Risk Factors Comparison 2025-03-13 to 2024-03-22 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information contained in this Annual Report on Form 10- K 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 Annual Report on Form 10- K also contains forward- looking statements that involve risks and uncertainties. See " Special Note Regarding Forward- Looking Statements. " Our actual results could differ materially and adversely from those anticipated in these forward- looking statements as a result of certain factors, including those set forth below. Risks Related to Our **Exploration of Strategic Options Any potential financial or strategic option we pursue in an effort to maximize shareholder value may not result in the identification of a suitable transaction, or if one is identified and pursued, may not be completed on attractive terms, or at all. In May 2024, in connection with the Company' s announcement that we failed to meet the primary endpoint of our ENLIGHTEN 1 Phase 3 clinical trial, we announced our interest in potential strategic alternatives. We have not yet engaged a financial adviser to assist us in this effort. Such alternatives may include a merger, sale, divestiture of assets, licensing, or other strategic transaction. The process of continuing to evaluate these strategic options may be costly, time- consuming and complex and we may incur significant costs related to this continued evaluation, such as legal, accounting and advisory fees and expenses and other related charges. Moreover, any potential financial or strategic option we pursue may not result in the identification of a suitable transaction, or if one is identified and pursued, may not be completed on attractive terms, or at all. There can be no assurance of completion of any particular course of action or a defined timeline for completion, and we can provide no assurance that any strategic alternative we pursue will have a positive impact on our results of operations or financial condition. We are attempting to sublease or assign our three leaseholds, which represent significant operating costs, and there can be no assurance that we will accomplish this effort on favorable terms, or at all, which could adversely affect our business, results of operations and financial condition. The Company has three leaseholds including two in Waltham, Massachusetts and one in Watertown, Massachusetts. These leaseholds represent significant operating costs for the Company. The Company has retained a broker to sublease or assign all three of the leaseholds in connection with the Company' s capital preservation efforts. There can be no assurance that the Company will find third parties to enter into a sublease or assignment of these leaseholds at terms that are favorable to the Company, on a timetable that is advantageous to the Company, or at all. The operating lease, as amended, for office and laboratory space in Watertown expires in April 2027 and comprises approximately 27, 311 square feet. The lease provides for base rent of $ 2. 0 million per year. The Company maintains a letter of credit of approximately $ 0. 3 million securing its obligations under the Watertown operating lease. The Company has two leases for space at 880 Winter Street in Waltham. The first lease comprises approximately 29, 000 square feet of office and lab space, and the lease provides for base rent of $ 2. 2 million per year, which will increase 3 % per year over the noncancellable term ending on June 30, 2033. In connection with the lease, a security deposit was delivered to the landlord in the form of an irrevocable standby letter of credit collateralized by $ 1. 1 million of deposits with the financial institution. In December 2023, the Company executed a sublease agreement for additional laboratory and office space located at 880 Winter Street in Waltham. The subleased premises comprise approximately 24, 000 square feet, and the sublease provides for base rent of $ 1. 8 million per year, which will increase 3 % per year over the noncancellable term ending on November 30, 2032. The Company provided the landlord with a security deposit in the form of a letter of credit in the amount of approximately $ 0. 6 million. Under all three leases, the Company is responsible for its share of real estate taxes, maintenance, and other operating expenses applicable to the respective leased premises. An inability to successfully sublease or assign all three of the leaseholds will negatively impact our capital preservation efforts and could materially and adversely affect our business, financial condition and the results of operations. In the future, we may engage in acquisitions or strategic partnerships that could disrupt our business, cause dilution to our stockholders, reduce our financial resources, cause us to incur debt or assume contingent liabilities, and subject us to other risks. In the future, we may enter into transactions to acquire other businesses, products, or technologies or enter into strategic partnerships, including licensing. If we do identify suitable acquisition or partnership candidates, we may not be able to make such acquisitions or partnerships on favorable terms, or at all. Any acquisitions or partnerships we make may not strengthen our competitive position, and these transactions may be viewed negatively by employees, customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business or partnership that are not covered by the indemnification we may obtain from the seller or our partner. In addition, we may not be able to successfully integrate any acquired personnel, technologies, and operations into our existing business in an effective, timely, and non- disruptive manner. Acquisitions or partnerships may also divert management attention from day- to- day responsibilities, lead to a loss of key personnel, increase our expenses, and reduce our cash available for operations and other uses. We cannot predict the number, timing, or size of future acquisitions or partnerships or the effect that any such transactions might have on our operating results. Risks Related to Our** 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 biotechnology 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 $ **93. 4 million and $** 62. 7 million ~~and $ 55. 3 million~~ for the ~~fiscal~~ years ended December 31, **2024 and** 2023 ~~and December 31, 2022,~~ 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 ~~and clinical~~ development activities. In ~~addition~~ **May 2024** , ~~we~~ **our Board approved a reduction in force by up to 87 employees, effective on or about May 21, 2024 with respect to approximately 80 employees and effective on or about June 20, 2024 with respect to approximately seven employees (the " May 2024 RIF "). The Board' s decision was based on the need to implement cost- reduction initiatives intended to reduce the Company' s ongoing operating expenses and maximize shareholder value. The Company incurred charges of approximately $ 10. 9 million in connection with this workforce reduction, primarily consisting of severance payments, employee benefits and related costs. Certain of these expenses have been paid to former employees as of the date of these consolidated financial statements and relate to the May 2024 RIF. The remaining expenses are included within accrued restructuring with anticipated payout at a later date, primarily pertaining to current employees. 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~~ **we may not achieve our** ~~-~~ **or maintain profitability in the future** ~~research and development and manufacturing activities, 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 **CRS** ~~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 ~~the two pivotal~~ **our ENLIGHTEN 2** Phase 3 ~~ENLIGHTEN~~ clinical ~~trials~~ **trial** of our most advanced product candidate, LYR- 210; • ~~continue the~~ **conduct another Phase 3 trial for LYR- 210 since our ENLIGHTEN 1 Phase 3** clinical **trial failed** ~~development of LYR- 220; • establish manufacturing and supply chain capacity sufficient~~ to **meet its primary endpoint, as** ~~provide clinical and commercial quantities of any product candidates for which~~ we ~~may obtain marketing approval~~ **announced in May 2024** ; • seek regulatory and marketing approvals for ~~product candidates that~~ **LYR- 210 if it** successfully ~~complete~~ **completes the requisite** 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, manufacturing, regulatory, quality, 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 ~~; • discover and develop additional product candidates; • expand internationally~~ ; • make royalty, milestone, or other payments under any future in- license agreements; • implement additional internal manufacturing capabilities, systems and infrastructure; and • operate as a public company. Furthermore, our ability to successfully develop, commercialize, and license our products and generate product revenue is subject to substantial additional risks and uncertainties. Each of our product candidates will require additional pre- clinical and / or clinical development, potential regulatory approval in multiple jurisdictions, the development of or securing of manufacturing supply, capacity, and expertise, the use of external vendors, the building of a manufacturing and commercial organization, substantial investment, and significant marketing efforts before we generate any revenue from product sales. As a result, we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. The amount of future losses and when, if ever, we will achieve profitability are uncertain. We have no products that have generated any

commercial revenue, do not expect to generate revenues from the commercial sale of products in the foreseeable future, and might never generate revenues from the sale of products. Our ability to generate revenue and achieve profitability will depend on, among other things, successful completion of the clinical development of our product candidates; obtaining necessary regulatory approvals from the FDA and international regulatory agencies; establishing cost- effective manufacturing, generating sales, and achieving market acceptance of our products and marketing infrastructure to commercialize our product candidates for which we obtain approval; and raising sufficient funds to finance our activities. We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations may be materially adversely affected. Our recurring losses from operations raise substantial doubt regarding our ability to continue as a going concern. We ~~currently~~ **continue to** operate with limited resources. We have incurred significant losses since our inception and have never generated revenue or profit, and it is possible we will never generate revenue or profit. Based on our current operating plans, and without additional funding **,** there is substantial doubt about our ability to continue as a going concern. See Part II, Item 7. " Management' s Discussion and Analysis of Financial Condition and Results of Operations " of this Annual Report on Form 10- K for a discussion of our expected cash runway. This cash runway estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Until such time as the Company can generate significant revenue from product sales, if ever, it plans to finance its operations through a combination of equity or debt financings, collaboration agreements, strategic alliances and licensing arrangements, but there can be no assurances that such financing will ~~continue to~~ be available to us on satisfactory terms, or at all. Securing additional financing may divert our management from our day- to- day activities, which may adversely affect our ability to develop and commercialize any of our product candidates. If we are unable to obtain funding, we would be forced to delay, reduce or eliminate our research and development programs, which would adversely affect our business prospects. In addition, if we are unable to raise capital, we will also need to implement **additional** cost ~~reductions~~ **reduction measures** , and any failure to effectively do so will harm our business, results of operations and future prospects. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations. If we are unable to continue as a going concern, investors could lose all or part of their investment in our Company. We ~~will~~ need significant additional funding in order to complete development of, manufacture, and obtain regulatory approval for our product candidates and commercialize our products, if approved. **Moreover, the failure of our ENLIGHTEN 1 Phase 3 trial to meet its primary endpoint has made it more difficult for us to raise capital.** If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts **, and / or discontinue operations** . We ~~will~~ continue to need additional capital, which we may raise through equity offerings, debt financings, marketing, and distribution arrangements and other collaborations, strategic alliances, and licensing arrangements or other sources. ~~Additional~~ **The failure to meet the primary endpoint of our ENLIGHTEN 1 Phase 3 clinical trial has made it significantly more difficult for us to raise more capital. Accordingly, we may be required to obtain further funding through public or private equity offerings, debt financings, royalty- based financing arrangements, collaborations and licensing arrangements or other** sources ~~of~~ **. Adequate additional** financing ~~might~~ **may** not be available **to us** on ~~favorable~~ **acceptable** terms, ~~if~~ **or** at all **. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy** . If we do not succeed in raising additional funds on acceptable terms, we might be unable to complete planned clinical trials or obtain approval of any of our product candidates from the FDA, or any foreign regulatory authorities, and could be forced to discontinue product development or reduce our operations. ~~In addition, attempting to secure additional financing may divert the time and attention of our management from day- to- day activities and harm our product candidate development efforts.~~ We will require substantial funds to further develop, manufacture, obtain approval for, and commercialize our product candidates, including LYR- 210, for which we initiated two ~~pivotal~~ Phase 3 clinical trials. **In May 2024 we suspended further development of LYR- 220.** We ~~will~~ **would** also require substantial **additional** funds to further develop, obtain approval for, and commercialize ~~our other product candidate~~ , LYR- 220 ~~, which has completed a Phase 2 clinical trial~~ . Our future funding requirements, both near and long- term, will depend on many factors, including, but not limited to: • the scope and results of our ~~pre- clinical studies and~~ clinical trials, including any unforeseen costs we may incur as a result of ~~pre- clinical study or clinical trial delays due to COVID- 19 or other causes; • the scope and results of our pre- clinical studies and clinical trials, including any unforeseen costs we may incur as a result of pre- clinical study or~~ clinical trial delays; • the timing of, and the costs involved in, obtaining regulatory approvals for LYR- 210 ~~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; **and** • the cost of establishing sales, marketing, manufacturing, 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 could also adversely impact our ability to access capital as and when needed. We maintain our cash and cash equivalents in accounts with major U. S. and multi- national financial institutions, and U. S. treasury bills and our deposits at these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position. Raising additional capital may cause dilution to our stockholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, as we

can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, debt financings, marketing, and distribution arrangements and other collaborations, strategic alliances, and licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our operations and our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, redeeming our stock, making certain investments, and engaging in certain merger, consolidation, or asset sale transactions, among other restrictions. If we raise additional funds through additional collaborations, strategic alliances, or marketing, distribution, or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We have no approved products. To date, we have no approved product on the market and have generated no product revenues. Unless we receive approval from the FDA or other regulatory authorities for our product candidates, we will not have product revenues. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from cash on hand and licensing fees and grants, if any. **LYR- 210 is at a** ~~Our product candidates are in various stages of~~ development **stage and we have suspended further efforts on LYR- 220** . We are a biotechnology company focused on the development and commercialization of novel integrated drug and drug delivery solutions for the localized treatment of patients with **CRS** ~~ENT diseases~~ . Our product candidates are in clinical development, and favorable results in early- stage clinical trials may not be predictive of success in later clinical trials and may not lead to commercially viable products for any of several reasons. For example, **we** ~~our product candidates may fail~~ **failed** to ~~be safe and effective~~ **meet the primary endpoint** in ~~current or~~ **our ENLIGHTEN 1 Phase 3 trial for LYR- 210 which has a material adverse effect on our development plans for LYR- 210. In May 2024 we also suspended further development of LYR- 220. LYR- 210, as well as LYR- 220, if in the** future ~~clinical trials or pre- clinical studies, or~~ we **decide** ~~may have inadequate financial or other resources~~ to **advance it,** ~~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~~ **it** can be commercialized. Our business is highly dependent on the success of our most advanced product candidate, LYR- 210, which ~~will require~~ **requires** ~~additional~~ **on- going** clinical testing before we can seek regulatory approval and potentially launch our product. If LYR- 210 does not receive regulatory approval or is not successfully commercialized, or is significantly delayed in doing so, our business will be harmed. A substantial portion of our business and future success depends on our ability to develop, obtain regulatory approval for, and successfully commercialize our most advanced product candidate, LYR- 210. We currently have no products that are approved for commercial sale and have not completed the development of any product candidates, and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures ~~over the next few years~~ will be devoted to LYR- 210 ~~and LYR- 220~~ , which will each require ~~additional~~ **continued** clinical development and potential additional pre- clinical development, management of clinical and medical affairs and manufacturing activities, regulatory approval in multiple jurisdictions, the securing of manufacturing supply, the building of a manufacturing and commercial organization, substantial investment, and significant marketing efforts before we can generate any revenues from any commercial sales. We cannot be certain that LYR- 210 ~~and LYR- 220~~ 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 ~~and LYR- 220~~ from the FDA or other regulatory bodies, we cannot be certain that our product candidates will be successfully commercialized, profitable, widely accepted in the marketplace, or more effective than other commercially available alternatives. Nor can we be certain that, if and when approved, the safety and efficacy profile of LYR- 210 and ~~LYR- 220~~ will be consistent with the profiles observed in clinical trials. We advanced LYR- 210 through our Phase 2 randomized, controlled, patient blinded LANTERN clinical trial, evaluating the safety and efficacy in surgically- naïve CRS patients who have failed previous medical management. The trial was designed to enroll 99 evaluable patients with the potential to increase to up to 150 patients and was initiated in May 2019 at sites in Australia, Austria, Czech Republic, New Zealand, and Poland. In December 2019, the FDA authorized our investigational new drug application, and, prior to ~~the~~ COVID- 19 ~~pandemic~~ , we planned to enroll patients in the United States. However, in light of developments relating to ~~the~~ COVID- 19 ~~pandemic~~ , as described below, we discontinued enrollment at 67 patients in our Phase 2 LANTERN clinical trial and did not enroll any patients in the United States. On December 7, 2020, we reported top- line results from our Phase 2 LANTERN clinical trial, including that LYR- 210 failed to meet the primary endpoint of the trial. We believe this was primarily due to the discontinuation of enrollment related to ~~the~~ COVID- 19 ~~pandemic~~ . As a result of the decrease in the number of patients enrolled from planned (99 evaluable) to actually enrolled (67) patients in our Phase 2 LANTERN clinical trial, a greater magnitude of change in composite score of the seven- day average of four cardinal symptoms from baseline at week 4 and / or a smaller standard deviation associated with the change from baseline at week 4 was required in order for the trial to achieve statistical significance for the primary endpoint. **On May 6, 2024, we reported top- line results from our Phase 3 ENLIGHTEN 1 clinical trial, including that LYR- 210 failed to meet its primary endpoint of demonstrating statistically significant improvement compared to sham control in the composite score of the three cardinal symptoms of CRS (nasal obstruction, nasal discharge, facial pain / pressure) at 24 weeks. The 52- week extension phase of the ENLIGHTEN 1 trial was completed in the fourth quarter of 2024. Safety data for LYR- 210 in the extension phase was generally consistent with the 24- week primary treatment phase, including for those patients that**

received a repeat dosing, resulting in a 12- month treatment period. ENLIGHTEN 2, the second Phase 3 trial of LYR- 210 in CRS, is ongoing and topline data is expected in the second quarter of 2025. There can be no assurance that we will achieve the primary endpoint or any other endpoints in the ENLIGHTEN **2** Phase 3 clinical ~~trials~~ **trial** ~~we conduct~~ for LYR- 210. If the required regulatory approvals for LYR- 210 are not obtained or are significantly delayed, or any approved products are not commercially successful, our business, financial condition, and results of operations may be materially harmed. **For example, the Company may need to revise its regulatory strategy for** LYR- 210 **since the Company failed** ~~is our most advanced product candidate, and if we experience regulatory or developmental issues with respect~~ to **meet the primary endpoint of the ENLIGHTEN 1 Phase 3 clinical trial** ~~LYR- 210, our development plans and business could be significantly harmed. Moreover, if we experience similar regulatory or developmental issues with LYR- 220 or future 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. **If LianBio is unable** to find a third party to acquire its rights under the LianBio License Agreement ~~,as defined below~~ ,it may materially harm our business,financial condition,results of operations and prospects.LianBio ~~Development (HK) Limited (as successor- in- interest to LianBio Inflammatory Limited),a private company limited by shares organized under the laws of Hong Kong,or LianBio HK,~~ announced that in October 2023 its ~~board~~ **Board** of ~~directors~~ **Directors** commenced a comprehensive strategic review of its business.The LianBio ~~HK~~ Board ultimately concluded that selling off assets and winding down operations was the best way to realize maximum shareholder value.LianBio ~~HK~~ reported that a substantial portion of the wind down activities,including fulfillment of transition service obligations under its existing agreements and gradual cessation of currently active clinical trials, **will** ~~was expected to~~ be completed by the end of 2024.LianBio ~~HK~~ announced in 2024 that it was further reducing the size of its workforce to approximately 50 employees with plans to reduce that number further over the course of 2024.LianBio ~~HK~~ stated it will maintain a core group of employees necessary to implement an orderly wind down and support its efforts to maximize the value of its remaining business and assets including the collaboration with the Company.Due to these developments,the future of the Company' s collaboration with LianBio ~~HK~~ is uncertain as LianBio **continues** ~~HK announced it~~ **its wind** ~~was winding~~ down,while seeking a third party to acquire LianBio ~~HK~~ **' s rights under the LianBio License Agreement.If LianBio is unable to find a third party to acquire LianBio' s rights under the LianBio License Agreement,it may materially harm our business,financial condition,results of operations and prospects.** Managing our obligations under our license and other strategic agreements may divert management time and attention, causing delays or disruptions to our business. We are party to the LianBio License Agreement ~~,~~ ~~as amended~~ . The LianBio License Agreement grants an exclusive license to develop and commercialize LYR- 210 in Greater China (mainland China, Hong Kong, Macau, and Taiwan), Singapore, South Korea, and Thailand, or the Territory. Furthermore, under the LianBio License Agreement, LianBio **HK** has the first right to obtain a license to develop and commercialize LYR- 220 **. Under the LianBio License Agreement, both parties agreed to negotiate prior to December 31, 2022 a clinical supply agreement to support clinical trials to be conducted by LianBio HK in the territory, i. e., PRC, Hong Kong, Macau, Taiwan, Singapore, South Korea, and Thailand. Subsequently, there was a side letter executed on December 27, 2022 which extended the negotiations of a supply agreement. Payments made by LianBio HK to the Company that have not yet been recognized as revenue are deferred as a contract liability on the Company' s consolidated balance sheet. The Company anticipated that the payments treated as a contract liability would be recognized as revenue as the clinical supply of LYR- 210 was delivered and over the remaining time it takes to conduct the applicable trials. As of December 31, 2024, the parties are not actively engaged in negotiations of the clinical supply agreement. At this point, it is uncertain whether such an agreement will be completed. In view of the uncertainty around the completion of the clinical supply agreement, the Company may decide to recognize such payments as revenue on an accelerated schedule** . We also may in the future enter into license and strategic agreements, which, subject us to various obligations, including diligence obligations, reporting and notification obligations, payment obligations for achievement of certain milestone as well as other material obligations. We may need to devote substantial time and attention to ensuring that we successfully integrate these transactions into our existing operations and are compliant with our obligations under these agreements, which may divert management' s time and attention away from our research and development programs or other day- to- day activities. Our license and strategic agreements are also complex and certain provisions in those agreements may be susceptible to multiple interpretations. In the event of any disagreement about the interpretation of these provisions, our management may need to devote a disproportionate amount of its attention to resolving these disagreements. Such disruptions may cause delays in our research and development programs and other business objectives. If LianBio is unable to find a....., results of operations and prospects. Our operating activities may be restricted by certain covenants in our license and strategic agreements, which could limit our development and commercial opportunities. In connection with our license and strategic agreements, we may agree to and be bound by negative covenants which may limit our development and commercial opportunities. For example, pursuant to the LianBio License Agreement, we made certain covenants to not commercialize a competing product anywhere in the Territory, nor collaborate with, enable, or otherwise authorize, license, or grant any right to any third party to commercialize a competing product anywhere in the Territory, subject to certain carve- outs. We also made certain covenants to grant an exclusive option to LianBio **HK** for the development and commercialization of LYR- 220 in the Territory. These provisions may inhibit our development efforts, prevent us from forming strategic collaborations to develop and potentially commercialize any other product candidates and may materially harm our business, financial condition, results of operations and prospects. Failure to obtain marketing approval in international jurisdictions would prevent our products from being marketed in such jurisdictions. In order to market and sell our products in jurisdictions outside of the United States, we or our third- party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain

approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. Additionally, we may be dependent on third- party collaborators to develop and commercialize our product candidates in certain international jurisdictions, such as in the case of our exclusive license agreement with LianBio **HK** for the development and commercialization of LYR- 210 in the Territory. In the agreement with LianBio **HK** , while we have agreed that we must use commercially reasonable efforts to complete a global Phase ~~III~~ **3** clinical trial for LR- 210 and seek regulatory approval in the United States, LianBio **HK** 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~~ **are party to** a collaboration **agreement** , and may enter into other collaborations, that place the development and commercialization of our product candidates outside our control, require us to relinquish important rights or may otherwise be on terms unfavorable to us, and if our collaborations are not successful, our product candidates may not reach their full market potential. Our drug development programs and the potential commercialization of our drug candidates will require substantial additional cash to fund expenses. For some of our drug candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies for the development and potential commercialization of those drug candidates in selected geographic territories or for selected patient populations. For example, we are party to the LianBio License Agreement to develop and commercialize LYR- 210 in the Territory. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration or successfully maintain a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed or existing collaboration and the proposed or existing collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject drug candidate, the costs and complexities of manufacturing and delivering such drug candidate to patients, the potential of competing therapies, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative drug candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our drug candidate. The terms of any existing or additional collaborations or other arrangements that we may establish may not be favorable to us. We may ~~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~~ **the future** ~~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 **lead product candidate and any future**

product candidates are expensive and time- consuming, their outcome is uncertain, and if our clinical trials do not meet safety or efficacy endpoints in these evaluations, or if we experience significant delays in these trials, our ability to commercialize our product candidates and our financial position will be impaired. We initiated ~~the pivotal~~ Phase 3 clinical trials for our most advanced product candidate, LYR- 210. ~~Additionally,~~ **In May 2024** we **suspended further** ~~plan to continue~~ clinical development on our other product candidate, LYR- 220 **, in order to preserve capital following our failure to meet our primary endpoint in the ENLIGHTEN 1 Phase 3 clinical trial for LYR- 210** . It is impossible to predict ~~when or~~ if **LYR- 210** ~~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 **. Given the similarities in the design of the ENLIGHTEN 1 and ENLIGHTEN 2 Phase 3 clinical trial, the risk that we fail to meet the primary endpoint in the ENLIGHTEN 2 Phase 3 clinical trial has increased since we failed to meet our primary endpoint in the ENLIGHTEN 1 Phase 3 clinical trial** . Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we may need to complete pre- clinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical development is a long, expensive, and uncertain process that is subject to significant delays. Due to known or unknown circumstances beyond our control, it may take us several years to complete our testing, and failure can occur at any stage of testing. The outcome of pre- clinical testing and early clinical trials may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. We cannot assure you that any clinical trial that we are conducting, or may conduct in the future, will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. Moreover, pre- clinical and clinical data are often susceptible to varying interpretations and analysis, and many companies that have believed their product candidates performed satisfactorily in pre- clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Delays associated with products for which we are directly conducting ~~pre- clinical studies or~~ clinical trials may cause us to incur additional operating expenses. The commencement and rate of completion of ~~pre- clinical studies or~~ clinical trials may be delayed by, or terminated because of, many factors, including: • the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our pre- clinical studies or clinical trials; • failure to obtain regulatory approval to commence a trial; • failure to reach, or delays in reaching, an agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • slower than expected rates of recruitment of patients or failure to recruit a sufficient number of patients; • modification of pre- clinical studies or clinical trial protocols; • changes in regulatory requirements for pre- clinical studies or clinical trials; • the impact of unusual placebo effects; • the lack of effectiveness during pre- clinical studies or clinical trials; • the emergence of unforeseen safety issues or undesirable side effects; • failure to obtain institutional review board, or the IRB, approval at each site; • delays, suspension, or termination of clinical trials by the IRB responsible for overseeing the trial at a particular trial site; • failure of patients in completing a trial or returning for post- treatment follow- up; • clinical sites deviating from trial protocol, dropping out of a trial, or failing to comply with regulatory requirements; • failure to address patient safety concerns that arise during the course of a trial; • failure to manufacture sufficient quantities of product candidate for use in clinical trials; • government, IRB, or other regulatory delays or " clinical holds " requiring suspension or termination of the trials; and • business interruptions resulting from pandemics. • We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates or significantly increase the cost of such trials, including: ▪ we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials; ▪ clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs; ▪ the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or fail to return for post- treatment follow- up at a higher rate than we anticipate; ▪ we may be unable to enroll a sufficient number of patients in our clinical trials to ensure adequate statistical power to detect any statistically significant treatment effects; ▪ our third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; ▪ regulators, IRBs, or independent ethics committees, or IECs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or may require that we or our investigators suspend or terminate clinical trials of our product candidates for various reasons, including non- compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks; ▪ we may experience delays in reaching or fail to reach agreement on acceptable pre- clinical study or clinical trial contracts or pre- clinical study or clinical trial protocols with prospective trial sites; ▪ the cost of pre- clinical studies or clinical trials of our product candidates may be greater than we anticipate and we may not have funds to cover the costs; ▪ the supply or quality of our product candidates or other materials necessary to conduct pre- clinical studies or clinical trials of our product candidates, or commercialize our products, may be insufficient or inadequate; ▪ regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; ▪ **recruitment for our clinical trials may be adversely affected by recruiting for competing trials or the approval of products competitive with our product candidates; and ▪** any current or future collaborators that conduct pre- clinical studies or clinical trials may face any of the above issues, and may conduct pre- clinical studies or clinical trials in ways they view as advantageous to them but that are suboptimal for us ~~; and ▪ any~~ **. If we are required to extend the duration of** current ~~or future collaborators that conduct pre- clinical studies or~~ clinical trials ~~may face any of the above issues, and may conduct pre- clinical studies or clinical trials in ways they view as advantageous to them but that are suboptimal for us. If we are required to extend the duration of current pre- clinical studies or clinical trials~~ or to conduct additional ~~pre- clinical studies or~~ clinical trials or other testing of our product candidates beyond

those that we currently contemplate, if we are unable to successfully complete ~~pre- clinical studies or~~ clinical trials of our product candidates or other testing, if the results of these trials, studies, or tests are not positive or are only modestly positive, if there are safety concerns, or if we determine that the observed safety or efficacy profile would not be competitive in the marketplace, we may: • incur unplanned costs; • be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all; • obtain marketing approval in some countries and not in others; • obtain marketing approval for indications or patient populations that are not as broad as intended or desired; • obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings; • be subject to additional post-marketing testing requirements; or • have the product removed from the market after obtaining marketing approval. We could encounter delays if a clinical trial is materially modified, suspended, or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial, or by the FDA or other regulatory authorities. Such authorities may impose a material modification, suspension, or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects for our product candidates, or other products or product candidates in the same drug class, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. Furthermore, we may rely on CROs and clinical trial sites to ensure the proper and timely conduct of clinical trials and while we would have agreements governing their committed activities, we would have limited influence over their actual performance, as described in " — Risks Related to Our Dependence on Third Parties. " Our most advanced product candidate, LYR- 210, is in clinical development and will require the completion of clinical testing before we are prepared to submit an NDA for regulatory approval. We cannot predict if or when we might complete the development of LYR- 210 and submit an NDA or whether any such NDA will be approved by the FDA. We may also seek feedback from the FDA or other regulatory authorities on our clinical development programs, and the FDA or such regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development programs. If the results of ongoing and future clinical trials for LYR- 210 are positive, we plan to submit an NDA in the United States. However, no assurance can be given that we will be successful in the near term, obtain regulatory approval, or have any commercial sales of LYR- 210. Any clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities. Pre- clinical and clinical data can be interpreted in different ways by different reviewers and regulators, which could delay, limit, or prevent regulatory approval. Drug- related adverse events **(" AEs")** 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. We ~~currently~~ **are no longer engaged in** ~~manufacture~~ **manufacturing** our ~~clinical products~~ **product candidates** ~~in- house, and expect to continue to do so in the future, and the inability to produce sufficient, high- quality products in- house could cause significant delays, an inability to meet future customer demand and reductions in revenue~~ . We **previously** transitioned most of our clinical manufacturing from a contract manufacturing organization, or CMO, to an in- house manufacturing facility at our Watertown headquarters to produce LYR- **210and** ~~210 and~~ LYR- 220 **, the latter of which we have since deprioritized** . We ~~also plan to scale up our in- house manufacturing capabilities in a new facility in Waltham, Massachusetts. We have~~ never **previously** completed a technical transfer process to an in- house facility, built, owned or operated a commercial manufacturing facility, and there is no guarantee that we will be successful doing so. **Since the May 2024 RIF, we are no longer engaged in the manufacture of our product candidates and we no longer intend to build out a commercial manufacturing capability.** We ~~have~~ **are** also ~~never scaled up a~~ **engaged in an effort to sublease or assign our three leaseholds which include** manufacturing **space** ~~process in- house, and as such, our efforts carry regulatory, financial and operational risks, which could impact the timing of our future commercial launch~~ . Throughout Item 1A, we refer to manufacturers, CMOs and suppliers interchangeably. Parts of our manufacturing process are still outsourced and we expect them to remain outsourced. Our CMOs provide multiple different types of services to us. For example, some CMOs provide raw materials for our in- house manufacturing effort; some CMOs perform analytical testing for our starting materials, intermediates, drug product, and stability studies; and some CMOs provide services like sterilizing, packaging, and labeling. **Currently** ~~In addition~~ , ~~as we transition from late- stage clinical trials toward approval and commercialization, and as we transition~~ our ~~clinical~~ manufacturing ~~processes from a~~ **activities are suspended and that suspension applies to third party**

~~CMO~~ **CMOs that provide materials and services related** to **our manufacturing. If we restart** our in- house ~~facilities~~ **manufacturing** , it is common that various aspects of the development program, such as manufacturing methods and equipment, are altered along the way in an effort to optimize cost of goods, processes and results. Such changes carry the risk that these manufacturing efforts will not achieve these successfully or in a cost- efficient manner, or that we will be subject to additional requirements by the FDA or other regulatory bodies. Slight deviations resulting from technology transfer, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects. Problems with our in-house manufacturing process could restrict our ability to meet our clinical and regulatory timelines, and market demand for our products. **As a result of** ~~We also may encounter problems hiring and retaining~~ the **May 2024 RIF, we no longer have a sufficient number of** experienced scientific, quality and manufacturing personnel needed to operate our ~~clinical and commercial~~ manufacturing processes, which **in the event we restart our manufacturing efforts,** could result in delays in production ~~or difficulties in maintaining compliance with applicable regulatory requirements~~ . Any problems in our manufacturing process or facilities, or that of our CMOs, licensees and suppliers, could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional capital or capabilities. Our pre- clinical studies and clinical trials may fail to demonstrate adequately the safety and efficacy of any of our product candidates and the development of our product candidates may be delayed or unsuccessful, which could prevent or delay regulatory approval and commercialization. ~~Both of our current~~ **Currently LYR- 210 is our only** product ~~candidates~~ **candidate** ~~are~~ **still** in clinical development. 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 COVID- 19,~~ or other problems, our developmental plans and business could be significantly harmed. If the development of LYR- 210 ~~, LYR- 220~~ , or any other future product candidate is unsuccessful, our ability to generate revenues will be **significantly and** adversely affected. Our development of current and future product candidates is subject to the risks of failure and delay inherent in the development of new products and product candidates, including: • delays in product development, pre- clinical, or clinical testing or manufacturing; • unplanned expenditures in product development, pre- clinical, or clinical testing or manufacturing; • failure to receive regulatory approvals; • failure to secure rights from third parties for new technology; • failure to achieve market acceptance; and • emergence of superior or equivalent products. In addition, product candidates in later stages of clinical trials may fail to show the desired safety profiles and efficacy results despite having progressed through pre- clinical studies and initial clinical trials. A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or pre- clinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit, or prevent regulatory approval. Additionally, we have not conducted, nor do we believe we are required to conduct, any head- to- head trials comparing LYR- 210 to other approved or experimental treatments for CRS. Any such head- to- head trial, if conducted, may show that LYR- 210 is not more effective than any of such other drugs. Material adverse differences in the relative efficacy of LYR- 210 could significantly harm the adoption of LYR- 210 and our business prospects. Because of these risks, our research and development efforts may not result in any commercially viable products. If a significant portion of these development efforts are not successfully completed, required regulatory approvals are not obtained, or any approved products are not commercially successful, our business, financial condition, and results of operations may be materially harmed. Success in pre- clinical or earlier clinical trials may not be indicative of results in future clinical trials. Success in pre- clinical studies and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Pre- clinical studies and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, study pharmacokinetics and pharmacodynamics, and understand the side effects of product candidates at various doses and schedules. Success in pre- clinical studies and early clinical trials does not ensure that later, large- scale efficacy trials will be successful nor does it predict final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in pre- clinical studies or having successfully advanced through initial clinical trials. In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced, or later. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late- stage clinical trials even after achieving promising results in pre- clinical studies and earlier- stage clinical trials. Data obtained from pre- clinical and clinical activities are subject to varying interpretations, which may delay, limit, or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations, and prospects. If the FDA does not conclude that **LYR- 210** ~~certain of our product candidates satisfy~~ **satisfies** the requirements for the Section 505 (b) (2) regulatory approval pathway, or if the requirements for ~~such product candidates~~ **LYR- 210** under Section 505 (b) (2) are not as we expect, the approval pathway for ~~those product candidates~~ **LYR- 210** may take significantly longer, cost significantly more, and entail significantly greater complications and risks than anticipated, and in either case may not be successful. We intend to seek FDA approval for ~~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, primarily in Europe, 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 GCP, including review and approval by an IEC and receipt of informed consent from subjects. In general, the patient population for any clinical trials conducted outside of the United States must be representative of the population for which we intend to seek approval for the product in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U. S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from our clinical trials of our product candidates, it would likely result in the need for additional trials, which would be costly and time- consuming and delay or permanently halt our development of our product candidates. In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the United States, such as: • regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct our clinical trials; • foreign exchange fluctuations; • manufacturing, customs, shipment, and storage requirements; • cultural differences in medical practice and clinical research; and • the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought. Interim and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between interim or preliminary data and final data could significantly harm our business prospects. LYR- 210 **will be regulated as a** ~~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 **, which may result in additional regulatory and other risks. LYR- 210 is expected to be regulated as a drug- device combination products** . We may experience delays in obtaining regulatory approval of ~~these product candidates~~ **LYR- 210** given the increased complexity of the review process when approval of a **combination product** ~~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. ~~On November 8, 2022, we announced a pause in enrollment of ENLIGHTEN II to align with internal manufacturing timelines for clinical trial supply. We re- started the trial in April of 2023 following a successful internal manufacturing campaign. We believe that focusing on our internal manufacturing capabilities reduces risk associated with technology transfer to third parties and increases our control over the process and associated costs.~~ 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 COVID- 19~~, future legislation or administrative action, or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may: • delay commercialization of, and our ability to derive product revenues from, our product candidates; • impose costly procedures on us; and • diminish any competitive advantages that we may otherwise enjoy. Even if we receive approval of an NDA or comparable foreign regulatory filing for our product candidates, the FDA or the applicable foreign regulatory body may approve our product candidates for a more limited indication than we originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs. We cannot be sure that we will ever obtain regulatory clearance for our product candidates. Failure to obtain FDA approval of our product candidates will severely undermine our business by leaving us without a commercially available product, and therefore without any source of revenues, until another product candidate can be developed or obtained and ultimately approved. There is no guarantee that we will ever be able to develop or acquire another product candidate or that we will be able to obtain FDA approval to commercialize such product candidate. Even if we obtain FDA approval for our product candidates in the United States, we may never obtain approval for or commercialize them in any other jurisdiction, which would limit our ability to realize their full market potential. We intend, either on our own or through collaborations or partnerships, to market our products in international markets. In order to market any products in the European Union and many other foreign jurisdictions, we must establish and comply with numerous and varying regulatory requirements on a country- by- country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional pre- clinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, costly, time- consuming, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. We cannot predict when or if, and in which territories, we, or any of our potential future collaborators, will obtain marketing approval to commercialize a product candidate. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that neither LYR- 210, ~~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 the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to future COVID- 19 related concerns, including providing guidance regarding the conduct of clinical trials. If global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.~~ If we encounter delays or difficulties enrolling patients in our clinical trials, our clinical development activities and receipt of regulatory approvals could be delayed or otherwise adversely affected. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. For example, we were unable to enroll patients in our Phase 2 LANTERN clinical trial in the United States from whom we intended to collect certain additional pharmacokinetic data due to ~~the~~ COVID- 19 ~~pandemic~~, and, as a result, we initiated a separate characterization study in September 2020 as a follow- on to our Phase 2 LANTERN clinical trial in order to collect such data. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may encounter delays in enrolling, or be unable to enroll, a sufficient number **or diversity** of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. We cannot predict how successful we will be at enrolling subjects in future clinical trials. The enrollment of patients depends on many factors, including: • the patient eligibility criteria defined in the protocol; • the size of the patient population required for analysis of the trial' s primary endpoints; • the proximity of patients to trial sites; • the design of the trial; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating; • the perceived risks and benefits of the product candidate in the trial; • the availability of alternative therapies; • our ability to obtain and maintain patient consents; • the risk that patients enrolled in clinical trials will drop out of the trials before completion; and • the impact of geopolitical **or other global** events ~~or other events such as the evolving COVID- 19 pandemic~~. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays, or both, which could have a harmful effect on our ability to develop LYR- 210 ~~, LYR- 220,~~ and / or any other future product candidates, or could render further development impossible. Our product candidates may cause serious **AEs** ~~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 **AEs** ~~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 for LYR- 210" in this Annual Report on Form 10- K.~~ In addition, subjects treated with LYR- 210 have experienced **AEs** ~~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 **AEs** ~~adverse events~~ were reported in 16 patients, and all treatment- related **AEs** ~~adverse events~~ except one (increased viscosity of upper respiratory secretion) were mild or moderate in nature. In addition, there was one patient in the LYR- 210 (2, 500 µg) group who had a serious **AE** ~~adverse event~~ of acarodermatitis in our Phase 2 LANTERN clinical trial, which was deemed to be not related to treatment **. In the 24- week treatment phase of the Phase 3 ENLIGHTEN 1 clinical trial, the most commonly reported AEs in the study population were epistaxis, nasal odor, upper respiratory tract infection and sinusitis. Safety data for LYR- 210 in the extension phase was generally consistent with the 24- week primary treatment phase, including for those patients that received a repeat dosing, resulting in a 12- month treatment period. The most commonly reported adverse events in the study population were chronic sinusitis, nasal odor, epistaxis, sinusitis, and nasopharyngitis** . If unacceptable side effects arise in the development of our product candidates, we, the FDA, the IRBs at the institutions in which our studies are conducted, could materially modify, suspend, or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease pre- clinical studies or clinical trials, require us to conduct additional animal or human studies regarding the safety and efficacy of our product candidates which we have not planned or anticipated, or deny approval of our product candidates for any or all targeted indications. Many product candidates that initially showed promise in early- stage testing have later been found to cause side effects that prevented further development of the product candidate. Treatment- related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We ~~currently~~ **have historically** ~~train~~ **trained** and ~~expect to~~ **may in the future** have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition, and prospects significantly. If any of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by any such product, including during any long- term follow- up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw approvals of such product; • we may be required to recall a product or change the way such product is administered to patients; • additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product; • regulatory authorities may require additional warnings on the label, such as a " black box " warning or contraindication; • regulatory authorities may require long- term patient registries for the product; • we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients; • the product could become less competitive; • we could be sued and held liable for harm caused to patients; and • our reputation may suffer. There can be no assurance that we will resolve any issues related to any product- related **AEs** ~~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 or in the process of conducting technology transfer with contract manufacturers. In addition, we brought our clinical manufacturing process in- house, which required the purchase of new equipment, raw materials and other materials to ensure we could manufacture our products in accordance with cGMPs. 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 or validation, 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 employees and independent contractors, including principal investigators, CROs, consultants, vendors, and any third parties we may engage in connection with research, development, regulatory, manufacturing, quality assurance, and other pharmaceutical functions and commercialization may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business. Misconduct by our employees and independent contractors, including principal investigators, CROs, consultants, vendors, and any third parties we may engage in connection

with research, development, regulatory, manufacturing, quality assurance, and other pharmaceutical functions and commercialization, could include intentional, reckless, or negligent conduct or unauthorized activities that violate: (i) the laws and regulations of the FDA, the European Medicines Agency, or the EMA, and other similar regulatory authorities, including those laws that require the reporting of true, complete, and accurate information to such authorities; (ii) manufacturing standards; or (iii) data privacy, security, fraud and abuse, and other healthcare laws and regulations. Specifically, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of pre- clinical studies or clinical trials, creation of fraudulent data in pre- clinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal, and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U. S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non- compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations. Our business and operations would suffer in the event of system failures. Our computer systems, as well as those of our CROs and other contractors, vendors, suppliers, and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters (including the impacts of climate change), international terrorism and conflicts, and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs and our business. For example, the loss of pre- clinical studies or clinical trial data from completed, ongoing, or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of ~~personal,~~ confidential ~~,~~ or proprietary information **or information that relates to individuals and / or constitutes " personal data, " " personal information, " " personally identifiable information, " or similar terms under applicable data privacy laws (collectively, " Personal 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 **increased remote work during and after** COVID- 19. Although, to our knowledge, we have not experienced any material security breach, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost, or stolen. Any such access, disclosure, or other loss of information could result in legal claims or proceedings (including class actions), liability under laws that protect the privacy of personal information, or significant regulatory penalties, and such an event could disrupt our operations, damage our reputation, and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our business reputation and delay our clinical development of our product candidates. Risks Related to Healthcare Laws and Other Legal Compliance Matters We **are** ~~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 **or HHS** , 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, **CMOs** ~~contract manufacturers~~, CROs, or other vendors fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things, delays in the approval of applications or supplements to approved applications; refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications; warning letters; fines; import and / or export restrictions; product recalls or seizures; injunctions; total or partial suspension of production; civil penalties; withdrawals of previously approved marketing applications or licenses; recommendations by the FDA or other regulatory authorities against governmental contracts; and / or criminal prosecutions. Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and could adversely affect our business. In the United States, the EU, and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could prevent or delay marketing approval of our products in development, restrict or regulate post- approval activities involving any product candidates for which we obtain marketing approval, impact pricing and reimbursement, and impact our ability to sell any such products profitably. In particular, there have been and continue to be a number of initiatives at the U. S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. In addition, new regulations are frequently adopted and interpretations of existing healthcare statutes may change over time. **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 **and Medicaid** 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 **,executive** 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~~ **June 17** , ~~2020~~ **2021** ,the U.S.Supreme Court ~~granted~~ **dismissed** the **most recent judicial challenge** ~~petitions for writs of certiorari~~ to ~~review~~ **the ACA brought by several states without specifically ruling on** the constitutionality of the ACA ~~,although it is unclear when or how the Supreme Court will rule~~ . **Thus** ~~It is also unclear how other efforts to challenge~~ , ~~repeal,or replace~~ the ACA will **remain in effect in its current form** ~~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~~ **2032** ,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.** For instance, in **March 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, which was previously capped at 100 % of a drug' s average manufacturer price, for single source and innovator**

multiple source drugs, beginning January 1, 2024. In August 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. The IRA includes several provisions that may impact our business to varying degrees, including provisions that establish a $ 2, 000 out- of- pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on many drugs reimbursed under Medicare Part D, allow the U. S. government to negotiate Medicare Part B and Part D pricing for certain high- cost drugs and biologics without generic or biosimilar competition, and require companies to pay rebates to Medicare for drug prices that increase faster than inflation **(first due in 2023)** . The IRA permits the Secretary of the Department of Health and Human Services (" HHS ") to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. ~~On August 29~~ **CMS has published the negotiated prices for the initial ten drugs** , **which will first be effective in** ~~2023~~ **2026** , **and** ~~HHS announced~~ the list of the ~~first ten~~ **subsequent 15** drugs that will be subject to ~~price negotiations~~ **negotiation** , although the Medicare drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated. In addition, in response to the..... 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 **, drug price reporting** and **other** transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing **. Some states have enacted legislation creating so- called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states** . 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, **AE** ~~adverse event~~ reporting, storage, recordkeeping, export, import, and advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA, the EMA, and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, establishment registration and drug listing requirements, continued compliance with cGMP requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians, and recordkeeping and GCP requirements for any clinical trials that we conduct post- approval. In addition, the sponsor of an approved NDA is subject to periodic inspections and other FDA monitoring and reporting obligations, including obligations to monitor and report **AEs** ~~adverse events~~ and other information such as the failure of a product to meet the specifications in the NDA. NDA sponsors must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials. The FDA may require changes in the labeling of already approved drug products and require that sponsors conduct post- marketing studies. Accordingly, we and others with whom we work must continue to expend time,

money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a REMS, which could include requirements for a medication guide, physician communication plans, or additional elements to ensure safe use, such as restricted distribution methods, patient registries, and other risk mitigation tools. If any of our product candidates receives marketing approval, the accompanying label may limit the approved use of our product, which could limit sales of the product. The FDA may also impose requirements for costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of our approved products. In addition, advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws. The FDA closely regulates the post- approval marketing and promotion of drugs to ensure they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off- label use, and if we market our products outside of their approved indications, we may be subject to enforcement action for off- label marketing. Violations of the FDA' s restrictions relating to the promotion of prescription products may also lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws. The distribution of product samples to physicians must comply with the requirements of the FDCA. NDA sponsors must obtain FDA approval for product, manufacturing, and labeling changes, depending on the nature of the change. Depending on the circumstances, failure to meet these post- approval requirements can result in criminal prosecution, fines, injunctions, consent decrees of permanent injunction, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre- marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. In addition, later discovery of previously unknown **AEs** ~~adverse events~~ or other problems with our products, or manufacturing processes, including **AEs** ~~adverse events~~ of unanticipated severity or frequency, or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including: • restrictions on manufacturing such products; • restrictions on the labeling or marketing of a product; • restrictions on product distribution or use; • requirements to conduct post- marketing studies or clinical trials; • warning letters or holds on clinical trials; • withdrawal of the products from the market; • refusal to approve pending applications or supplements to approved applications that we submit; • recall of products; • fines, restitution, or disgorgement of profits or revenues; • suspension or withdrawal of marketing approvals; • refusal to permit the import or export of our products; • product seizure or detention; or • injunctions or the imposition of civil or criminal penalties. Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues. If regulatory sanctions are applied or if regulatory approval is withheld or withdrawn, the value of our Company and our operating results will be adversely affected. The FDA' s policies may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of LYR- 210 ~~, 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 **. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. Further, three decisions from the U. S. Supreme Court in July 2024 may lead to an increase in litigation against regulatory agencies that could create uncertainty and thus negatively impact our business. The first decision overturned established precedent that required courts to defer to regulatory agencies' interpretations of ambiguous statutory language. The second decision overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. The third decision extended the statute of limitations within which entities may challenge agency actions. These cases may result in increased litigation by industry against regulatory agencies and impact how such agencies choose to pursue enforcement and compliance actions. However, the specific, lasting effects of these decisions, which may vary within different judicial districts and circuits, is unknown. We also cannot predict the extent to which FDA and SEC regulations, policies, and decisions may become subject to increasing legal challenges, delays, and changes** . Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed, approved, or commercialized in a timely manner, or at all, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, and other events that may otherwise affect the government agency' s ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third- party payors, patient organizations, and customers will be subject

to applicable healthcare regulatory laws, which could expose us to penalties. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third- party payors, patient organizations, and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our product candidates, if approved. Such laws include: • the U. S. federal Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, any good, facility, item, or service, for which payment may be made, in whole or in part, under U. S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the U. S. federal civil and criminal false claims laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U. S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease, or conceal an obligation to pay money to the U. S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U. S. federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act; • the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary' s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies; • the U. S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items, or services; similar to the U. S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics, and medical devices; • the U. S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children' s Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) **, certain other healthcare professionals (including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse midwives)** and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members ~~. Such obligations include payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse midwives~~ ; • federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; • analogous U. S. state laws and regulations, including: state anti- kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by any third- party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U. S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws that require the registration of pharmaceutical sales representatives; and • similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom are compensated in the form of stock options for consulting services provided, may not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, exclusion from government- funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non- compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time- consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Our business, financial condition, and results of operations may suffer in the event of information technology system failures, cyberattacks, data security incidents or deficiencies in our cybersecurity.

We rely on our information technology systems and those of our third- party service providers for both internal and external operations that are critical to our business. We face numerous and evolving cybersecurity risks that threaten the confidentiality, integrity and availability of our information technology systems and data we and our third- party providers maintain, including ~~personal~~ **Personal** ~~information~~ **Information**, clinical trial data, ~~and~~ confidential and proprietary intellectual property, financial information, trade secrets, and other business information **(together, " Confidential Information ")**. Our information technology systems and ~~data~~ **Confidential Information**, and those of our third- party service providers, contractors and consultants are vulnerable to attack, interruption and damage from computer viruses and malware (e. g. ransomware), bugs, misconfigurations, malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation- state and nation- state- supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. Attacks upon information technology systems and ~~data~~ **Confidential Information** are increasing in their frequency, levels of persistence, sophistication and intensity- including attacks conducted using artificial intelligence- and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems and data change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security incidents that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. There can also be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with, or effective in protecting our information technology systems and data. While we do not believe that we have experienced any material system failure or incident, from time to time, we and our third party providers have been the target of cybersecurity attacks, and we expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and number. While we do not believe that any incidents have had a material impact on our operations or financial results to date, we cannot guarantee that material incidents will not occur in the future. If such an incident were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We could also incur liabilities and the further development of our product candidates could be delayed. Further, any adverse impact to the availability, integrity or confidentiality of our information technology systems or data could expose us to legal claims or proceedings (including class actions), enforcement actions and investigations by regulatory authorities, and potentially result in penalties, fines and significant legal liability. We could also experience negative reputational impacts that cause an erosion of trust, and / or significant incident response, system restoration or remediation and future compliance costs. Any or all of the foregoing could materially adversely affect our business, results of operations, and financial condition. Finally, cyber insurance we maintain may not be sufficient to cover the financial, legal, business or reputational losses that may result from an incident, and we cannot guarantee that applicable insurance will be available to us in the future on economically reasonable terms or at all. We are subject to governmental regulation and other legal obligations, particularly related to privacy, data protection, and information security, and we are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business. We, and third parties on our behalf, receive, store, handle, transmit, use and otherwise process business information and information related to individuals, including from and about trial patients as well as our employees, business contacts, and service providers. We and our partners are subject to diverse state, federal, and international laws and regulations relating to data privacy and security, including, in the United States, the California Consumer Privacy Act, or the CCPA, and, in the EU and the European Economic Area, or EEA, the General Data Protection Regulation, or the GDPR. New privacy rules are being enacted in the United States and globally, and existing ones are being updated and strengthened, creating an ever evolving patchwork of privacy laws. For example, the CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches. Complying with these numerous, complex, and often changing laws and regulations is expensive and difficult, and failure or perceived failure to comply with any privacy laws or data security laws or any security incident or breach involving the misappropriation, loss, or other unauthorized use or disclosure of personal information, whether by us or another third- party, could adversely affect our business, financial condition, and results of operations, including but not limited to: damage to our reputation, an erosion of trust, and negative media attention; investigation costs; material fines and penalties; compensatory, special, punitive, and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services, and / or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; and injunctive relief. In Europe, the GDPR requires us, among other things, to make detailed disclosures to data subjects, to disclose the legal basis on which we can process ~~personal~~ **Personal** ~~data~~ **Information**, to obtain valid consent for processing, to appoint data protection officers when sensitive ~~personal~~ **Personal** ~~data~~ **Information**, 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~~ **Personal** ~~data~~ **Information** from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having " adequate " data protection laws, which could increase our costs and our ability to efficiently process personal data from the EEA. If we do not comply with our obligations under the GDPR, we could be exposed to fines of up to

the greater of € 20 **. 0** million or up to 4 % of our total global annual revenue in the event of a significant breach. In addition, we may be the subject of litigation and / or adverse publicity, which could adversely affect our business, results of operations, and financial condition. Additionally, following the United Kingdom' s withdrawal from the EEA and the EU, companies have to comply with the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £ 17. 5 million or 4 % of global turnover. We cannot assure you that our third- party service providers with access to our or our customers', suppliers', trial patients', and employees' ~~personal~~ **Personal** ~~information~~ **Information** and other ~~sensitive or confidential~~ **Confidential** ~~information~~ **Information** will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and / or which could in turn adversely affect our business, results of operations, and financial condition. We cannot assure you that our contractual measures and our own privacy and security- related safeguards will protect us from the risks associated with the third- party processing, storage, and transmission of such information. We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us. Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act. We are not currently classified as a **"** covered entity **"** or **"** business associate **"** under HIPAA. However, any person may be prosecuted under HIPAA' s criminal provisions either directly or under aiding- and- abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive **protected** ~~individually identifiable~~ health information from a HIPAA- covered healthcare provider or research institution that has not satisfied HIPAA' s requirements for disclosure of **protected** ~~individually identifiable~~ health information. In addition, we may maintain sensitive ~~personally~~ **Personal** ~~identifiable information~~ **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 **protected** health information **under** ~~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~~ **Personal** ~~data~~ **Information** 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~~ **Personal** ~~data~~ **Information** , including genetic, biometric, or health data, which could limit our ability to use and share ~~personal~~ **Personal** ~~data~~ **Information** or could cause our costs to increase. Moreover, patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our business. If we, our CROs, or other contractors or consultants fail to comply with applicable federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing, and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security, or reputational damage. We are subject to environmental, health, and safety laws and regulations, **as well as regulations regarding our employees or other social considerations,** and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities. Our operations, including our development, testing, and manufacturing activities, are subject to numerous environmental, health, and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release, and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds, and compounds that have a toxic effect on reproduction, laboratory procedures, and exposure to blood- borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions. As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Moreover, certain environmental laws may impose liability without regard to fault or legality of the action at the time of its occurrence. Environmental, health, and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, our ~~in- house manufacturing efforts or our~~ development efforts may be interrupted or delayed **. There is also increasing scrutiny from various stakeholders, including policymakers, on environmental and social matters, including climate change and human capital; this may result in additional regulations (or changes to interpretation of existing regulations) or other stakeholder engagement, which if we fail to successfully navigate may result in various adverse impacts on our business** . We and our employees are increasingly

utilizing social media tools as a means of communication both internally and externally. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our product candidates or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our policies and other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our product candidates in social media could seriously damage our reputation, brand image, and goodwill, regardless of the truthfulness of such posts. Any of these events could have a material adverse effect on our business, prospects, operating results, and financial condition and could adversely affect the price of our common stock. Risks Related to Commercialization Developments by competitors may render our products or technologies obsolete or non- competitive or may reduce the size of our markets. Our industry has been characterized by extensive research and development efforts, rapid developments in technologies, intense competition, and a strong emphasis on proprietary products. We face potential competition from many different sources, including pharmaceutical, biotechnology, and specialty pharmaceutical companies either marketing or developing therapeutics to treat CRS. Academic research institutions, governmental agencies, as well as public and private institutions are also potential sources of competitive products and technologies. Our competitors may have or may develop superior technologies or approaches, which may provide them with competitive advantages. Our potential products may not compete successfully. If these competitors access the marketplace before we do with better or less expensive therapeutics, our product candidates, if approved for commercialization, may not be profitable to sell or worthwhile to continue to develop. Technology in the pharmaceutical industry has undergone rapid and significant change, and we expect that it will continue to do so. Any compounds, products, or processes that we develop may become obsolete or uneconomical before we recover any expenses incurred in connection with their development. The success of our product candidates will depend upon factors such as product efficacy, safety, reliability, availability, timing, scope of regulatory approval, acceptance, and price, among other things. Other important factors to our success include speed in developing product candidates, completing clinical development and laboratory testing, obtaining regulatory approvals, and manufacturing and selling commercial quantities of potential products. Our product candidates are intended to compete directly or indirectly with existing products and treatments. Even if approved and commercialized, our product candidates may fail to achieve market acceptance with hospitals, physicians, or patients. Hospitals, physicians, or patients may conclude that our potential products are less safe or effective or otherwise less attractive than these existing treatments. If our product candidates do not receive market acceptance for any reason, our revenue potential would be diminished, which would materially adversely affect our ability to become profitable. In addition, physicians may prefer to treat patients with CRS by performing ethmoid sinus surgeries which may reduce demand for our product candidates, once approved. There are a number of companies developing or marketing therapies for the treatment and management of CRS that may compete with our current product candidates, including many major pharmaceutical and biotechnology companies. These companies include, among others: Sanofi, GlaxoSmithKline, Regeneron, Optinose, Medtronic, Genentech and Novartis. Most of our competitors, including many of those listed above, have substantially greater capital resources, robust product candidate pipelines, established presence in the market, and expertise in research and development, manufacturing, pre- clinical and clinical testing, obtaining regulatory approvals and reimbursement, and marketing approved products than we do. As a result, our competitors may achieve product commercialization or patent protection earlier than we can. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified clinical, regulatory, scientific, sales, marketing, and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop or that would render any products that we may develop obsolete or noncompetitive. The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels, and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue. The availability of coverage and adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers, and other third- party payors are essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates, assuming FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for our products or procedures using our products by governmental authorities, private health insurers, and other organizations will have an effect on our ability to successfully commercialize our product candidates. Obtaining coverage and adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Separate reimbursement for the product itself or the treatment or procedure in which our product is used may not be available. A decision by a third- party payor not to cover or separately reimburse for our products or procedures using our products could reduce physician utilization of our products once approved. Assuming there is coverage for our product candidates or procedures using our product candidates by a third- party payor, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Similarly, our product candidates are physician- administered treatments and as such, separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. To the extent separate coverage and reimbursement should become

available for LYR- 210, we anticipate that it will be sold to physicians on a " buy and bill " basis. Buy and bill products must be purchased by healthcare providers before they can be administered to patients. Healthcare providers subsequently must seek reimbursement for the product from the applicable third- party payor, such as Medicare or a health insurance company. Healthcare providers may be reluctant to administer our product candidates, if approved, because they would have to fund the purchase of the product and then seek reimbursement, which may be lower than their purchase price, or because they do not want the additional administrative burden required to obtain reimbursement for the product. We do not know if, or at what level, physicians may receive reimbursement for treating patients with CRS with our product candidates, or for performing the procedure to insert our product candidates, or if such reimbursement will be deemed adequate by such physicians. Further, the status of reimbursement codes for any of our product candidates, if approved, could also affect reimbursement. J- Codes are reimbursement codes maintained by the ~~Centers for Medicare and Medicaid Services, or~~ CMS ~~,~~ that are a component of the Healthcare Common Procedure Coding System and are typically used to report injectable drugs that ordinarily cannot be self- administered. We currently do not have a specific J- Code for any of our product candidates. If our product candidates are approved, we may apply for one but cannot guarantee that a J- Code will be granted. To the extent separate coverage or reimbursement is available for any product candidate, if approved, and a specific J- Code is not available, physicians would need to use a non- specific miscellaneous J- Code to bill third- party payors for these physician- administered drugs. Because miscellaneous J- Codes may be used for a wide variety of products, health plans may have more difficulty determining the actual product used and billed for the patient. These claims must often be submitted with additional information and manually processed, which can delay claims processing times as well as increase the likelihood for claim denials and claim errors. We cannot be sure that coverage and reimbursement in the United States, the EU, or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future. Third- party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third- party payors may refuse to provide coverage and reimbursement for particular drugs and biologics when an equivalent generic drug, biosimilar, or a less expensive therapy is available. It is possible that a third- party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third- party therapeutics may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on our product candidates. There is significant uncertainty related to the insurance coverage and reimbursement of newly- approved products. In the United States, third- party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third- party payors may require pre- approval of coverage for new or innovative drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third- party payors will decide with respect to the coverage and reimbursement for our product candidates. No uniform policy for coverage and reimbursement for products exists among third- party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost- containment initiatives in the EU and other jurisdictions have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially- reasonable revenue and profits. Moreover, increasing efforts by governmental and third- party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Our clinical studies were designed to demonstrate the safety and efficacy of LYR- 210 based on FDA requirements and may not be seen as compelling to physicians or patients. Our success depends on the medical community' s acceptance of LYR- 210, if approved, as a treatment for CRS patients. LYR- 210 was previously studied in an open- label, Phase 1 clinical trial with 20 patients in New Zealand and Australia, which achieved its primary endpoint of safety at week 4. In the Phase 1 trial, we also observed that patients generally experienced significant and rapid, clinically meaningful and durable improvement in SNOT- 22 scores. Significant reduction in SNOT- 22 scores was observed at week 1, and this reduction persisted through week 25, which

was the end of the trial. In our Phase 2 LANTERN clinical trial, we reported positive top- line results but failed to achieve the primary endpoint. Although not statistically significant at week 4 (the primary endpoint), at the 7, 500 µg dose, LYR- 210 achieved statistically significant improvement in 4CSS in favor of the treatment arm as measured by the change from baseline at weeks 16, 20, and 24. Furthermore, at the 7, 500 µg dose, LYR- 210 achieved statistically significant improvement in SNOT- 22 score in favor of the treatment arm at weeks 8, 16, 20, and 24. Even if the results of these clinical trials suggest a favorable safety and efficacy profile, the study designs and results, and the designs and results of future clinical trials we conduct, may not be viewed as compelling to our physician customers or patients. If physicians do not find our data compelling, even if LYR- 210 receives marketing approval they may choose not to use our products or limit their use. ~~We cannot assure you~~ **Our Phase 3 ENLIGHTEN 1 clinical trial failed to meet its primary endpoint of demonstrating statistically significant improvement compared to sham control in the composite score of the three cardinal symptoms of CRS (nasal obstruction, nasal discharge, facial pain / pressure) at 24 weeks. The 52- week extension phase of the ENLIGHTEN 1 trial was completed in the fourth quarter of 2024. Safety data for LYR- 210 in the extension phase was generally consistent with the 24- week primary treatment phase, including for those patients** that **received a repeat dosing, resulting in a 12- month treatment period. LYR- 210 was generally well tolerated, with no product- related serious adverse events. The most commonly reported adverse events in the study population were chronic sinusitis, nasal odor, epistaxis, sinusitis, and nasopharyngitis. ENLIGHTEN 2, the second Phase 3 trial of LYR- 210 in CRS, is ongoing and topline data is expected in the second quarter of 2025. There can be no assurance that we will achieve the primary endpoint or** any ~~data that we or others~~ **other endpoints in the ENLIGHTEN 2** ~~generate, including from any pivotal~~ Phase 3 clinical **trial** ~~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 **ever** ~~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, or if we are unable to achieve an optimal cost of goods, we may not generate significant product revenues or become profitable. The degree of market acceptance of LYR- 210 ~~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 technology; • 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 implant requirements of the FDA, the EMA, or other regulatory authorities, including any limitations or warnings contained in a product' s approved labeling; • the prevalence and severity of any side effects; and • any restrictions on the use of our product together with other medications. If our product candidates are approved, but do not achieve an adequate cost of goods or level of acceptance by physicians, healthcare payors, and patients, we may not generate sufficient revenue from these products, and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third- party payors on the benefits of our product candidates may require significant resources and may never be successful. In addition, our ability to successfully commercialize our product candidates will depend on our ability to manufacture our products at commercial scale, differentiate our products from competing products, and defend the intellectual property of our products. Because we expect sales of LYR- 210, if approved, to generate substantially all of our product revenues for a substantial period, the failure of this product to find market acceptance would harm our business and could require us to seek additional financing. If physicians or patients are not willing to change current practices and adopt our office- based administration procedure for LYR- 210 ~~and LYR- 220, our products~~ may fail to gain market acceptance, and our business will be harmed. ~~Our product candidates~~ **While we believe ear** , **nose** ~~LYR- 210 and LYR- 220, are bioabsorbable polymeric matrices designed to be administered in a non- invasive, in- office procedure by an~~ **and throat (''** ENT **'')** ~~physician under endoscopic visualization via a single- use applicator. While we believe ENT~~ physicians will be able to administer ~~our product candidates~~ **LYR- 210** , if successfully developed and approved, in conjunction with an endoscopy procedure, thereby making the placement aligned with the existing care continuum for CRS patients and eliminating the need for ENT physicians to schedule separate surgical time, ENT physicians may not adopt our in- office procedure for a number of reasons, including: • lack of significant experience with the placement procedure via a single- use applicator; • lack of availability of adequate insurance coverage or reimbursement for the placement procedure; • perceived inadequacy of evidence supporting clinical benefits or cost- effectiveness of the placement procedure and / or our products in general over existing alternatives; • a perception that patients may be unable to tolerate the placement procedure in the physician office setting; and • liability risks generally associated with the use of new products and procedures. If ENT physicians do not adopt the placement procedure for any reason, including those listed above, our ability to grow our business would be impaired, even if LYR- 210 ~~and LYR- 220 receive~~ **receives** marketing approval. We believe recommendations and support of our products by notable ENT physicians could influence market acceptance and adoption. If we do not receive support from influential ENT physicians, our ability to achieve broad market acceptance for our products may be impaired. In addition, if patient receptivity toward treatment in an ENT physician office setting becomes less favorable in the future, this shift could negatively impact

market acceptance of our products. Any negative change due to patient receptivity could also be compounded by patients reporting to physicians or other patients through word- of- mouth or social media. Additionally, while it is currently more cost-effective to the healthcare system for providers to perform the placement procedure in an ENT physician' s office than endoscopic sinus surgery in an operating room, healthcare economics are subject to change. If the use of our products were to cease being more cost- effective than endoscopic sinus surgery due to changes in reimbursement economics, our products may fail to gain market acceptance, ~~our future growth would be limited,~~ and our business may be adversely affected. If we are unable to successfully establish manufacturing, sales, marketing, and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing LYR- 210 ~~or LYR- 220~~, if approved, and we may not be able to generate any revenue. We do not have commercial infrastructure for the manufacturing, sales, marketing, or distribution of all of our products, and the cost of establishing and maintaining such an organization may exceed the cost- effectiveness of doing so. ~~We expect~~ **The failure** to ~~build~~ **meet** our ~~own focused manufacturing, sales, distribution, and marketing infrastructure to market~~ **primary endpoint in the ENLIGHTEN 1 Phase 3 trial has also adversely affected the Company' s commercialization plans for** LYR- 210 ~~and LYR- 220 in the United States, if approved. There are significant expenses and risks involved with establishing our own manufacturing, 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 manufacturing, 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 **: • the failure to meet the primary endpoint of our ENLIGHTEN 1 Phase 3 trial and its effects on our ability to pursue a development strategy for LYR- 210 and to raise capital to operate the business; • the loss of skilled personnel as a result of the May 2024 RIF;** • our ability to manufacture sufficient quantities of our products; • our inability to recruit and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products; • our inability to equip medical and sales personnel with effective materials, including medical and sales literature to help them educate physicians and other healthcare providers regarding applicable diseases and our future products; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; • our inability to develop or obtain sufficient operational functions to support our commercial activities; • unforeseen costs and expenses associated with creating an independent sales and marketing organization; and • our inability to set a suitable price or establish reasonable reimbursement rates for our product candidates. We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of LYR- 210, ~~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 **, in the future** 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~~ **The success of our business** may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties. Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. We are evaluating the opportunities for the development and commercialization of our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approvals in other countries we may be required to comply with numerous and varying regulatory requirements of such countries regarding the safety and efficacy of our product candidates and governing, among other things, clinical trials and commercial sales, pricing, and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including: • our customers' ability to obtain reimbursement for our product candidates in foreign markets; • our inability to directly control commercial activities if we are relying on third parties; • the burden of complying with complex and changing foreign regulatory, tax, accounting, and

legal requirements; and • reduced protection of intellectual property rights in some foreign countries, among others. Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions, and changes in tariffs **, including under the new U. S. Presidential administration** . 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; ~~and •~~ formulating and manufacturing products; and launching, marketing, and selling products, among others. If **in the future** we obtain approval to commercialize any products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business. If ~~either~~ LYR- 210 ~~or LYR- 220~~ is approved for commercialization, we **may** ~~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. 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 **from the degradation or dislodgment of the** LYR- ~~220, or from the degradation or dislodgment of the LYR-~~ 210 **implant** ~~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 significant consequences including: • impairment of our business reputation and significant negative media attention; and • product recalls, withdrawals or labeling, marketing, or promotional restrictions, among others. We ~~currently~~ **suspended the** manufacture **of** our clinical materials in- house **. If we restart our manufacturing** , ~~but~~ we may rely on third parties for certain development and manufacturing- related services and we do not currently have long- term contracts with any of these parties. **Our** ~~Any inability to scale up our internal manufacturing capabilities, successfully transfer our manufacturing process to our in-~~

~~house facility, or our~~ continued reliance on third parties increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts. We have previously relied on third parties for certain development and manufacturing- related services during clinical development of our product candidates, and may rely on third parties for certain manufacturing- related services if any of our product candidates receive marketing approval. Certain of these manufacturers are critical to our production and the loss of these manufacturers to one of our competitors or otherwise, or an inability to obtain quantities at an acceptable cost or quality, could delay, prevent, or impair our ability to timely conduct pre- clinical studies or clinical trials, and would materially and adversely affect our development and commercialization efforts. The facilities used by certain third- parties involved in the production of our product candidates or components of our product candidates may require FDA clearance pursuant to inspections that may be conducted after we submit an NDA to the FDA. While we may be able to mitigate risks through our diligence and contracting processes, when we utilize third parties for manufacturing, we are dependent on them for compliance with cGMP requirements for manufacture of drug products and other laws and regulations. If these third- party manufacturers cannot successfully manufacture or supply material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and / or maintain regulatory approval for their manufacturing facilities. Some of our **CMOs** ~~contract manufacturers~~ may not have produced a commercially- approved product and therefore may not have obtained the requisite FDA approvals to do so. In addition, we are limited in our ability to ensure third- party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for, or market our product candidates, if approved. The failure of our third- party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, we may be unable to establish any agreements with third- party manufacturers **,** or to do so on acceptable terms **, or to do so on a timely schedule** . Even if we are able to establish agreements with third- party manufacturers, reliance on third- party manufacturers or suppliers entails additional risks, including: • breach of the manufacturing agreement by the third party; • misappropriation of our proprietary information, including our trade secrets and know- how; and • termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time- consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our product candidates. The extent to which geopolitical **or other global** events ~~such as the current conflict between Russia and Ukraine, or other events such as the evolving COVID- 19 pandemic~~ impact our ability to procure sufficient supplies for the development of our products and product candidates will depend on the severity and duration of the event, and the actions undertaken to contain its negative effects and may cause delays. If our current third- party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. We rely on third parties to conduct our pre- clinical studies and clinical trials. Any failure by a third party to conduct the clinical trials according to GCPs and in a timely manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize our product candidates. We are dependent on third parties to conduct our pre- clinical studies and clinical trials, including our planned and ongoing clinical trials for LYR- 210 **. If we decide to conduct future clinical trials for LYR- 210 or other product candidates** , ~~and~~ we expect to rely on third parties to conduct **those** 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 involve additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Our relationships with these third parties may also be adversely affected by geopolitical **or other global** events ~~such as the current conflict between Russia and Ukraine, or other events such as the evolving COVID- 19 pandemic~~ . For instance, COVID- 19 and government measures taken in response ~~have~~ had a significant impact on our CROs, and we expect that they ~~will~~ **could** 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 additional 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. If we seek, but are not able to establish, collaborations, we may have to alter our development and commercialization plans. Our product development programs and the potential commercialization of our product candidates will require substantial additional capital. We may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of our product candidates. We face significant competition in seeking appropriate collaborators. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue. Data provided by collaborators and others upon which we rely that has not been independently verified could turn out to be false, misleading, or incomplete. We rely on third- party vendors, such as CROs, scientists, and collaborators to provide us with significant data and other information related to our projects, pre- clinical studies, or clinical trials and our business. If such third parties provide inaccurate, misleading, or incomplete data, our business, prospects, and results of operations could be materially adversely affected. We do not have multiple sources of supply for some of the components used in LYR- 210 ~~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. 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. 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 biotechnology companies, our commercial success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity and is therefore costly, time consuming, and inherently uncertain. Recent wide- ranging patent reform legislation in the United States, including the Leahy- Smith America Invents Act, or the Leahy- Smith Act, could increase those uncertainties and costs. The Leahy- Smith Act includes a number of significant changes to U. S. patent law, including provisions that affect the way patent applications are prosecuted and may also affect patent litigation. Under the Leahy- Smith Act, the United States transitioned from a " first- to- invent " to a " first- to- file " system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. This will require us to be cognizant going forward of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. The Leahy- Smith Act also enlarged the scope of disclosures that qualify as prior art, and it expanded the scope of procedures that a third party may use to challenge a U. S. patent, including post grant review and inter partes review procedures. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U. S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. The Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. In addition, recent court rulings in cases such as Association for Molecular Pathology v. Myriad Genetics, Inc., BRCA1- & BRCA2- Based Hereditary Cancer Test Patent Litigation, and Promega Corp. v. Life Technologies Corp. have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future actions by the U. S. Congress, the U. S. courts, the USPTO, and the relevant law- making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. We may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and independent contractors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee' s former employers or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, or our ability to hire personnel, which, in any case of the foregoing, could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The USPTO, European, and other patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on patents and / or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and / or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non- U. S. patent agencies. The USPTO and various non- U. S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. We employ law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market, which could have a material adverse effect on our business. Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court. If we initiated legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and / or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product

candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our product candidates. Such a loss of patent protection could have a material adverse impact on our business. A defendant could also challenge our ownership of patents assigned to us. We cannot be certain that a third party would not challenge our rights to these patents and patent applications. Any legal proceeding or enforcement action can also be expensive and time- consuming. Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time. The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non- provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. For patents that are eligible for extension of patent term, we expect to seek extensions of patent terms in the United States and, if available, in other countries. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional equivalent indications approved during the period of extension). We might not be granted an extension because of, for example, failure to apply within applicable periods, failure to apply prior to the expiration of relevant patents or otherwise, or failure to satisfy any of the numerous applicable requirements. Moreover, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to obtain approval of competing products following our patent expiration by referencing our clinical and pre- clinical data and launch their product earlier than might otherwise be the case. If this were to occur, it could have a material adverse effect on our ability to generate revenue. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, and defending our intellectual property in countries throughout the world could be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. Therefore, we may choose not to pursue or maintain protection for certain intellectual property in certain jurisdictions. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent such competitors from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuit that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. In addition, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to " work " the invention in that country, or the third party has patented improvements) or limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our trademarks of interest and our business may be adversely affected. While we seek to protect the trademarks we use in the United States and in other countries, we may be unsuccessful in obtaining registrations and / or otherwise protecting these trademarks. If that were to happen, we may be prevented from using our names, brands, and trademarks unless we enter into appropriate royalty, license, or coexistence agreements, which may not be available or may not be available on commercially reasonable terms. Over the long term, if we are unable to establish name recognition based on our trademarks, trade names, service marks, and domain names, then we may not be able to compete effectively, resulting in a material adverse effect on our business. Our registered or unregistered trademarks or trade names may be challenged, infringed, diluted, or declared generic, or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trademarks and trade names similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks, then we may not be able to compete effectively and our business may be

adversely affected. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Effective trademark protection may not be available or may not be sought in every country in which our products are made available. Any name we propose to use for our products in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed product names, we may be required to expend significant additional resources in an effort to identify a usable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. Our proprietary rights may not adequately protect our technologies and product candidates, and do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative: • others may be able to make products that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own; • others, including inventors or developers of our patented technologies who may become involved with competitors, may independently develop similar technologies that function as alternatives or replacements for any of our technologies without infringing our intellectual property rights; • we might not have been the first to conceive and reduce to practice the inventions covered by our patents or patent applications; • we might not have been the first to file patent applications covering certain of our patents or patent applications; • it is possible that our pending patent applications will not result in issued patents **, or** ; • ~~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 **The May 2024 RIF was undertaken to significantly reduce our ongoing operating expenses but it may not result in our intended outcomes** and ~~Managing Growth~~ **may yield unintended consequences and additional costs. In connection with the May 2024 RIF, we incurred charges of approximately $ 4. 1 million in connection with the reduction in force, primarily consisting of severance payments, employee benefits and related costs.** We **incurred** ~~will need to expand our organization, and~~ **an** ~~we may experience difficulties~~ **additional $ 6. 8 million** in ~~managing~~ **charges for the restructuring subsequent to the May 2024 RIF.** ~~this~~ **This** ~~growth~~ **amount primarily relates to ongoing retention efforts for current employees and have been reflected within the financial statements as of December 31** , ~~which~~ **2024. The May 2024 RIF may result in unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended number of employees, decreased morale among our remaining employees, and the risk that we may not achieve the anticipated benefits of the May 2024 RIF. In addition, while positions have been eliminated certain functions necessary to our operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. The reduction in workforce** could ~~disrupt~~ **also make it difficult for us to pursue,** ~~our~~ **or** ~~operations. We expect~~ **prevent us from pursuing, new opportunities and initiatives due** to ~~continue~~ **insufficient personnel, or require us** to **incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. If we are unable to realize the anticipated benefits from the May 2024 RIF, or if we** experience significant ~~growth in~~ **adverse consequences from** the ~~number of~~ **May 2024 RIF,** our ~~employees~~ **business, financial condition,** and **results** ~~the scope~~ of ~~our~~ operations ~~, particularly in the areas of product development, regulatory affairs, and sales, marketing, and distribution over the next few years. As of December 31, 2023, we had 88 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 or retain qualified employees, directors, officers, or other significant personnel, or experience increases in our compensation costs, our business may~~ materially **adversely affected** ~~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 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 above or 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 employees, customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business or partnership that are not covered by the indemnification we may obtain from the seller or our partner. In addition, we may not be able to successfully integrate any acquired personnel, technologies, and operations into our existing business in an effective, timely, and non- disruptive manner. Acquisitions or partnerships may also divert management attention from day- to- day responsibilities, lead to a loss of key personnel, increase our expenses, and reduce our cash available for operations and other uses. We cannot predict the number, timing, or size of future acquisitions or partnerships or the effect that any such transactions might have on our operating results~~ . Risks Related to Our Common Stock

Our common stock may be delisted from Nasdaq if we cannot regain compliance with Nasdaq' s continued listing requirements, which could harm our business, the trading price of our common stock, our ability to raise additional capital and the liquidity of the market for our common stock. On July 19, 2024, we received a Notice from Nasdaq notifying us that for the last 30 consecutive business days, the bid price for our common stock, par value $ 0. 001 per share, had closed below the $ 1. 00 per share minimum bid price requirement for continued inclusion on The Nasdaq Global Market as set forth in Nasdaq Listing Rule 5450 (a) (1) (" the Minimum Bid Price Requirement "). The Notice had no effect at the time on the listing of our common stock, which continues to trade on Nasdaq under the symbol " LYRA. " In accordance with Nasdaq Listing Rule 5810 (c) (3) (C), we had a period of 180 calendar days, or until January 15, 2025 (the " Compliance Date ") to regain compliance with the Minimum Bid Price Requirement. To regain compliance with the Minimum Bid Price Requirement, the closing bid price of the common stock must be at least $ 1. 00 per share for a minimum of 10 consecutive business days prior to the Compliance Date. The Notice also specified that, in the event we do not regain compliance with the Minimum Bid Price Requirement by the Compliance Date, we may be eligible for a second 180 calendar day compliance period. To qualify, we submitted an application to transfer the listing of the common stock to The Nasdaq Capital Market, which requires us to meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and paid an application fee to Nasdaq and provided written notice of our intention to cure the deficiency during the additional compliance period. Prior to the Compliance Date, we notified Nasdaq that we intend to cure our bid price deficiency under Nasdaq Listing Rule 5450 (a) (1) during the second 180- day compliance period. In connection with this effort, we also submitted a timely application with Nasdaq to change our

listing tier from the Nasdaq Global Market to the Nasdaq Capital Market and we paid the requisite fee to Nasdaq. We were notified by Nasdaq on January 31, 2025 that Nasdaq had granted our request to transfer the listing of our common stock from The Nasdaq Global Market tier to The Nasdaq Capital Market tier, effective February 4, 2025. The transfer of the listing of our common stock from The Nasdaq Global Market to The Nasdaq Capital Market took effect with the open of business on February 4, 2025. On January 31, 2025, Nasdaq granted our request for a second 180- calendar day period, or until July 14, 2025 to regain compliance with the Minimum Bid Price Requirement. To regain compliance, we must evidence a closing bid price of at least $ 1. 00 per share for a minimum of 10 consecutive business days. As part of its review process, Nasdaq will make a determination of whether it believes we will be able to cure this deficiency. If the Company does not qualify for or fails to regain compliance during the additional compliance period, then Nasdaq will notify us of its determination to delist our common stock, at which point we would have an opportunity to appeal the delisting determination to a Nasdaq hearings panel. There can be no assurance that, if we decide to appeal any delisting determination, such appeal would be successful. We intend to monitor the closing bid price of our common stock and may, if appropriate, consider implementing available options to regain compliance with the Minimum Bid Price Requirement. There can be no assurance that we will be able to regain compliance with the Minimum Bid Price Requirement or maintain compliance with any other listing requirements. Delisting from any Nasdaq market could make trading our common stock more difficult for investors, potentially leading to declines in our share price and liquidity. In addition, without a Nasdaq market listing, stockholders may have a difficult time getting a quote for the sale or purchase of our common stock, the sale or purchase of our common stock would likely be made more difficult and the trading volume and liquidity of our common stock could decline. Delisting from Nasdaq could also result in negative publicity and could also make it more difficult for us to raise additional capital. The absence of such a listing may adversely affect the acceptance of our common stock as currency or the value accorded by other parties. If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on an over- the- counter quotation system, such as the OTCQB market, where an investor may find it more difficult to sell our common stock or obtain accurate quotations as to the market value of our common stock. We cannot assure you that our common stock, if delisted from Nasdaq, will be listed on another national securities exchange or quoted on an over- the counter quotation system. The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock. Our stock price may be volatile. The stock market in general and the market for smaller biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above your purchase price. The market price for our common stock may be influenced by many factors, including: • the success of competitive products or technologies; • actual or expected changes in our growth rate relative to our competitors; • results of clinical trials of our product candidates or those of our competitors; • developments related to our existing or any future collaborations; • regulatory actions with respect to our product candidates or our competitors' products and product candidates; • regulatory or legal developments in the United States and other countries; • development of new product candidates that may address our markets and make our product candidates less attractive; • changes in physician, hospital, or healthcare provider practices that may make our product candidates less useful or appealing; • announcements by us, our partners, or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations, or capital commitments; • developments or disputes concerning patent applications, issued patents, or other proprietary rights; • the ~~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 or reimbursement systems; • market conditions in the pharmaceutical and biotechnology sectors; • short selling activities; • general economic, industry, and market conditions; and • the other factors described in this " Risk Factors " section and elsewhere in this Annual Report on Form 10- K. In addition, the trading prices for common stock of other biotechnology companies may become highly volatile as a result of geopolitical events such as the current ~~conflict~~ **conflicts** between Russia and Ukraine ~~, or~~ **and in** ~~other~~ -- **the Middle East** ~~events such as the evolving COVID- 19 pandemic~~ . The extent to which such events may impact our business, pre- clinical studies, and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence. ~~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 March 1, 2024, 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 70. 49 % 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 ~~57~~ **14** . ~~2~~ **6** million shares of our common stock **and certain accompanying warrants** have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration

statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 or until the rights terminate pursuant to the terms of the ninth amended and restated investor rights agreement between us and such holders. We have also registered all shares of common stock that we may issue under our equity compensation plans, which can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. We are an " emerging growth company, " and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors. We are an " emerging growth company, " as defined in the JOBS Act, and may remain an emerging growth company until December 31, 2025. However, if certain events occur prior to such date, including if we become a " large accelerated filer, " our annual gross revenues exceed $ 1. 235 billion, or we issue more than $ 1. 0 billion of non- convertible debt in any three- year period, we will cease to be an emerging growth company prior to such date. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include: • not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting; • not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor' s report providing additional information about the audit and the financial statements; • reduced disclosure obligations regarding executive compensation; and • exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We have taken advantage of reduced reporting burdens in our Annual Reports on Form 10- K and our Quarterly Reports on Form 10- Q including by providing only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline, even if our business is doing well. The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property, or our stock performance, or if our target pre- clinical studies or clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. We are a " smaller reporting company " and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors. We are considered a " smaller reporting company. " We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from disclosing certain executive compensation information and three years of financial statements. We are also exempt from the requirement to obtain an external audit on the effectiveness of internal control over financial reporting provided in Section 404 (b) of the Sarbanes- Oxley Act. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock prices may be more volatile. Provisions in our restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of our Company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our restated certificate of incorporation and our amended and restated bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control of our Company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our Board of Directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Among other things, these provisions include those establishing: • a classified ~~board~~ **Board** of ~~directors~~ **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~~ **Board** of ~~directors~~ **Directors** to elect a director to fill a vacancy created by the expansion of the ~~board~~ **Board** of ~~directors~~ **Directors** or the resignation, death, or removal of a director, which prevents stockholders from filling vacancies on our ~~board~~ **Board** of ~~directors~~ **Directors** ; • the ability of our ~~board~~ **Board** of ~~directors~~ **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~~ **Board** of ~~directors~~ **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~~ **Board** of ~~directors~~

Directors , the chief executive officer, the president, or the ~~board~~ **Board** of ~~directors~~ **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~~ **Board** of ~~directors~~ **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~~ **significant** costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices. As a public company, we incur significant legal, accounting, and other expenses. The Sarbanes- Oxley Act of 2002, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq ~~Global~~ **Capital** 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~~ **continue to** ~~evaluating~~ **evaluate** these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Pursuant to Section 404 of the Sarbanes- Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. We may discover significant deficiencies or material weaknesses, which we may not successfully remediate on a timely basis or at all. Any failure to remediate any significant deficiencies or material weaknesses identified by us or to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. The identification of one or more material weaknesses could result in an adverse reaction in the financial markets

due to a loss of confidence in the reliability of our financial statements. Because we do not anticipate paying any cash dividends on our common shares in the foreseeable future, capital appreciation, if any, would be your sole source of gain. On March 20, 2012, we declared and paid a special cash dividend of $ 0. 2630467 per share of our common stock, par value $ 0. 001, which we refer to as the Special Dividend, which totaled approximately $ 42, 115 in the aggregate. Other than the Special Dividend, we have never declared or paid any cash dividends on our common shares. We currently anticipate that we will retain future earnings for the development, **and** operation ~~, 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. Litigation could be costly and time- consuming and could result in additional liabilities. We may from time to time be subject to legal proceedings and claims that arise in the ordinary course of business or otherwise, such as claims brought by us against ~~,~~ vendors or collaborators, and / or claims brought by our customers in connection with commercial disputes and employment claims made by our current or former employees. Claims may also be asserted by or on behalf of a variety of other parties, including government agencies, patients, or vendors of our customers, or stockholders. Any litigation involving us may result in substantial costs, operationally restrict our business, and may divert management' s attention and resources, which may seriously harm our business, overall financial condition, and results of operations. Insurance may not cover existing or future claims, be sufficient to fully compensate us for one or more of such claims, or continue to be available on terms acceptable to us. A claim brought against us that is uninsured or under insured could result in unanticipated costs, thereby adversely impacting our results of operations and resulting in a reduction in the trading price of our stock. We could be subject to securities class action litigation. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business. Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities. We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, and property, auto, workers' compensation, umbrella, and directors' and officers' insurance. Any additional product liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If we obtain marketing approval for LYR- 210 ~~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~~ **Board** of ~~directors~~ **Directors**, our board committees, or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations. Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect the Company' s current and projected business operations and its financial condition and results of operations. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. The Company maintains the majority of its cash and cash equivalents in accounts with major U. S. institutions, and our deposits at certain of these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our current and projected business operations, our financial condition and results of operations. Our ability to use our net operating losses and research and development credits to offset future taxable income may be subject to certain limitations. As of December 31, ~~2023~~ **2024**, we had net operating loss carryforwards, or NOLs, of $ ~~128~~ **171**. ~~3~~ **5** million for federal income tax purposes and $ ~~48~~ **84**. ~~3~~ **2** million for state income tax purposes, which may be available to offset our future taxable income, if any ~~, and~~ **. Our federal net operating loss carryforwards** begin to expire at various dates through ~~2043~~ **2037** ~~. As of December 31~~, ~~2023, we also had federal~~ and **our** state **net operating loss** ~~research and development credit~~ carryforwards ~~of $ 5. 3 million, which~~ begin to expire at various dates through ~~2043~~ **2044 . As of December 31, 2024, we also had federal research and development credit carryforwards of $ 6. 4 million, which begin to expire at various dates through 2044, and state research and development credit carryforwards of $ 2. 0 million, which begin to expire at various dates through 2039**. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, or IRC, as amended, or the Code, a corporation that undergoes an " ownership change, " generally defined as a greater than 50 % change

by value in its equity ownership over a three- year period, is subject to limitations on its ability to utilize its pre- change NOLs and its research and development credit carryforwards to offset future taxable income. The Company had performed an IRC 382 study **in 2022** ~~during the prior year~~ which resulted in identifying three separate ownership changes that occurred on March 31, 2006, January 17, 2020, and April 13, 2022. We performed an update assessment to our **IRC** 382 analysis in conjunction with the May 2023 financing noting no additional ownership change **. Also, as a result of the IRC 382 study performed in 2022, we wrote off $ 125. 8 million of state net operating losses and $ 2. 8 million of state research and development credits. We updated our IRC 382 study in 2023 given the changes to the Massachusetts apportionment to single sales resulting in a reduced amount of $ 121. 2 million** . For these reasons, in the event we experience a change of control, we may not be able to utilize a material portion of the NOLs or research and development credit carryforwards even if we attain profitability. New tax legislation may impact our results of operations and financial condition. The Inflation Reduction Act of 2022 introduced, among other changes, a 15 % corporate minimum tax on certain United States corporations and a 1 % excise tax on certain stock redemptions by United States corporations. The U. S. government may enact further significant changes to the taxation of business entities. **In particular, presidential, congressional, state and local elections in the United States could result in significant changes in, and uncertainty with respect to, tax legislation, regulation and government policy directly affecting our business or indirectly affecting us because of impacts on our suppliers and vendors.** The likelihood of these changes being enacted or implemented is unclear. We are currently unable to predict the ultimate impact of the Inflation Reduction Act or any such further changes on our business. Unstable global, political or economic conditions may have serious adverse consequences on our business, financial condition and share price. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest and inflation rates, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. If the equity and credit markets continue to deteriorate, or the United States enters a recession, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. In addition, international terrorism and conflicts could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. Related sanctions, export controls or other actions have and may in the future be initiated by nations including the U. S., the EU or Russia (e. g., potential cyberattacks, disruption of energy flows, etc.), which could adversely affect our business and / or our supply chain, our CROs, CMOs and other third parties with which we conduct business. Any of the foregoing could harm our business, results of operations and price of our common stock may be adversely affected. We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition, and prospects. If a natural disaster, power outage, or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities on which we rely, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. **Climate change is expected to increase the frequency and intensity of such events, as well as contribute to various chronic changes in meteorological and hydrological patterns, and may also adversely impact our access to or cost of any insurance.** We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. For example, following Hurricane Maria, shortages in production and delays in a number of medical supplies produced in Puerto Rico resulted, and any similar interruption due to a natural disaster affecting us or any of our third- party manufacturers could materially delay our operations. International terrorism, political unrest, and wars, or other events such as ~~the~~ COVID- 19 ~~pandemic~~ have previously and could in the future adversely impact our business and operations, including our clinical trials. International terrorism, political unrest and wars could delay or disrupt our business activity, and if any conflict escalates or spills over to or otherwise impacts additional regions, it could heighten many of the other risk factors described in this Item 1A. In addition, the COVID- 19 global pandemic and government measures taken in response have had a significant impact, both direct and indirect, on **our** businesses and commerce, as worker shortages ~~have~~ occurred; supply chains **were** ~~have been~~ disrupted; facilities and production **were** ~~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, **fell** ~~has fallen~~ . If ~~the COVID- 19 pandemic resurges, our business and operations could be adversely affected again. Similarly, if~~ another pandemic unfolds or if a geopolitical crisis escalates, our business and operations could be adversely affected. ~~We are subject to various risks associated with increased scrutiny of environmental, social, and governance matters. Companies across industries are facing increasing scrutiny from a variety of stakeholders related to their environmental, social and governance (" ESG ") practices, including regarding climate change and diversity & inclusion, among others. While we may, from time to time, engage in efforts to improve our ESG profile or respond to stakeholder expectations, such efforts may be costly and may not have the desired effect. Any negative perception of our ESG performance, whether or not accurate, could result in negative stakeholder sentiment, which may result in a reduction in interest in our stock or products, issues in attracting / retaining employees or business partners, or other adverse impacts on our business. There are also increasing regulatory obligations, disclosure- related and otherwise, on companies regarding ESG matters. For example, various policymakers, including the SEC and the State of California, have adopted or are considering adopting requirements for companies to provide significantly expanded disclosure on climate- related information, which may require us to incur additional costs and require attention from management, including in connection with internal controls on matters that have not previously been subject to such requirements. These and other stakeholder expectations may result in increased scrutiny that could increase any of the risks identified in this risk factor.~~

~~Certain customers and suppliers may be subject to similar expectations, which may augment or create additional risks, including risks that may not be known to us. 80~~