agreement will be paid in Dollars by wire transfer to an account designated by the receiving Party (which account the receiving Party may update from time to time in writing).

6.7 Late Payments. Without limiting any other rights or remedies available to Lyra hereunder, any late payment by Lian will bear interest, to the extent permitted by Laws, at an annual rate of [***] or the highest rate permitted by applicable Law (whichever is lower), computed from the dated such payment was due until the date Lian makes the payment.

ARTICLE 7
INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS

7.1 Ownership of Intellectual Property.

(a) Inventions. Lyra will own all Inventions developed or generated by or on behalf of Lian (including by its Affiliates, or any of its employees, Sublicensees, independent contractors, or agents) that are solely related to the Licensed Product and not related to any other product Controlled by Lian ("Assigned Inventions"), and otherwise ownership will follow inventorship for any and all inventions, Know-How, developments, or discoveries, whether patentable or non-patentable, invented or otherwise developed or generated by either Party alone (including its Affiliates, or any of its or their employees, Sublicensees, independent contractors, or agents) or jointly by both Parties (including jointly by their Affiliates, or any of its or their employees, Sublicensees, independent contractors, or agents) the performance of a Party's obligations or exercise of its rights under this Agreement (collectively, "Inventions") and such inventorship will be determined in accordance with United States patent Laws.

(b) Assignment Obligation. Each Party will assign, and will cause its Affiliates to assign, its rights, and cause all employees of such Party or Affiliate who perform activities for such Party or Affiliate under this Agreement to be under an obligation to assign their rights, in any Patent Rights and Know-How, whether or not patentable, resulting therefrom to such Party or Affiliate to effectuate the terms and conditions set forth in Section 7.1(a) (Inventions). Without limiting the foregoing, Lian will and hereby does assign to Lyra all of Lian's rights, title, and interests in and to any Assigned Inventions, and Lyra hereby accepts such assignment. With respect to any activities of a Party or its Affiliate or exercise of its or their rights under this Agreement that are subcontracted to a Person that is not an employee, the Party or such Affiliate retaining such subcontractor will include in the applicable subcontract an assignment to such Party or such Affiliate of all rights in Patent Rights and Know-How developed or generated by such subcontractor resulting from such activities or exercise of its rights, and in any event will include in the applicable subcontract a license to such Party or Affiliate that is sublicensable (through multiple tiers) to the other Party under this Agreement, of any Patent Rights and Know-How developed or generated by such contractor or subcontractor resulting from such activities. Lian and its Affiliates shall ensure that its and their Sublicensees provide Lian with sufficient rights in all Assigned Inventions so

that Lian can assign to Lyra all rights and title in and to all Assigned Inventions, as provided herein.

7.2 Prosecution and Maintenance of the Licensed Patent Rights and Joint Patent Rights.

(a) In the Territory. As between the Parties, Lyra will have the first right, at its expense, to Prosecute the Licensed Patent Rights and Joint Patent Rights in all Regions in the Territory, at Lyra's sole cost and expense. Lyra will keep Lian reasonably informed of all steps with regard to and the status of such Prosecution of such Patent Rights, including by providing Lian with (i) copies of all correspondence and material communications it sends to or receives from any patent office or agency in the Territory relating to such Patent Rights, (ii) a draft copy of all applications, in each case ((i) and (ii)), sufficiently in advance of filing or response to permit reasonable review and comment by Lian, and (iii) a copy of applications as filed, together with notice of its filing date and serial number. Before Lyra submits any material filing, including a new patent application, or response to such patent authorities with respect to any Licensed Patent Rights or Joint Patent Rights, Lyra will provide Lian with a reasonable opportunity to review and comment on such filing or response and will incorporate any reasonable and timely comments or suggestions provided by Lian regarding the Prosecution of such Licensed Patent Rights or Joint Patent Rights under this Section 7.2(a) (In the Territory). For clarity, Lyra may deem unreasonable (and, therefore, have no obligation to incorporate) any comments from Lian that Lyra reasonably believes would be detrimental to Lyra's Prosecution strategy of such Licensed Patent Rights outside of the Territory (even if such comments may be considered reasonable to incorporate regarding such Prosecution in the Territory).

(b) Step-In Right. If Lyra elects not to continue to Prosecute a given Patent Right within the Licensed Patent Rights or Joint Patent Rights in the Territory pursuant to Section 7.2(a) (In the Territory), then Lyra will give Lian notice thereof within a reasonable period (but not less than [***] days) prior to allowing such Patent Rights to lapse or become abandoned or unenforceable, and Lian will have the right, but not the obligation, to assume the Prosecution of such Patent Rights in such Region, including paying any required fees to maintain such Patent Rights in such Region, all at Lian's sole expense and through patent counsel or agents of its choice. Upon transfer of Lyra's responsibility for Prosecuting any of the Patent Rights to Lian under this Section 7.2(b) (Step-In Right), (i) Lyra will promptly deliver to Lian copies of all necessary files related to the Patent Rights with respect to which responsibility has been transferred and will take all actions and execute all documents reasonably necessary for Lian to assume such Prosecution, and (ii) such Patent Right shall no longer extend the Royalty Term pursuant to Section 6.2(b) (Royalty Term).

(c) Cooperation. Each Party will, and will cause its Affiliates to, reasonably cooperate, with the other Party with respect to the Prosecution of Licensed Patent Rights and Joint Patent Rights pursuant to this Section 7.2 (Prosecution and Maintenance of the Licensed Patent Rights and Joint Patent Rights), including with respect to obtaining patent term restoration, supplemental protection certificates or their equivalents, and patent terms extension with respect to the Licensed Patent Rights and Joint Patent Rights in any Region where applicable.

(d) Patents Controlled by One Party. Except as otherwise provided under this Agreement, as between Lyra and Lian, each Party will have the sole right (but not the obligation) to Prosecute, at its own cost and expense, all Patent Rights that are Controlled by such Party or its Affiliates.

7.3 Third Party Infringement.

(a) Notice. Each Party will promptly notify the other in writing if such Party becomes aware of any (i) suspected, threatened, or actual infringement by any Third Party of any Licensed Patent Right or Joint Patent Right in the Territory or (ii) unauthorized use or misappropriation of any Licensed Know-How by any Third Party that impacts or may impact the other Party's rights granted hereunder, and, in each case, will provide the other Party with all evidence in such Party's possession or control supporting such infringement or unauthorized use or misappropriation (each, an "Infringement").

(b) Lian First Right. As between the Parties, Lian will have the first right, but not the obligation, using counsel of its choosing and at its sole expense, to institute any Action alleging Infringement of the Licensed Technology within the scope of the exclusive license granted to Lian in Section 2.1(a)(i) or the non-exclusive license granted to Lian in Section 2.1(a)(ii) (subject to the restrictions set forth therein) or any Joint Patent Rights in the Field in the Territory (any such Action, an "Infringement Action"). Lyra shall have the right, at its own cost and expense, to be represented in any Infringement Action by counsel of its own choice. Lian will notify Lyra of its decision to commence an Infringement Action, will keep Lyra apprised in writing of any such Infringement Action and will consider Lyra's reasonable interests and requests regarding such Infringement Action.

(c) Lyra Right. If Lian fails to commence a suit to enforce the Licensed Technology or Joint Patent Rights against such Infringement Action (or to settle or otherwise secure the abatement of such Infringement Action) within (i) [***] after its receipt or delivery of notice under Section 7.3 (Third Party Infringement), or (ii) [***] before the time limit, if any, set forth in the appropriate Laws for the filing of such actions, whichever comes first, or ceases to diligently pursue such Infringement Action, then Lyra will have the right, but not the obligation, at its own expense to institute such Infringement Action against the applicable Third Party infringer(s).

(d) Cooperation. In any Infringement Action brought under the Licensed Technology or Joint Patent Rights pursuant to Section 7.3(b) (Lian First Right) and Section 7.3(c) (Lyra Right), each Party will, and will cause its Affiliates to, reasonably cooperate with each other, in good faith, relative to the other Party's efforts to protect the Licensed Technology and Joint Patent Rights, and will join such suit as a party, if requested by the other Party. Furthermore, the Party initiating any Infringement Action pursuant to Section 7.3(b) (Lian First Right) or Section 7.3(c) (Lyra Right) will consider in good faith all reasonable and timely comments from the other Party on any proposed arguments asserted or to be asserted in litigation related to the enforcement or defense of any such Patent Rights. Neither Party will have the right to settle any Infringement Action under this Section 7.3 (Third Party Infringement) in a manner that diminishes the rights or interests of the other Party under this Agreement without the consent of such other Party, which consent will not be unreasonably withheld.

(e) Allocation of Recoveries. Any settlements, damages or monetary awards recovered by either Party pursuant to any Infringement Action will (i) first be allocated to reimbursing the Parties for their reasonable out-of-pocket expenses in making such recovery (which amounts will be allocated pro rata if insufficient to cover the totality of such expenses), and (ii) (A) [***] or (B) [***].

7.4 Claimed Infringement. Each Party will promptly notify the other Party if a Third Party brings any Action alleging patent infringement by Lian or Lyra or any of their respective Affiliates or Sublicensees with respect to the Development, Manufacture or Commercialization of any Licensed Product or Joint Patent Rights (any such Action, an "Infringement Claim") in the Territory. Lian will have the right, but not the obligation, to control the defense and response to any such Infringement Claim in the Field in the Territory with respect to Lian's activities, at

Lian's sole cost and expense, and Lyra will have the right, at its own expense, to be represented in any such Infringement Claim in the Territory by counsel of its own choice. Lyra will have the sole right, but not the obligation, to control the defense and response to any such Infringement Claim with respect to Lyra's activities, including any such Infringement Claim in the Territory or outside of the Territory. Upon the request of the Party controlling the response to the Infringement Claim, the other Party will reasonably cooperate with the controlling Party in the reasonable defense of such Infringement Claim. The other Party will have the right to consult with the controlling Party concerning any Infringement Claim and to participate in and be represented by independent counsel in any associated litigation. If the Infringement Claim is brought against both Parties, then each Party will have the right to defend against the Infringement Claim. The Party defending an Infringement Claim under this Section 7.4 (Claimed Infringement) will (a) consult with the other Party as to the strategy for the prosecution of such defense, (b) consider in good faith any comments from the other Party with respect thereto and (c) keep the other Party reasonably informed of any material steps taken and provide copies of all material documents filed, in connection with such defense. The Party controlling the defense against an Infringement Claim will have the right to settle such Infringement Claim on terms deemed reasonably appropriate by such Party, provided, that, neither Party will have the right to settle any Infringement Claim under this Section 7.4 (Claimed Infringement) in a manner that diminishes the rights or interests of the other Party under this Agreement without the consent of such other Party, which consent will not be unreasonably withheld.

7.5 Common Interest. All information exchanged between the Parties regarding the Prosecution, enforcement, and defense, of Licensed Patent Rights and Joint Patent Rights under this Article 7 (Intellectual Property Ownership, Protection and Related Matters) will be deemed Confidential Information of the disclosing Party. In addition, the Parties acknowledge and agree that, with regard to such Prosecution, enforcement, and defense, the interests of the Parties as collaborators and licensor and licensee are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Patent Rights under this Article 7 (Intellectual Property Ownership, Protection and Related Matters), including privilege under the common interest doctrine and similar or related doctrines. Notwithstanding any provision to the contrary set forth in this Agreement, to the extent a Party has a good faith belief that any information required to be disclosed by such Party to the other Party under this Article 7 (Intellectual Property Ownership, Protection and Related Matters) is protected by attorney-client privilege or any other applicable legal privilege or immunity, such Party will not be required to disclose such information, and the Parties will in good faith cooperate to agree upon a procedure (including entering into a specific common interest agreement, disclosing such information on a "for counsel eyes only" basis or similar procedure) under which such information may be disclosed without waiving or breaching such privilege or immunity.

ARTICLE 8
CONFIDENTIALITY AND PUBLICITY

8.1 Confidential Information.

(a) Confidentiality Obligation. During the Term and for a period of [***] years after any termination or expiration of this Agreement, each Party agrees to, and will cause its Affiliates and Sublicensees and contractors to, keep in confidence and not to disclose to any Third Party, or use for any purpose, except to exercise its rights or perform its obligations under this Agreement, any Confidential Information of the other Party, without the prior written consent of such disclosing Party. The Parties agree that (i) the existence and terms of this Agreement are the Confidential Information of each Party; (ii) the reports provided by Lian to Lyra pursuant to Section 3.5(b) (Reporting)

and Section 4.4(c) (Reporting Obligation) are the Confidential Information of Lian; and (iii) the Licensed Know-How, unpublished applications within the Licensed Patent Rights, and Assigned Inventions are the Confidential Information of Lyra.

(b) Permitted Disclosures. Each Party agrees that it and its Affiliates will provide or permit access to the other Party's Confidential Information only to the receiving Party's employees, consultants, advisors, licensees, collaboration partners, and Sublicensees, and to the employees, consultants and advisors of the receiving Party's Affiliates, in each case on a need to know basis who are subject to obligations of confidentiality and non-use with respect to such Confidential Information no less stringent than the obligations of confidentiality and non-use of the receiving Party pursuant to this Section 8.1 (Confidential Information). Each Party will remain responsible for any failure by its Affiliates, licensees, collaboration partners, or Sublicensees, and its and its Affiliates' respective employees, consultants and advisors, to treat such Confidential Information as required under this Section 8.1 (Confidential Information) as if such Affiliates, employees, consultants, advisors, licensees, collaboration partners, and Sublicensees were parties directly bound to the requirements of this Section 8.1 (Confidential Information).

(c) Confidentiality Limitation. Notwithstanding any provision to the contrary set forth in this Agreement, each Party may use and disclose the other Party's Confidential Information as follows: (i) under appropriate written confidentiality and non-use obligations substantially equivalent to those in this Agreement, to its Affiliates, *bona fide* potential or actual collaboration partners, licensors, Sublicensees, licensees, strategic partners or securitization partners, and to employees, directors, agents, consultants, and advisers of any other Third Parties, (ii) to its financial advisors, attorneys and accountants, *bona fide* actual or potential acquisition partners, financing sources or investors and underwriters on a need to know basis, in each case under appropriate confidentiality and non-use obligations (which may include professional ethical obligations) no less stringent than those in this Agreement, but of duration customary in confidentiality agreements entered into for a similar purpose; provided, however, that each Party will remain responsible for any failure by any of the foregoing individuals to treat such Confidential Information as required under Section 8.1 (Confidential Information) as if such individuals were parties directly bound to the requirements of this Section 8.1 (Confidential Information), (iii) as required by any court or other governmental body or as otherwise required by applicable Laws (including any such disclosures as are required by a Regulatory Authority in connection with seeking Regulatory Approval, Pricing and Reimbursement Approval, import authorization for any Licensed Product in the Territory, or the rules or regulations of the United States Securities and Exchange Commission or similar Regulatory Authority in a country other than the United States or of any stock exchange or listing entity (including in connection with the public sale of securities)); provided, that, notice is promptly given to the other Party and the disclosing Party cooperates with reasonable requests from the other Party to seek a protective order or other appropriate remedy to protect the Confidential Information, (v) with the disclosing Party's prior written consent, to the extent such use or disclosure is reasonably necessary for the Prosecution of the Licensed Patent Rights. Notwithstanding any provision to the contrary contained in this Article 8 (Confidentiality and Publicity), Confidential Information that is permitted or required to be disclosed will remain otherwise subject to the confidentiality and non-use provisions of Section 8.1(b) (Permitted Disclosures) and this Section 8.1(c) (Confidentiality Limitation). If either Party concludes that a copy of this Agreement must be filed with the United States Securities and Exchange Commission or similar Governmental Authority in a country other than the United States, then such Party will, a reasonable time prior to any such filing, provide the other Party with a copy of such agreement showing any provisions hereof as to which the

Party proposes to request confidential treatment, will provide the other Party with an opportunity to comment on any such proposed redactions and to suggest additional redactions, and will take such Party's reasonable comments into consideration before filing such agreement and use reasonable efforts to have terms identified by such other Party afforded confidential treatment by the applicable Regulatory Authority.

(d) Secrecy of Licensed Know-How. Without limiting the generality of Section 8.1(a) (Confidentiality Obligation), during the Term, each Party will protect, and will cause, to the extent applicable, its Affiliates and Sublicensees, and its and their respective officers, directors, employees, and agents to protect, the secrecy and confidentiality of the Licensed Know-How, Assigned Inventions, Product Inventions and unpublished applications within the Patent Rights using at least the same degree of care as it uses to prevent the disclosure of its own other confidential information of like importance and in any event a reasonable duty of care.

8.2 Publicity. The Parties acknowledge the importance of supporting each other's efforts to publicly disclose results and significant developments regarding the Licensed Product in the Field in the Territory, and each Party may make such disclosures from time to time, subject to the terms and conditions of this Agreement, including this Section 8.2 (Publicity). Such disclosures may include achievement of milestones, significant events in the Development process with respect to Licensed Products, or Commercialization activities with respect to Licensed Products.

(a) On a date to be agreed by the Parties, the Parties will jointly issue a press release regarding the signing of this Agreement. Except as set forth in the preceding sentence and for disclosures permitted in accordance with Section 8.1(b) (Permitted Disclosures), whenever either Party elects to make any public disclosure regarding milestones or other significant events in the Development or Commercialization of the Licensed Products in the Field in the Territory, it will first notify the other Party of such planned press release or public announcement and provide a draft for review no less than [***] in advance of issuing such press release or making such public announcement (or, with respect to press releases and public announcements that are required by applicable Laws, with as much advance notice as possible under the circumstances if it is not possible to provide notice at least [***] in advance). Each Party will have the right to review and approve any such planned press release or public announcement proposed by the other Party with respect to Licensed Products in the Field in the Territory, or that includes Confidential Information of the other Party. In such case, (i) the reviewing Party will attempt to provide such approval as soon as reasonably possible and will not unreasonably withhold such approval; (ii) the reviewing Party will provide explanations of its disapproval of such press release; and (iii) a Party desiring to make such public disclosure may issue such press release or public announcement without such prior review by the other Party if (A) the contents of such press release or public announcement have previously been made public other than through a breach of this Agreement by such Party, and (B) such press release or public announcement is consistent with the previously issued press release or other publicly available information; and provided that [***]. The Party reviewing a press release provided under this clause (i) of this Section 8.2(a) (Publicity) will review and approve or disapprove such press release within [***] Business Days after its receipt thereof.

(b) In the event that either Party proposes to publish or present the results of Development or Commercialization carried out on the Licensed Product in the Field in the Territory, including any oral presentation or abstract that contain clinical data or pertain to results of Clinical Trials or other studies in the Field in the Territory, such publication or presentation will be subject to the prior review by the other Party for protection of such other Party's Confidential Information and to identify concerns regarding competitive

disadvantage arising from such publication or presentation. Each Party will provide to the other Party the opportunity to review a draft of any proposed publication that covers the results of Development or Commercialization of Licensed Products in the Field in the Territory during the Term, and the submitting Party (i) will remove from such proposed publication any Confidential Information of the other Party as reasonably requested by the other Party and (ii) will not submit such publication or presentation until the concerns of the other Party regarding any such potential competitive disadvantage are resolved by the JSC.

ARTICLE 9
REPRESENTATIONS AND WARRANTIES; CERTAIN COVENANTS

9.1 Mutual Representations and Warranties. Each Party represents, warrants, and covenants to the other Party that, as of the Effective Date:

(a) Organization. It is a corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

(b) Authority. It has full right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement, it has the right to grant to the other the licenses and sublicenses granted pursuant to this Agreement, and this Agreement and the performance by such Party of this Agreement do not violate such Party's charter documents, bylaws or other organizational documents.

(c) Consents. Except for any Marketing Authorizations, Regulatory Approvals, Regulatory Filings, Manufacturing approvals or similar approvals necessary for the Development, Manufacture or Commercialization of Licensed Products, all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons required to be obtained by it in connection with the execution, delivery and performance of this Agreement have been obtained.

(d) No Conflict. It is not under any obligation, contractual or otherwise, to any Person that would materially affect the diligent and complete fulfillment of obligations under this Agreement and the execution and delivery of this Agreement by such Party, and the performance of such Party's obligations under this Agreement (as contemplated as of the Effective Date) and the licenses and sublicenses to be granted by such Party pursuant to this Agreement (i) do not conflict with or violate any requirement of Laws applicable to such Party, (ii) do not conflict with or violate any order, writ, judgment, injunction, decree, determination, or award of any court or Governmental Authority presently in effect applicable to such Party, and (iii) do not conflict with, violate, breach or constitute a default under, or give rise to any right of termination, cancellation or acceleration of, any contractual obligations of such Party or any of its Affiliates.

(e) Enforceability. This Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms, subject to the general principles of equity and subject to bankruptcy, insolvency, moratorium, judicial principles affecting the availability of specific performance and other similar Laws affecting the enforcement of creditors' rights generally.

(f) Compliance with Laws. The Parties will, and will ensure that their respective Affiliates and Sublicensees will, comply in all material respects with all applicable Laws in exercising their rights and fulfilling their obligations under this Agreement. Without limiting the generality of the foregoing, the Parties will conduct all Development, and Commercialization activities relating to the Licensed Product under this Agreement in

accordance with applicable Laws (including data privacy Laws, current international regulatory standards, including, as applicable, GMP, GLP, GCP, and other rules, regulations and requirements), Export Control Laws, Anti-Corruption Laws and all other applicable Laws concerning bribery, money laundering, or corrupt practices or that in any manner prohibit the giving of anything of value to any official, agent, or employee of any government, political party, or public international organization, candidate for public office, health care professional, or to any officer, director, employee, or representative of any other organization specifically including the U.S. Foreign Corrupt Practices Act, and the UK Bribery Act, in each case, in connection with the activities conducted pursuant to this Agreement. The Parties will cause all permitted collaborators, contractors, subcontractors, Sublicensees, or other Persons that provide services to such Party in connection with this Agreement to comply with such Party's obligations under this Section 9.1(f) (Compliance with Laws).

9.2 Additional Representations and Warranties of Lyra. Lyra represents and warrants to Lian that, as of the Effective Date:

(a) Licensed Patent Rights. All Licensed Patent Rights as of the Effective Date are listed in Schedule 1.75 (Licensed Patents). Lyra is the sole and exclusive owner of the Licensed Patent Rights, all of which are free and clear of any claims, liens, charges or encumbrances. All Licensed Patent Rights have been filed and Prosecuted in good faith in the patent offices in accordance with applicable Laws, and all applicable fees have been paid on or before the due date for payment. All issued Licensed Patent Rights are valid and, to Lyra's knowledge, subsisting and enforceable.

(b) Licensed Know-How. Lyra Controls the Licensed Know-How, and has the right to grant the licenses under the Licensed Know-How to Lian on and the terms set forth in this Agreement. Lyra has the right to use and disclose (in each case, under appropriate circumstances of confidentiality) the Licensed Know-How free and clear of any claims, liens, charges or encumbrances.

(c) Licensed Technology. Lyra has not granted to any Third Party, including any academic organization or agency, any license, option or other rights to research, Develop, Manufacture, use or Commercialize the Licensed Product in the Field in the Territory. No Third Party has any license, option or other rights or interest in or to the Licensed Technology in the Field in the Territory other than the rights that are expressly reserved or contingent under this Agreement.

(d) Control. Lyra or its Affiliates Controls all Patent Rights and Know-How owned, invented, or licensed by Lyra as of the Effective Date that are necessary or actually used as of the Effective Date to Develop, Commercialize, Manufactured and otherwise, use, offer for sale, sell, have sold, and import the Licensed Products.

(e) Licensed Marks. Lyra owns or Controls the Licensed Marks, and has the right to grant the licenses under the Licensed Marks to Lian on the terms set forth in this Agreement.

(f) Delivery of Documentation. Prior to the Effective Date, Lyra has made available to Lian true, complete, and correct copies of: (i) all existing material Regulatory Filings in its possession and control relating to Licensed Products, (ii) all material adverse information with respect to the safety and efficacy of the Licensed Products in Lyra's or its Affiliates' (to the extent applicable, in accordance with Section 2.1(b)) (Lian Right of Access and Reference) possession and control, and (iii) all material data and results relating to the Development of the Licensed Products in Lyra's or its Affiliates' possession and control (to the extent applicable, in accordance with Section 2.1(b)) (Lian Right of Access and Reference).

(g) Third Party Challenges. There are no claims, judgments, or settlements against, or amounts with respect thereto, made against Lyra or any of its Affiliates relating to the Licensed Patent Rights or the Licensed Know-How, and no claim or litigation has been received by Lyra or its Affiliates or, to Lyra's knowledge, threatened by any Person (i) alleging that the Licensed Patent Rights are invalid or unenforceable, (ii) asserting the misuse of any of the Licensed Patent Rights, (iii) challenging Lyra's Control of the Licensed Patent Rights (i.e., alleging that a Third Party has a right or interest in or to the Licensed Technology), or (iv) alleging misappropriation of the Know-How of any Third Party used in the Development, Manufacture or Commercialization of Licensed Products by or on behalf of Lyra prior to the Effective Date.

(h) Non-Infringement of Third Party IP. To Lyra's knowledge, the Development, Manufacture, or Commercialization of the Licensed Product, as conducted by Lyra, its Affiliates, or its or their Sublicensees on or prior to the Effective Date does not infringe any Patent Right or misappropriate or otherwise violate or misappropriate any Know-How of any Person (in the case of pending Patent Rights, evaluating them as if issued). No claim of infringement of the Patent Rights or misappropriation of the Know-How of any Third Party has been received by the Lyra, or to Lyra's knowledge, threatened, against Lyra, any of its Affiliates or its or their Sublicensees with respect to the Development, Manufacture or Commercialization of Licensed Products. To Lyra's knowledge, the Development, Manufacture, or Commercialization of the Licensed Product will not infringe, misappropriate or otherwise violate any Intellectual Property of any Third Party.

(i) Absence of Litigation. There are no judgments or settlements against or owed by Lyra or its Affiliates or Sublicensees, or, to Lyra's knowledge, pending litigation against Lyra or its Affiliates or Sublicensees, or litigation threatened against Lyra or its Affiliates or Sublicensees, in each case, related to the Licensed Product, including any such litigation any relating to any Regulatory Filings, Regulatory Approvals, or Marketing Authorizations Controlled by Lyra, its Affiliates or its Sublicensees.

(j) Maintenance of Regulatory Filings, Good Laboratory, and Clinical Practices. Lyra Controls all Regulatory Filings pertaining to the Licensed Product in the Field in the Territory. Lyra and its Affiliates and Sublicensees have generated, prepared, maintained, and retained all Regulatory Filings and Marketing Authorizations relevant to Licensed Products in the Field in the Territory in its control that are required to be maintained or retained pursuant to and in material compliance with applicable Laws, and have conducted in material compliance with applicable Laws, including GLP and GCP all Development of Licensed Products in the Field conducted prior to the Effective Date.

(k) Confidentiality of Know-How. Lyra has taken commercially reasonable measures consistent with its usual business practice (but in any event no less than industry standard practices) to protect the secrecy, confidentiality, and value of all Licensed Know-How. To Lyra's knowledge, the Licensed Know-How existing as of the Effective Date has been kept confidential or has been disclosed to Third Parties only under terms of confidentiality.

(l) Assignment of Third Party Rights; Third Party Consents.

(i) Lyra has obtained from each of its employees and agents, and from the employees and agents of its Affiliates, who are performing Development activities under the Global Development Plan for Licensed Products, rights to any and all Know-How created by such employees and agents in the course of such activities that relates to Licensed Products, such that Lian will, by virtue

of this Agreement, receive from Lyra, without payments beyond those required by Article 6 (Financial Provisions), all licenses and other rights granted to Lian under this Agreement.

(ii) Each Person who has or has had any ownership rights in or to any Licensed Patent Rights purported to be owned solely by Lyra, has assigned and has executed an agreement assigning its entire rights, title, and interests in and to such Licensed Patent Rights to Lyra, and to Lyra's knowledge, no current officer, employee, agent, or consultant of Lyra or any of its Affiliates is in violation of any term of any assignment or other agreement, in each case, regarding the protection of the Licensed Patent Rights.

(iii) Prior to the Effective Date, Lyra has obtained all consents from Third Parties necessary to grant Lian the licenses and rights Lyra purports to grant to Lian under this Agreement.

(m) Statements to Regulatory Authorities. Neither Lyra nor any of its Affiliates, nor, to Lyra's knowledge, its Sublicensees nor any of its or their respective officers, employees, or agents has made an untrue statement of material fact or fraudulent statement to any Regulatory Authority with respect to the Development or Commercialization of Licensed Products, or failed to disclose a material fact required under applicable Laws to be disclosed to any Regulatory Authority with respect to the Development or Commercialization of Licensed Products.

(n) Compliance with Laws. All of the studies, tests, and pre-clinical and Clinical Trials of Licensed Products conducted prior to, or being conducted as of, the Effective Date by or on behalf of Lyra have been and are being conducted in all material respects in accordance with applicable Laws.

(o) No Other Disclosures. To Lyra's knowledge, (i) there are no scientific or technical facts or circumstances that have not been disclosed to Lian that would adversely affect the scientific, therapeutic, or commercial potential of the Licensed Products; (ii) there is nothing within Lyra's Control that has not been disclosed to Lian and that could adversely affect the acceptance, or the subsequent approval, by any Regulatory Authority of any Regulatory Filing; and (iii) there are no safety, efficacy, or regulatory issues that would preclude Lian from exploiting the Licensed Products in the Territory in accordance with this Agreement and applicable Law.

9.3 No Conflict. During the Term, Lyra and its Affiliates will not grant any interest in the Licensed Technology that is inconsistent with the terms and conditions of this Agreement.

9.4 No Debarment. Each of Lyra and Lian represents and warrants that neither it nor any of its or its Affiliates' employees or agents performing under this Agreement has ever been, or is currently: (a) debarred under 21 U.S.C. § 335a or by any Regulatory Authority; (b) excluded, debarred, suspended, or otherwise ineligible to participate in federal health care programs or in federal procurement or non-procurement programs; (c) listed on the FDA's Disqualified and Restricted Lists for clinical investigators; or (d) convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. Each of Lyra and Lian further covenants that if, during the Term of this Agreement, it becomes aware that it or any of its or its Affiliates' employees or agents performing under this Agreement is the subject of any investigation or proceeding that could lead to that Party becoming a debarred entity or individual, an excluded entity or individual or a convicted entity or individual, then such Party will promptly notify the other Party. This provision will survive termination or expiration of this Agreement.

9.5 NO OTHER WARRANTIES. EXCEPT AS EXPRESSLY STATED IN SECTION 9.1 (MUTUAL REPRESENTATIONS AND WARRANTIES), SECTION 9.2 (ADDITIONAL REPRESENTATIONS AND WARRANTIES OF LYRA) AND SECTION 9.4 (NO DEBARMENT), NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WARRANTIES OF TITLE, NON-INFRINGEMENT OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY WITH RESPECT TO THE LICENSED PRODUCT, VALIDITY, ENFORCEABILITY, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 10
INDEMNIFICATION; DAMAGES

10.1 Indemnification by Lyra. Lyra will defend, indemnify and hold harmless Lian, its Affiliates and their respective directors, officers, employees and agents (each, a "Lian Indemnified Party"), from, against and in respect of any and all Third Party Losses incurred or suffered by any Lian Indemnified Party to the extent resulting from or relating to: (a) any breach of any representation or warranty made by Lyra in this Agreement, or any breach by Lyra of any obligation, covenant, or agreement in this Agreement; (b) the gross negligence or intentional misconduct of Lyra or any of its Affiliates, Sublicensees, or contractors, or any of their respective directors, officers, employees, or agents, in performing Lyra's obligations or exercising Lyra's rights under this Agreement; (c) activities conducted by or on behalf of Lyra or its Affiliates or (sub)licensees or contractors related to the Development, Manufacture, or Commercialization of Licensed Products anywhere in the world prior to the Effective Date; (d) the Development, Manufacture, or Commercialization of the Licensed Products by or on behalf of Lyra, any of its Affiliates, Sublicensees (other than Lian), or contractors outside the Territory; or (e) Lyra's or its Affiliate's status as an applicant or a holder of any Regulatory Approval for the Licensed Products; provided, however, that Lyra's obligations pursuant to this Section 10.1 (Indemnification by Lyra) will not apply to the extent such Third Party Losses result from Third Party Losses for which Lyra has an obligation to indemnify Lian pursuant to Section 10.2 (Indemnification by Lian).

10.2 Indemnification by Lian. Lian will defend, indemnify and hold harmless Lyra, its Affiliates, and each of their respective directors, officers, employees and agents (each, a "Lyra Indemnified Party") from, against and in respect of any and all Third Party Losses incurred or suffered by any Lyra Indemnified Party to the extent resulting from or relating to: (a) any breach of any representation or warranty made by Lian in this Agreement, or any breach by Lian of any obligation, covenant, or agreement in this Agreement, (b) the gross negligence or intentional misconduct of, or violation of Laws by, Lian, any of its Affiliates, Sublicensees, or contractors, or any of their respective directors, officers, employees, or agents, in performing Lian's obligations or exercising Lian's rights under this Agreement, (c) the Development, Manufacture, or Commercialization of the Licensed Product by or on behalf of Lian or its Affiliates or Sublicensees (other than Lyra) or contractors; or (d) Lian's or its Affiliate's status as an applicant or a holder of any Regulatory Approval for the Licensed Products; provided, however, that Lian's obligations pursuant to this Section 10.2 (Indemnification by Lian) will not apply to the extent such Third Party Losses result from Third Party Losses for which Lyra has an obligation to indemnify Lian pursuant to Section 10.1 (Indemnification by Lyra).

10.3 Claims for Indemnification.

(a) Notice. An Indemnified Party entitled to indemnification under Section 10.1 (Indemnification by Lyra) or Section 10.2 (Indemnification by Lian) will give prompt written notification to the Indemnifying Party from whom indemnification is sought of the commencement of any Action by a Third Party for which indemnification may be sought (a "Third Party Claim") or, if earlier, upon the assertion of such Third Party

Claim by a Third Party; provided, however, that failure by an Indemnified Party to give notice of a Third Party Claim as provided in this Section 10.3(a) (Notice) will not relieve the Indemnifying Party of its indemnification obligation under this Agreement, except and only to the extent that such Indemnifying Party is materially prejudiced as a result of such failure to give notice.

(b) Defense. Within [***] days after delivery of a notice of any Third Party Claim in accordance with Section 10.3(a) (Notice), the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such Third Party Claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, then the Indemnified Party may control such defense (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not to be unreasonably withheld). The Party not controlling such defense may participate therein at its own expense.

(c) Cooperation. The Party controlling the defense of any Third Party Claim will keep the other Party advised of the status and material developments of such Third Party Claim and the defense thereof and will reasonably consider recommendations made by the other Party with respect thereto. The other Party will reasonably cooperate with the Party controlling such defense and its Affiliates and agents in defense of the Third Party Claim, with all out-of-pocket costs of such cooperation to be borne by the Party controlling such defense.

(d) Settlement. The Indemnified Party will not agree to any settlement of such Third Party Claim without the prior written consent of the Indemnifying Party, which consent will not be unreasonably withheld. The Indemnifying Party will not agree to any settlement of such Third Party Claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party (other than a monetary obligation on the Indemnifying Party), without the prior written consent of the Indemnified Party, which will not be unreasonably withheld (unless such compromise or settlement involves (i) any admission of legal wrongdoing by the Indemnified Party, (ii) any payment by the Indemnified Party that is not indemnified under this Agreement, or (iii) the imposition of any equitable relief against the Indemnified Party (in which case, (i) through (iii), the Indemnified Party may withhold its consent to such settlement in its sole discretion)).

(e) Mitigation of Loss. Each Indemnified Party will take and will procure that its Affiliates and Sublicensees take all such reasonable steps and actions as are necessary or as the Indemnifying Party may reasonably require in order to mitigate any Third Party Claims (or potential losses or damages) under this Article 10 (Indemnification; Damages). Nothing in this Agreement will or will be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

10.4 Insurance. Each Party, at its own expense, will maintain liability insurance (or self-insure) with respect to its activities under this Agreement in an amount consistent with industry standards. Each Party will provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request. Without limiting the foregoing, during the Term and thereafter for the period of time required below, each Party will maintain on an ongoing basis comprehensive general liability insurance policies which are consistent with normal business practices of prudent companies similar situated in such Party's territory. Not later than [***] days following receipt of written request from a Party, the other Party will provide to the requesting Party a certificate of insurance evidencing such insurance policies. Each Party will maintain such insurance or self-insurance coverage without interruption during the Term

and for a period of [***] thereafter, and, if applicable, will provide certificates or letters evidencing such insurance coverage without interruption as reasonably requested during the period of time for which such coverage must be maintained. Each Party will be provided at least [***] days' prior written notice of any cancellation or material decrease in the other Party's insurance coverage limits described above. Notwithstanding the foregoing, either Party's failure to maintain adequate insurance will not relieve that Party of its obligations set forth in this Agreement.

ARTICLE 11
LIMITATION OF LIABILITY

11.1 NO CONSEQUENTIAL OR PUNITIVE DAMAGES. EXCEPT AS SET FORTH IN SECTION 11.2 (EXCLUSION FROM LIABILITY LIMITATION), NEITHER PARTY NOR ANY OF ITS AFFILIATES OR AFFILIATED ENTITIES WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS OR THE PERFORMANCE OF ITS OBLIGATIONS HEREUNDER, OR ANY LOST PROFITS ARISING OUT OF THIS AGREEMENT, IN EACH CASE, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY, OR OTHERWISE, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES.

11.2 EXCLUSION FROM LIABILITY LIMITATION. THE LIMITATIONS AND DISCLAIMER SET FORTH IN SECTION 11.1 (NO CONSEQUENTIAL OR PUNITIVE DAMAGES) WILL NOT APPLY TO A CLAIM: (A) FOR GROSS NEGLIGENCE OR WILLFUL MISCONDUCT; (B) FOR A BREACH OF SECTION 2.9 (NON-COMPETE), Article 8 (CONFIDENTIALITY AND PUBLICITY); OR (C) FOR INDEMNIFIABLE LOSSES PURSUANT TO SECTION 10.1 (INDEMNIFICATION BY LYRA) OR SECTION 10.2 (INDEMNIFICATION BY LIAN), AS APPLICABLE.

ARTICLE 12
TERM AND TERMINATION

12.1 Term. Unless terminated earlier in accordance with this Article 12 (Term and Termination), this Agreement will become effective as of the Effective Date and will continue in full force, on a Region-by-Region basis, until the expiration of the Royalty Term applicable to such Licensed Product in such Region(the "Term").

12.2 Paid-Up License Upon End of Royalty Term. Upon the expiration of the Royalty Term for a given Licensed Product in a given Region in the Territory, the licenses and rights of reference granted to Lian pursuant to Section 2.1 (License Grants; Rights of Reference) will become perpetual, irrevocable, fully paid-up, royalty free, fully sublicensable, and transferable with respect to such Licensed Product in such Region.

12.3 Early Termination.

(a) Termination for Material Breach. Upon (i) any material breach of this Agreement by Lyra or (ii) any material breach of this Agreement by Lian (the Party so allegedly breaching being the "Breaching Party"), the other Party (the "Non-Breaching Party") will have the right, but not the obligation, to terminate this Agreement by providing written notice to the Breaching Party within [***] days in the case of a payment breach, or [***] days in the case of any other material breach, which notice will, in each case (A) expressly reference this Section 12.3(a) (Termination for Material Breach), (B) reasonably describe the alleged breach that is the basis of such termination, and (C) clearly state the Non-Breaching Party's intent to terminate this Agreement if the alleged

breach is not cured within the applicable cure period. Notwithstanding the foregoing, if such material breach, by its nature, is curable, but is not reasonably curable within the applicable cure period, then such cure period will be extended if the Breaching Party provides a written plan for curing such breach to the Non-Breaching Party and uses reasonable efforts to cure such breach in accordance with such written plan; provided, however, that no such extension will exceed [***] days without the prior written consent of the Non-Breaching Party. In addition, if the Breaching Party disputes (A) whether it has materially breached this Agreement, (B) whether such material breach is reasonably curable within the applicable cure period, or (C) whether it has cured such material breach within the applicable cure period, then the dispute will be resolved pursuant to Article 13 (Dispute Resolution), and the applicable cure period will be tolled during the pendency of such dispute resolution procedure.

(b) Termination by Lian for Convenience. Lian may, upon [***] days' prior written notice to Lyra, terminate this Agreement for convenience, without cause, and for any or no reason, in its entirety.

(c) Termination for Bankruptcy. This Agreement may be terminated, to the extent permitted by applicable Laws, by either Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, that in the case of any involuntary bankruptcy, reorganization, liquidation or receivership proceeding such right to terminate will only become effective if the Party subject to such proceeding consents to the involuntary bankruptcy or such proceeding is not dismissed within [***] days after the filing thereof.

(d) Patent Challenge. Lyra has the right to terminate this Agreement upon written notice to Lian in the event that Lian or any of its Affiliates or Sublicensees directly or indirectly challenges in a legal or administrative proceeding the patentability, enforceability or validity of any Patent Rights within the Licensed Technology (a "Patent Challenge") and does not withdraw such Patent Challenge within [***] days of written notice from Lyra; provided that, if such Patent Challenge is brought by Lian or its Affiliates and it is withdrawn within such [***]-day period, Lian shall promptly reimburse Lyra for all costs and expenses incurred by or on behalf of Lyra in defending and responding to such Patent Challenge; and provided further that this Section 12.3(d) (Patent Challenge) will not apply to any Patent Challenge that (i) is first made by Lian or any of its Affiliates or Sublicensees in defense of a claim of patent infringement brought by the Lyra under the applicable Patent Rights or any Patent Challenge, (ii) was brought by an Acquirer prior to the effective date of such Change of Control, or (iii) is brought by any non-Affiliate Sublicensee if Lian (A) causes such Patent Challenge to be terminated or dismissed (or in the case of ex-parte proceedings, multi-party proceedings, or other Patent Challenges in which the challenging party does not have the power to unilaterally cause the Patent Challenge to be withdrawn, causes such Sublicensee to withdraw as a party from such Patent Challenge and to cease actively assisting any other party to such Patent Challenge), or (B) terminates such Sublicensee's sublicense to the Patent Rights being challenged by the Sublicensee, in each case, within [***] days after the Lyra's notice to Lian under this Section 12.3(d) (Patent Challenge).

(e) Termination for Cessation of Development or Commercialization. Lyra may terminate this Agreement in the event that Lian and its Affiliates and Sublicensees do not conduct any material Development or Commercialization activities with respect to any Licensed Product for a continuous period of longer than [***] and such failure to conduct any material Development or Commercialization activity is not: (i) [***], (ii)

[***], (iii) [***], or (iv) [***] or (v) [***]. Such termination will be effective [***] days after Lian's receipt of written notice thereof, provided that, Lian may submit a written plan within [***] Business Days after Lian's receipt of such written notice that is reasonably calculated to remedy such failure to conduct any material Development or Commercialization activities with respect to a Licensed Product. If such cure plan is reasonably acceptable to Lyra and Lian commences any material Development or Commercialization activities in accordance with the terms of such cure plan during such [***] day period and provides satisfactory written documentation thereof to Lyra, then this Agreement will not terminate upon the expiration of such [***] day period.

12.4 Alternative Remedy In Lieu of Termination. Lyra stipulates and agrees that Lian's decision to enter into this Agreement and invest in the Development of the Licensed Products is premised upon the assumption that Lyra will perform its obligations under this Agreement, and that a material breach of certain obligations under this Agreement as explicitly set forth in this Section 12.4 (Alternative Remedy in Lieu of Termination) by Lyra will undermine the economic fundamentals of the transaction for Lian, and that in such event Lian's damages arising from Lyra's breach would be of uncertain amount and difficult to prove. If Lian has a right to terminate this Agreement pursuant to Section 12.3(a) (Termination for Material Breach) as a result of a breach (*i.e.*, such breach constitutes a material breach and is not cured within the applicable cure period and following any dispute resolution proceedings) by Lyra of [***], then Lian may elect, in lieu of so terminating and as Lian's sole and exclusive remedy with respect to such breach, to have this Agreement continue on all the terms herein save that all Milestone Payments and royalties payable thereafter by Lian to Lyra hereunder will be reduced by [***]. [***].

12.5 Effects of Termination.

(a) Effects of Termination Generally. Upon any termination of this Agreement, then the Parties' rights, licenses and obligations under this Agreement will terminate and neither Party will have any further rights or obligations under this Agreement from and after the effective date of termination, except as set forth in this Section 12.5 (Effects of Termination).

(b) Winding Down of Activities. If there are any on-going Development or Commercialization activities at termination or expiration of this Agreement, then the Parties will negotiate in good faith and adopt a plan to wind-down such activities in an orderly fashion or, at Lyra's election, promptly transition such activities from Lian to Lyra or its designee, with due regard for patient safety and the rights of any subjects that are participants in any Clinical Trials of the Licensed Products, and take any actions it deems reasonably necessary or appropriate to avoid any human health or safety problems and in compliance with all applicable Law.

(c) License Grant to Lyra.

(i) Upon termination of this Agreement, Lian, on behalf of itself and its Affiliates hereby grants (effective on delivery of the notice of termination) to Lyra an irrevocable, perpetual, transferable, exclusive, sublicensable (through multiple tiers), license under the Lian Technology in existence and actually used by Lian or its Affiliates or Sublicensees, in each case, as of the applicable effective date of termination to Develop, Manufacture, Commercialize and otherwise, use, offer for sale, sell, have sold, and import the Licensed Product in the Field in or for the Territory (the "Reversion License"). If any rights granted by Lian under the Reversion License are Controlled by Lian or its Affiliates or Sublicensees pursuant to an agreement with a Third Party, then Lyra will pay

all amounts due under any such agreement to the extent reasonably allocable to Lyra's exercise of the rights granted thereunder.

(ii) If Lyra or its or their Affiliates or Sublicensees exercises the Reversion License or the rights granted pursuant to Section 12.5(h) (Transfer of Regulatory Filings and Regulatory Approvals) and this Agreement has been terminated by Lian pursuant to Section 12.3(a) (Termination for Material Breach), then Lyra will pay to Lian, in consideration of the rights granted to Lyra, if Lyra (or its Affiliate, licensee or distributor) sells a Licensed Product under the Reversion License, within [***] after termination of this Agreement, then Lyra will pay to Lian [***]. The definition of "Net Sales" in Section 1.86 of this Agreement shall apply to the Net Sales of such product for determining the foregoing *mutatis mutandis*, and the terms of Section 6.3 (Royalty Payment Adjustments) and Section 6.4 (Audits) shall apply *mutatis mutandis*.

(d) Discontinuation of JSC. Upon termination of this Agreement in its entirety, the JSC will cease to exist.

(e) Accrued Obligations. Expiration or termination of this Agreement for any reason will not release either Party from any obligation or liability that, on the effective date of such expiration or termination, has already accrued to the other Party or that is attributable to a period prior to such expiration or termination.

(f) Survival. This Section 12.5(f) (Survival), the provisions set forth in the following Sections, as well as, to the extent applicable, any other Sections or defined terms referred to in such Sections or Articles or necessary to give them effect, will survive any expiration or termination of this Agreement in its entirety: Section 2.2(c) (Sublicense Survival), Section 2.4 (License Grant to Lyra), Section 2.6 (Rights in Bankruptcy) (solely with respect to any termination under Section 12.3(c) (Termination for Bankruptcy)), Article 6 (Financial Provisions) (solely with respect to payments payable prior to expiration and termination and as necessary to effectuate Section 12.5(c)(ii)), Section 7.1 (Ownership of Intellectual Property), Section 7.5 (Common Interest), Article 8 (Confidentiality and Publicity), Section 9.5 (No Other Warranties), Article 10 (Indemnification; Damages), Article 11 (Limitation of Liability), Section 12.2 (Paid-Up License Upon End of Royalty Term), Section 12.5 (Effects of Termination), Article 13 (Dispute Resolution), and Article 14 (Miscellaneous). Furthermore, any other provisions required to interpret the Parties' rights and obligations under this Agreement, including applicable definitions in Article 1 (Definitions), will survive to the extent required. Except as otherwise expressly provided in this Agreement, including all rights and obligations of the Parties under this Agreement, including this Section 12.5(f) (Survival), any licenses granted under this Agreement, will terminate upon expiration or termination of this Agreement for any reason.

(g) Inventory.

(i) Appointment as Exclusive Distributor. If Lian is Commercializing any Licensed Product in any Region in the Territory as of the effective date of termination of this Agreement, then, at Lyra's election (in its sole discretion) on a Region-by-Region basis in the Territory, [***], Lian will appoint Lyra or its designee as its exclusive distributor of such Licensed Product in such Region and grant Lyra or its designee the right to appoint sub-distributors, to the extent not prohibited by an written agreement between Lian or any of its Affiliates and any Third Party.

(ii) Sell-Off Period. At Lian's request, for a period of [***] following termination of this Agreement in any Region, Lian shall sell or otherwise dispose of any Licensed Products in such terminated Regions, as applicable, on hand at the time of such termination or in the process of Manufacturing (the "Sell-Off Period").

(iii) Lyra Buy-Back. Upon expiration of any Sell-Off Period in any Region or in the event that Lyra exercises its right to be appointed Lian's exclusive distributor pursuant to Section 12.4(g)(i) (Appointment as Exclusive Distributor), Lyra will have the right to purchase all of Lian's and its Affiliates' remaining inventory of Licensed Products held as of the effective date of expiration of such Sell-Off Period or such appointment at a price equal to (A) [***], if supplied by Lyra or (B) if Manufactured by Lian, [***].

(h) Transfer of Regulatory Filings and Regulatory Approvals. Following the effectiveness of any termination of this Agreement pursuant to Section 12.3 (Early Termination), after Lyra's written request, Lian will, to the extent permitted under applicable Laws and not commercially infeasible, and at Lyra's sole cost and expense (unless the applicable termination giving rise to Lyra's rights under this Section 12.5(h) (Transfer of Regulatory Filings and Regulatory Approvals) was for Lian's material breach pursuant to Section 12.3(a) (Termination for Material Breach), in which case such transfer will be at Lian's sole cost and expense), assign and transfer to Lyra all Regulatory Filings, filings for Pricing and Reimbursement Approval and Marketing Authorizations for Licensed Products that are held by or owned by Lian or its Affiliates or Sublicensees as of the effective date of termination and will take such actions and execute such other instruments, assignments, and documents as may be necessary to effect the transfer of rights under such Regulatory Filings, filings for Pricing and Reimbursement Approval and Marketing Authorizations to Lyra. If applicable Laws or relevant Regulatory Authorities prevent or delay the transfer of ownership of any such Regulatory Filing, filing for Pricing and Reimbursement Approval and Marketing Authorizations to Lyra, or if it is commercially infeasible for Lian to do so, then Lian will grant, and hereby does grant, to Lyra and its Affiliates, Sublicensees, and licensees an exclusive and irrevocable right of access and right of reference to such Regulatory Filing, filing for Pricing and Reimbursement Approval and Marketing Authorizations for Licensed Products in the Field in the Territory, as the case may be, and will reasonably cooperate with Lyra, at Lyra's expense (unless the applicable termination giving rise to Lyra's rights under this Section 12.5(h) (Transfer of Regulatory Filings and Regulatory Approvals) was for Lian's material breach pursuant to Section 12.3(a) (Termination for Material Breach) in which case such transfer will be at Lian's sole cost and expense), to make the benefits of such Regulatory Filings, filings for Pricing and Reimbursement Approval and Marketing Authorizations available to Lyra or its designee(s).

(i) Transfer of Data. Following the effectiveness of any termination of this Agreement pursuant to Section 12.3 (Early Termination), after Lyra's written request, Lian will, [***], (A) promptly provide to Lyra copies of all data described in Section 2.5(b) (Lyra Right of Access and Reference) to the extent not previously provided to Lyra under this Agreement, (B) provide access within the Territory to the data and samples obtained from trial subjects described in the third sentence of Section 2.5 (Lyra Right of Access and Reference), and (C) assign and transfer, and hereby does assign and transfer, and shall ensure that its Affiliates and its and their Sublicensees, and its or their employees, agents or independent contractors will assign, all of their rights, title and interest in any and all such data and samples referenced in the foregoing clauses (A) and (B), provided that Lian's obligations under the foregoing clauses (B) and (C) will be to subject to applicable Law and Lian's contractual rights and obligations with

respect thereto.

(j) Assignment of Third Party Agreements. To the extent requested by Lyra, Lian will promptly upon request assign and transfer to Lyra or its designee (i) all of Lian's rights, title and interests in and to all clinical trial agreements, manufacturing and supply agreements, and distribution agreements (to the extent assignable) in Lian's Control, in each case, to the extent such agreements solely relate to such Licensed Product and are necessary or useful for the Development, Manufacture, or Commercialization of such Licensed Product, and (ii) all of Lian's rights, title, and interests in and to any promotional materials, training materials, medical education materials, packaging and labeling, and all other literature or other information related to such Licensed Product and copyrights and any registrations for the foregoing.

(k) Return of Confidential Information. Within [***] after the effective date of termination (but not expiration) of this Agreement in its entirety, each Party will, and cause its Affiliates to (i) destroy, all tangible items solely comprising, bearing or containing any Confidential Information of the other Party that are in such first Party's or its Affiliates' possession or Control, and provide written certification of such destruction, or (ii) prepare such tangible items of the other Party's Confidential Information for shipment to such other Party, as such other Party may direct, at the first Party's expense; provided, however, that, in any event, (A) each Party may retain copies of the Confidential Information of the other Party to the extent necessary to perform its obligations or exercise its rights that survive expiration or termination of this Agreement; and (B) each Party may retain copies of the Confidential Information of the other Party for its legal archives.

(l) Cooperation. Each Party will cause its Affiliates, Sublicensees, and contractors to comply with the obligations in this Section 12.5 (Effects of Termination).

ARTICLE 13
DISPUTE RESOLUTION

13.1 Dispute Resolution; Escalation. The Parties recognize that disputes as to certain matters arising out of or in connection with this Agreement may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising out of or in connection with this Agreement in an expedited manner by mutual cooperation. To accomplish this objective, any and all disputes between the Parties arising out of or in connection with this Agreement (other than (a) matters within the purview of the JSC, which will be resolved in accordance with Section 5.5 (Decision-Making; Escalation to Senior Officers) and (b) matters for which this Agreement expressly provides are subject to a Party's discretion or sole decision-making authority), will first be referred to the Senior Officers for resolution. The Senior Officers will attempt to resolve the matter in good faith. If the Senior Officers fail to resolve such matter within [***] Business Days after the date on which the matter is referred to the Senior Officers (unless a longer period is agreed to by the Parties), then either Party may submit the dispute for final resolution by binding arbitration in accordance with Section 13.2 (Arbitration).

13.2 Arbitration. Except as set forth in Section 12.5(c) (License Grant to Lyra) and this Section 13.2 (Arbitration), each dispute, difference, controversy or claim arising in connection with or related or incidental to, or question occurring under, this Agreement or the subject matter hereof that cannot be resolved pursuant to Section 13.1 (Dispute Resolution; Escalation) will be referred to and finally resolved by arbitration in accordance with the International Chamber of Commerce (the "Rules") by an arbitral tribunal composed of three arbitrators, all of whom will have previous judicial experience and significant experience in the biopharmaceutical industry, with each Party appointing one arbitrator and the third arbitrator to be selected by agreement of

the two arbitrators appointed by the Parties. If the two initial arbitrators are unable to select a third arbitrator within [***] days, then the third arbitrator will be appointed in accordance with ICC rules. The foregoing arbitration proceedings may be commenced by either Party by notice to the other Party. Unless otherwise agreed by the Parties, all such arbitration proceedings commenced by (a) Lyra will be held in [***] and (b) by Lian will be held in [***]; provided, however, that proceedings may be conducted by telephone or video conference call with the consent of the Parties and the arbitrators. All arbitration proceedings will be conducted in the English language. The arbitrators will consider grants of equitable relief and orders for specific performance as co-equal remedies along with awards of monetary damages. The arbitrators will have no authority to award punitive damages. Each Party will pay its own expenses. The Parties hereby agree that the arbitrators have authority to issue rulings and orders regarding all procedural and evidentiary matters that the arbitrators deem reasonable and necessary with or without petition therefore by the Parties as well as the final ruling and judgment. All rulings by the arbitrators will be final. Notwithstanding any provision to the contrary set forth in this Agreement, any Party may seek equitable measures of protection in the form of attachment of assets or injunctive relief (including specific performance and injunctive relief) in any matter relating to the proprietary rights and interests of either Party from any court of competent jurisdiction, pending a decision by the arbitral tribunal in accordance with this Section 13.2 (Arbitration). The Parties hereby exclude any right of appeal to any court on the merits of such matter. The provisions of this Section 13.2 (Arbitration) may be enforced and judgment on the award (including equitable remedies) granted in any arbitration hereunder may be entered in any court having jurisdiction over the award or any of the Parties or any of their respective assets. Except to the extent necessary to confirm an award or as may be required by Laws, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. Nothing in this Section 13.2 (Arbitration) will preclude either Party from seeking interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding. Notwithstanding the Parties' agreement to arbitrate, unless the Parties agree in writing in any particular case, claims and disputes between the Parties relating to or arising out of, or for which resolution depends in whole or in part on a determination of the interpretation, scope, validity, enforceability or infringement of, Patent Rights or of any Licensed Marks will not be subject to arbitration under this Agreement, and the Parties may pursue whatever rights and remedies may be available to them under law or equity, including litigation in a court of competent jurisdiction, with respect to such claims and disputes.

13.3 JURY WAIVER. EACH PARTY, TO THE EXTENT PERMITTED BY LAW, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY ACTION OR OTHER LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS IT CONTEMPLATES TO ARBITRATE AS SET FORTH IN SECTION 13.2 (ARBITRATION). THIS WAIVER APPLIES TO ANY ACTION OR LEGAL PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT OR OTHERWISE.

ARTICLE 14
MISCELLANEOUS

14.1 Assignment.

(a) General. This Agreement and the rights and obligations of each Party under this Agreement will not be assignable, delegable, transferable, pledged or otherwise

disposed of by either Party without the prior written consent of the other Party; provided, however, that either Party may assign or transfer this Agreement together with all of its rights and obligations hereunder, without such consent (but with written notice to the other Party), (i) to an Affiliate or (ii) to a successor in interest in connection with the transfer or sale of all or substantially all of its business or assets to which this Agreement relates, or in the event of its merger or consolidation, reorganization, or similar transaction. Any permitted assignment of the rights and obligations of a Party under this Agreement will be binding on, and inure to the benefit of and be enforceable by and against, the successors and permitted assigns of the assigning Party. Any assignment or attempted assignment in violation of this Section 14.1 (Assignment) will be null and void.

(b) Securitization. Notwithstanding anything to the contrary in Section 14.1(a) (General) or elsewhere in this Agreement, Lyra may assign to a Third Party its right to receive the milestone payments and the royalty payments owed under Article 6 (Financial Provisions) (such assignment, a "Securitization Transaction") without the prior written consent of Lian. Further, in connection with a contemplated Securitization Transaction, subject to Section 8.1(c) (Confidentiality Limitation), Lyra may disclose to such Third Party certain Confidential Information of Lian (including a redacted version of this Agreement and the royalty reports contemplated under Section 6.2(c) (Royalty Payments and Reports)) without the prior written consent of Lian, solely to the extent necessary to enable such Third Party to evaluate the Securitization Transaction opportunity (provided that such Third Party is under obligations of confidentiality and non-use with respect to such Confidential Information that are no less stringent than the terms of Article 8 (Confidentiality and Publicity)), and to allow such Third Party to exercise its rights under this Section 14.1(b) (Securitization). As part of any consummated Securitization Transaction, Lyra may assign, without the prior written consent of Lian, its right to receive the royalty reports under Section 6.2(c) (Royalty Payments and Reports) to the counterparty in such Securitization Transaction. Notwithstanding anything to the contrary set forth in this Agreement, if Lyra proposes to enter into a Securitization Transaction with a Third Party that is engaged in the Development, Manufacture, or Commercialization of pharmaceutical products that compete with any product of Lian, then any disclosure of Lian's Confidential Information to such Third Party will be subject to Lian's prior written consent, not to be unreasonably withheld.

14.2 Choice of Laws. This Agreement will be governed by and interpreted under the Laws of the State of New York, without regard to the conflicts of law principles thereof. Except as otherwise expressly provided under this Agreement, any dispute, controversy, claim or difference of any kind whatsoever arising out of or in connection with this Agreement will be resolved exclusively in accordance with Section 13.2 (Arbitration); provided, however, that all questions concerning (a) inventorship of Patent Rights under this Agreement will be determined in accordance with Section 7.1 (Ownership of Intellectual Property) and (b) the construction or effect of Patent Rights will be determined in accordance with the Laws of the country, Region or other jurisdiction in which the particular patent within such Patent Rights has been filed or granted, as the case may be. Any communication or proceedings resulting from disputes under this Agreement will be in English language. The Parties agree to exclude the application to this Agreement of the United Nations Conventions on Contracts for the International Sale of Goods (1980).

14.3 Notices. All notices that are required or permitted hereunder will be in writing and sufficient if delivered by internationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, and in each case, addressed as follows (with a courtesy copy sent by email, which will not constitute notice):

If to Lyra:

[***].
[***]
[***]
Attention: [***]
Email: [***]

With copies to:

[***]
[***]
[***]
Attention: [***]
Email: [***]

If to Lian or LianBio:

[***]
[***]
[***]
[***]
[***]
[***]
Attention: [***]
Email: [***]

With copies to:

[***]
[***]
[***]
[***]
[***]
Fax: [***]
Email: [***]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) on [***] after dispatch if sent by internationally-recognized overnight courier; or (b) on the [***] after dispatch if sent by registered or certified mail, postage prepaid, return receipt requested.

14.4 Severability. In the event that one or more provisions of this Agreement is held invalid, illegal or unenforceable in any respect, then such provision will not render any other provision of this Agreement invalid or unenforceable, and all other provisions will remain in full force and effect and will be enforceable, unless the provisions that have been found to be invalid or unenforceable will substantially affect the remaining rights or obligations granted or undertaken by either Party. The Parties agree to attempt to substitute for any invalid or unenforceable provision a provision which achieves to the greatest extent possible the economic objectives of the invalid or unenforceable provision.

14.5 Integration. This Agreement, together with all schedules attached hereto, constitutes the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes all previous arrangements between the Parties with respect to the subject matter hereof, whether written or oral, including, effective as of the Effective Date, the Prior CDA and the Term Sheet (provided that, in each case, all information disclosed or exchanged under such agreement will be treated as Confidential Information hereunder). In the event of a conflict between the Development Plans or any schedules or attachments to this Agreement, on the one

hand, and this Agreement, on the other hand, the terms of this Agreement will govern. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement.

14.6 Waivers and Amendments. The failure of any Party to assert a right under this Agreement or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. The exercise by any Party of any right or election under the terms or covenants herein will not preclude or prejudice any Party from exercising the same or any other right it may have under this Agreement, irrespective of any previous action or proceeding taken by the Parties hereunder. Notwithstanding the authority granted to the JSC under this Agreement, (a) no waiver will be effective unless it has been given in writing and signed by the Party giving such waiver, and (b) no provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

14.7 Independent Contractors; No Agency. Neither Party will have any responsibility for the hiring, firing or compensation of the other Party's or such other Party's Affiliates' employees or for any employee benefits with respect thereto. No employee or representative of a Party or its Affiliates will have any authority to bind or obligate the other Party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on such other Party, without such other Party's written approval. For all purposes, and notwithstanding any other provision to the contrary set forth in this Agreement, each Party's legal relationship under this Agreement to the other Party will be that of independent contractor, and the relationship between the two Parties will not constitute a partnership, joint venture, or agency, including for all tax purposes, except as otherwise required by applicable Law.

14.8 Affiliates, Sublicensees, and Contractors. To the extent that this Agreement imposes obligations on Affiliates, Sublicensees, or contractors of a Party, such Party will cause its Affiliates and its Sublicensees and contractors to perform such obligations, as applicable. Either Party may use one or more of its Affiliates, Sublicensees, or contractors to perform its obligations and duties or exercise its rights under this Agreement, solely to the extent permitted and as specified in this Agreement; provided that (a) each such Affiliate, Sublicensee, or contractor will perform any such obligations delegated to it in compliance with the applicable terms and conditions of this Agreement as if such Affiliate, Sublicensee, or contractor were a party hereto, (b) the performance of any obligations of a Party's by its Affiliates, Sublicensees, or contractors will not diminish, reduce, or eliminate any obligation of such Party under this Agreement, and (c) subject to such Party's assignment to an Affiliate pursuant to Section 14.1 (Assignment), such Party will remain liable under this Agreement for the prompt payment and performance of all of its obligations under this Agreement. Subject to this Section 14.8 (Affiliates, Sublicensees, and Contractors), if a Party exercises its rights and performs its obligations under this Agreement through one or more of its Affiliates, "Lyra" will be interpreted to mean "Lyra or its Affiliates" and "Lian" will be interpreted to mean "Lian or its Affiliates" where necessary to give each Party's Affiliates the benefit of the rights provided to such Party in this Agreement and the ability to perform its obligations under this Agreement.

14.9 Force Majeure. Neither Party will be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in achieving any objective, satisfying any condition, or performing any obligation under this Agreement to the extent that such failure or delay is caused by or results from acts or events beyond the reasonable control of such Party, including acts of God, embargoes, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotions, strikes, lockouts, or other labor disturbances (other than strikes, lockouts, or labor disturbances involving a Party's own employees), government actions, fire, earthquakes, floods, epidemics, pandemics, the spread of infectious diseases, and quarantines ("Force Majeure") and for so long as such failure or delay continues to be caused by or result from such Force Majeure. The Parties agree the effects of

the COVID-19 pandemic that is ongoing as of the Effective Date (including related government orders) may not be invoked as a Force Majeure for the purposes of this Agreement, because the pandemic is ongoing and those effects may be reasonably foreseeable as of the Effective Date. Notwithstanding the foregoing, a Party will not be excused from making payments owed hereunder due to any such Force Majeure circumstances affecting such Party. The affected Party will notify the other Party in writing of any Force Majeure circumstances as soon as reasonably practical, will provide a good faith estimate of the period for which its failure or delay in performance under this Agreement is expected to continue based on currently available information, and will undertake reasonable efforts necessary to mitigate and overcome such Force Majeure circumstances and resume normal performance of its obligations hereunder as soon a reasonably practicable under the circumstances. If the Force Majeure continues, then the affected Party will update such notice to the other Party on a weekly basis to provide updated summaries of its mitigation efforts and its estimates of when normal performance under this Agreement will be able to resume.

14.10 No Third Party Beneficiary Rights. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they will not be construed as conferring any rights on any other Third Party. This Agreement is not intended to and will not be construed to give any Third Party any interest or rights (including any Third Party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby, other than, to the extent provided in Article 10 (Indemnification; Damages), the Indemnified Parties.

14.11 Non-exclusive Remedy. Except as expressly provided herein, the rights and remedies provided herein are cumulative and each Party retains all remedies at law or in equity, including the Parties' ability to receive legal damages or equitable relief, with respect to any breach of this Agreement.

14.12 Interpretation. The Article and Section headings used herein are for reference and convenience only, and will not enter into the interpretation of this Agreement. Except as otherwise explicitly specified to the contrary, (a) references to an Article, Section or Schedule means an Article or Section of, or a Schedule to this Agreement and all subsections thereof, unless another agreement is specified; (b) references in any Section to any clause are references to such clause of such Section; (c) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto; (d) references to particular Laws mean such Laws as in effect as of the relevant time, including all rules and regulations thereunder and any successor Laws in effect as of the relevant time, and including the then-current amendments thereto; (e) words in the singular or plural form include the plural and singular form, respectively; (f) unless the context requires a different interpretation, the word "or" has the inclusive meaning that is typically associated with the phrase "and/or"; (g) the terms "including," "include(s)," "such as," "e.g." and "for example" mean including the generality of any description preceding such term and will be deemed to be followed by "without limitation"; (h) whenever this Agreement refers to a number of days, such number will refer to calendar days unless Business Days are specified, and if a period of time is specified and dates from a given day or Business Day, or the day or Business Day of an act or event, it is to be calculated exclusive of that day or Business Day; (i) "monthly" means on a calendar month basis; (j) "quarter" or "quarterly" means on a Calendar Quarter basis; (k) "annual" or "annually" means on a Calendar Year basis; (l) "year" means a 365-day period unless Calendar Year is specified; (m) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement; (n) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa); (o) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein will be

interpreted in a correlative manner; (p) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (q) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement (including any Schedules); (r) neither Party or its Affiliates will be deemed to be acting "on behalf of" the other Party under this Agreement, except to the extent expressly otherwise provided; (s) provisions that require that a Party, or the JSC hereunder "agree", "consent" or "approve" or the like will be deemed to require that such agreement, consent or approval be specific and in writing in a written agreement, letter or approved minutes, but, except as expressly provided herein, excluding e-mail and instant messaging; and (t) the word "will" will be construed to have the same meaning and effect as the word "shall".

14.13 Further Assurances. Each Party will duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement (including working collaboratively to correct and clerical, typographical, or other similar errors in this Agreement).

14.14 Ambiguities; No Presumption. Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties hereto and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption will apply against any Party as being responsible for the wording or drafting of this Agreement or any such provision, and ambiguities, if any, in this Agreement will not be construed against any Party under the rule of construction, irrespective of which Party may be deemed to have authored the ambiguous provision.

14.15 Export Control. This Agreement is made subject to any restrictions required by applicable Laws concerning the export of products or technical information from the U.S. or other countries which may be imposed upon or related to the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technology licensed to it or other technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, except in compliance with U.S. export Laws and regulations.

14.16 Execution in Counterparts; Electronic Signatures. This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, will be deemed to be an original, and all of which counterparts, taken together, will constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail will be deemed to be original signatures.

14.17 LianBio Guarantee. LianBio hereby [***] guarantees, [***], the due and punctual payment and performance of all obligations of Lian under this Agreement (the "Lian Obligations"). LianBio agrees that the Lian Obligations may be extended, modified, or renewed, in whole or in part, without notice or further assent from it, and that it will remain bound upon its guarantee notwithstanding any extension, modification, or renewal of any Lian Obligation. [***].

[Remainder of this page intentionally blank.]

IN WITNESS WHEREOF, each Party has caused this Agreement to be duly executed by its authorized representative under seal, in duplicate on the Effective Date.

LYRA THERAPEUTICS, INC.

_____
Name:
Title:

LIANBIO INFLAMMATORY LIMITED

_____
Name:
Title:

LIANBIO
(solely for purposes of Sections 2.9(a) and 14.17 (LianBio Guarantee))

_____
Name:
Title:

SCHEDULE 1.73

LICENSED KNOW-HOW

[***]

SCHEDULE 1.75

LICENSED PATENTS

[***]

SCHEDULE 1.79

LYR-210 PRODUCT

[***].

SCHEDULE 1.80

LYR-220 PRODUCT

[***].

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)) 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) [Intentionally omitted];

   (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 9, 2021

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, R. Don Elsey, 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)) 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) [Intentionally omitted];

   (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 9, 2021

By: /s/ R. Don Elsey
R. Don. Elsey
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, 2021, 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 9, 2021

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, 2021, 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 9, 2021

By: /s/ R. Don Elsey
R. Don. Elsey
Chief Financial Officer
(Principal Financial and Accounting Officer)