Risk Factors Comparison 2025-03-19 to 2024-03-13 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10- K, including our financial statements and the related notes thereto, " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " and the information contained under the heading " Cautionary Note Regarding Forward- Looking Statements " before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. We may update these risk factors in our periodic and other filings with the SEC. The following is a summary of the principal risk factors described in this section: ● We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through clinical trials, seek regulatory approval and pursue commercialization of any approved product candidates. The future viability of our company ~~may~~ **will** depend on our ability to ~~raise~~ **fund future operations and capital requirements with** additional capital ~~to~~ **from external** ~~finance~~ **financing** ~~our future operations~~ . ● We have a history of losses and our future profitability remains uncertain **. Our net losses and significant cash used in operating activities have raised substantial doubt regarding our ability to continue as a going concern** . ● We are primarily dependent on the success of our product candidates, YUTREPIA and L606, and these product candidates may fail to receive final marketing approval (in a timely manner or at all) **for some or all of the indications for which we are seeking approval** or may not be commercialized successfully. ● United Therapeutics has initiated multiple lawsuits against us in which it has claimed that YUTREPIA is infringing its patents, ~~a~~ **two** separate ~~lawsuit~~ **lawsuits** against us that we and a former United Therapeutics employee, who later joined us as an employee, conspired to misappropriate certain trade secrets of United Therapeutics and engaged in unfair or deceptive trade practices **and that United Therapeutics is entitled to an ownership interest in a portion of our intellectual property** , and a separate lawsuit against the FDA **asserting that** ~~seeking to challenge~~ the FDA **improperly** ~~' s acceptance~~ --- **accepted** ~~of our~~ **for review an** ~~amended~~ **amendment to our** NDA for YUTREPIA ~~. Final judgment was entered by Judge Andrews of the U. S. District Court for the District of Delaware in one of the lawsuits finding that one of the three asserted United Therapeutics' patents is both valid and infringed and ordering that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the infringed patent, which will be in 2027. The Patent Trial and Appeal Board, or the PTAB, found that this same patent was unpatentable, and on December 20, 2023, the United States Court of Appeals for the Federal Circuit affirmed this decision by the PTAB. However, although the PTAB' s decision has now been affirmed on appeal, Judge Andrews may need to lift the injunction in his order before we are able to obtain final FDA approval for YUTREPIA, and there are no assurances whether and when Judge Andrews would do so. Even if Judge Andrews was to lift his existing injunction, United Therapeutics is currently seeking injunctive relief in two additional lawsuits~~ . These lawsuits, and other lawsuits that United Therapeutics may file in the future, may result in our company being further delayed in its efforts to commercialize YUTREPIA ~~or~~ **,** result in substantial damage claims against us if we launch YUTREPIA and we are later found to infringe **or to have misappropriated trade secrets, or result in United Therapeutics owning an interest in a portion of our intellectual property. ● Our clinical trials, including our planned pivotal clinical trial of L606, may be delayed or may not be successful and delays to such clinical trials may cause our costs to increase and significantly impair our ability to commercialize our product candidates** . ● Liquidia PAH does not hold the FDA regulatory approval for Treprostinil Injection, the RG Cartridge or pumps used to administer Treprostinil Injection and is dependent on Sandoz, Chengdu and the pump manufacturers to manufacture and supply Treprostinil Injection, the RG Cartridge and pumps used to administer Treprostinil Injection, respectively, in compliance with FDA requirements, and is more broadly dependent on their FDA and healthcare compliance relative to Treprostinil Injection, the RG Cartridge and the pumps used to administer Treprostinil Injection, respectively. ● Treprostinil Injection is presently administered subcutaneously via ~~Smiths~~ **ICU** Medical' s CADD- MS 3 infusion pump. ~~Smiths~~ **ICU** Medical no longer manufactures **or supports** the CADD- MS 3 infusion pump **. It** ~~and has indicated its~~ - **is** ~~intention to discontinue service and maintenance of~~ **expected that, over time, the** CADD- MS 3 infusion pumps **that are currently** ~~on January 1, 2025. In addition, should components of the CADD- MS 3 pump become unavailable~~ -- **available and in** ~~before January 1, 2025, Smiths Medical' s ability to~~ service **will require maintenance** and **therefore** ~~maintain such pumps may terminate earlier than anticipated. For instance, we are aware of a shortage of a critical component of the CADD- MS 3 infusion pump that may cause~~ - **cease to be** ~~the number of CADD- MS 3 infusion pumps~~ available ~~for the administration of Treprostinil Injection to be depleted prior to January 1, 2025~~ . In the event the specialty pharmacies are unable to access sufficient quantities of operable pumps or in the event we are unable to identify or develop a new pump prior to the current pumps becoming unavailable, the commercial success of Treprostinil Injection may be adversely affected. ● Sales of Treprostinil Injection are dependent on market acceptance of generic treprostinil for parenteral administration and the medical devices used for administration of Treprostinil Injection, including the ~~Smiths~~ **ICU** Medical infusion pumps, any future pumps that we develop, and the RG Cartridge, by patients, health care providers and by third- party payors, while interactions with these persons and entities are subject to compliance requirements. The commercial success of Treprostinil Injection may also be impacted by increasing generic competition which may result in declining prices for Treprostinil Injection. ● We expect that we will need further financing for our existing business and future growth, which may not be available on acceptable terms, if at all. Failure to obtain funding on acceptable terms and on a timely

basis may require us to curtail, delay or discontinue our product development efforts or other operations. The failure to obtain further financing may also prevent us from capitalizing on other potential product candidates or indications which may be more profitable than YUTREPIA and / or L606 or for which there may be a greater likelihood of success. ● We face significant competition from large pharmaceutical companies, among others, in developing our products and in gaining regulatory approval to bring them to market in time to achieve commercial success, and our operating results will suffer if we are unable to compete effectively, including if one or more such products have a superior product profile to YUTREPIA and / or L606. ● Our financing facility with ~~Healthcare~~ **HealthCare** Royalty Partners IV, L. P. ~~, or~~ **(“** HCR **”)** ~~, requires mutual agreement of both HCR and us in order to draw down on the facility. HCR may not agree to make additional advances pursuant to the facility. Failure to receive further funding from HCR may result in our having insufficient financing for our existing business plan. Our financing facility with HCR also~~ contains operating and financial covenants that restrict our business and financing activities, and is subject to acceleration in specified circumstances, which may result in HCR taking possession and disposing of any collateral. ● Our products may not achieve market acceptance **or third- party payor coverage** . ● Our product candidates are based on proprietary, novel technology, which have not been used to manufacture any products that have been previously approved by the FDA, making it difficult to predict the time and cost of development and of subsequently obtaining final regulatory approval. In addition, we may experience unexpected challenges as we ramp up our manufacturing capacity to meet demand or during commercial manufacturing, which may result in our inability to supply sufficient quantities of product to meet demand. **36** ● Our business and operations may be adversely affected by the effects of **global** health **emergencies, including pandemics and** epidemics ~~, including the COVID- 19 pandemic~~ . ~~31~~ ● We may not be able to build **or maintain** a commercial operation, including establishing and maintaining marketing and sales capabilities or entering into agreements with third parties to market and sell our drug products. ● We depend on third parties for clinical and commercial supplies, including single suppliers for the active ingredient, the device, encapsulation and packaging of YUTREPIA and single suppliers for the drug product and device for L606. In the event of any disruption in these supplies, our ability to develop and commercialize, and the timeline for commercialization of, YUTREPIA and / or L606 may be adversely affected. ● We rely on third parties to conduct our preclinical studies and clinical trials. ● We may become involved in litigation to protect our intellectual property, to enforce our intellectual property rights or to defend against claims of intellectual property infringement by third parties, which could be expensive, time- consuming and may not be successful. ● We depend on skilled labor, and our business and prospects may be adversely affected if we lose the services of our skilled personnel, including those in senior management, or are unable to attract new skilled personnel. ● We expect that the market price of our common stock may be volatile, and you may lose all or part of your investment. ● As a public company, we are obligated to develop and maintain proper and effective internal control over financial reporting and any failure to do so may adversely affect investor confidence in us and, as a result, the trading price of our shares. Risks Related to our Financial Position and Need for Additional CapitalWe expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through clinical trials, seek regulatory approval and pursue commercialization of any approved product candidates. The future viability of our company ~~may~~ **will** depend on our ability to ~~raise~~ **fund future operations and capital requirements with** additional capital ~~to~~ **from external** ~~finance~~ **financing** ~~our future operations~~ . We are subject to risks and uncertainties common to early- stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and the ability to secure additional capital to fund operations. We expect to incur significant expenses and may incur significant operating losses for the foreseeable future as we advance product candidates through clinical trials, seek regulatory approval and pursue commercialization of any approved product candidates. **We do not expect to generate significant revenue unless and until we are able to obtain marketing approval for and successfully commercialize one or more of our product candidates.** In addition, if we obtain marketing approval for any of our product candidates, we would incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. These efforts require significant amounts of capital, adequate personnel and infrastructure, and extensive compliance- reporting capabilities ~~. If we have not received full FDA approval and begun product sales of YUTREPIA or are unable to access additional capital by the date of issuance of our second quarter 2024 financial statements, there could be substantial doubt about our ability to continue as a going concern as of that date. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect~~ . Even if our development efforts are successful, it is uncertain when, if ever, we will realize significant revenue from product sales. The future viability of our company ~~may~~ **will** depend on our ability to ~~raise~~ **fund future operations and capital requirements with** additional capital ~~to~~ **from external** ~~finance~~ **financing** ~~our future operations~~ . We may seek additional funding through public or private financings, debt financing or collaboration. Our inability to obtain funding, when needed, would have a negative impact on our financial condition and ability to pursue our business strategies. We have a history of losses and our future profitability remains uncertain. **Our net losses and significant cash used in operating activities have raised substantial doubt regarding our ability to continue as a going concern.** We have incurred net losses of $ ~~78~~ **130** . ~~5~~ **4** million during the year ended December 31, ~~2023~~ **2024** , **and $ 78. 5 million** and $ 41. 0 ~~million and $ 34. 6~~ million during the years ended December 31, **2023 and** 2022 ~~and 2021~~ , respectively. We also had negative operating cash flows for each of these periods. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~429~~ **559** . ~~1~~ **5** million. Since our incorporation, we have invested heavily in the development of our product candidates and technologies, as well as in recruiting management and scientific personnel. To date, we have not commenced the commercialization of our product candidates and all of our revenue has been derived from up- front fees and milestone payments made to us in ~~connection~~ **37connection** with licensing and collaboration arrangements we have entered into and the Promotion Agreement, under which we share in the profit derived from the sale of Treprostinil Injection in the United States. These up- front fees and ~~32milestone~~ -- **milestone** payments have been, and combined with revenue generated from Treprostinil Injection may continue to be, insufficient to match our operating

expenses. We expect to continue to devote substantial financial and other resources to the clinical development of our product candidates and, as a result, must generate significant revenue to achieve and maintain profitability ~~or raise additional capital to fund clinical development~~ . We may continue to incur losses and negative cash flow and may never transition to profitability or positive cash flow. **These factors raise substantial doubt about our ability to continue as a going concern and to satisfy our estimated liquidity needs for one year from the issuance of the consolidated financial statements included in this Annual Report on Form 10- K. Accordingly, we will require additional funding over the next twelve months to continue our operations and maintain compliance with debt covenants, and could be required to delay, reduce, or eliminate research and development programs, product portfolio expansion, or commercialization efforts, which could adversely affect our business prospects, or potentially force us to cease operations.** We ~~may~~ **expect that we will** need further financing for our existing business and future growth, which may not be available on acceptable terms, if at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our product development efforts or other operations. The failure to obtain further financing may also prevent us from capitalizing on other potential product candidates or indications which may be more profitable than YUTREPIA and / or L606 or for which there may be a greater likelihood of success. We ~~may~~ **expect that we will** need to raise additional funds to meet our future funding requirements for the continued research, development and commercialization of our product candidates and technology **. Our future funding requirements will be heavily determined by the timing of the potential commercialization of YUTREPIA and the resources needed to support development of our product candidates** . In the event that funds generated from our operations are insufficient to fund our future growth, we may raise additional funds through the issuance of equity or debt securities or by borrowing from banks or other financial institutions. We cannot assure you that we will be able to obtain such additional financing on terms that are acceptable to us, or at all. Global and local economic conditions could negatively affect our ability to raise funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing, even if obtained, may be accompanied by restrictive covenants that may, among others, limit our ability to pay dividends or require us to seek consent for payment of dividends, or restrict our freedom to operate our business by requiring consent for certain actions. If we ~~need additional financing and~~ fail to obtain financing on terms that are favorable to us, we will not be able to implement our growth plans, and we may be required to significantly curtail, delay or discontinue one or more of our research, development or manufacturing programs or the commercialization of any approved product. Furthermore, if we ~~need additional financing and~~ fail to obtain additional financing on terms that are acceptable to us, we may forgo or delay the pursuit of opportunities presented by other potential product candidates or indications that may later prove to have greater commercial potential than the product candidates and indications that we have chosen to pursue. Our financing facility with **HealthCare** ~~HCR requires mutual agreement of both HCR and us in order to draw down on our financing facility, contains operating and financial covenants that restrict our business and financing activities, and is subject to acceleration in specified circumstances, which may result in HCR taking possession and disposing of any collateral. Our financing facility with Healthy Care~~ Royalty Partners **IV** , L. P. (" HCR ") contains ~~restrictions~~ **operating and financial covenants** that **restrict** ~~limit our flexibility in operating~~ our business **and financing activities, and is subject to acceleration in specified circumstances, which may result in HCR taking possession and disposing of any collateral** . Under the terms of the ~~Revenue~~ **revenue** ~~Interest~~ **interest** ~~Financing~~ **financing agreement with HCR dated January 9, 2023, as amended (the " HCR** Agreement ~~, amended, (the " RIFA ")~~ ~~, HCR has agreed to pay us an aggregate investment amount of up to $ 100. 0 million (the " Investment Amount "). Under the terms of the RIFA, $ 32. 5 million of the Investment Amount was funded in January 2023 at the initial closing, $ 10. 0 million of the Investment Amount was funded in July 2023 in connection with our entry into a license agreement with Pharmosa, $ 25. 0 million of the Investment Amount was funded in January 2024, and additional tranches of $ 10. 0 million and $ 22. 5 million of the Investment Amount will be funded fifteen business days after the mutual agreement of HCR and us to fund such amount. In the event we and HCR do not mutually agree to the funding of the third and / or fourth tranche of the Investment Amount, we will be unable to draw the full amount of the Investment Amount. In addition, under the terms of the RIFA~~ , we may not, among other actions, without the prior written consent of HCR, (a) pay any dividends or make any other distribution or payment or redeem, retire or purchase any capital stock, except in certain prescribed circumstances, (b) create, incur, assume, or be liable with respect to any indebtedness except certain permitted indebtedness, or make or permit any payment on any indebtedness, except under certain limited circumstances, or (c) make any sale, transfer, out- license, lease or other disposition of any property or any economic interest, other than certain limited exceptions. Additionally, we are required ~~(i) during the period from January 1, 2024 through December 31, 2024,~~ to maintain at all times a minimum cash balance of $ ~~7. 5 million, and (ii) during all periods after December 31, 2024, to maintain at all times a minimum cash balance of $~~ 15. 0 million. Our obligations under the ~~RIFA~~ **HCR Agreement** are collateralized by all of our assets and property, subject to limited exceptions. ~~33If~~ **38If** we breach certain of our covenants in the ~~RIFA~~ **HCR Agreement** and are unable to cure such breach within the prescribed period or are not granted waivers in relation to such breach, it may constitute an event of default under the ~~RIFA~~ **HCR Agreement** , giving HCR the right to require us to repay the then outstanding obligations immediately, and HCR could, among other things, foreclose on the collateral granted to them to collateralize such indebtedness, which includes our intellectual property, if we are unable to pay the outstanding debt immediately. Our management has broad discretion in using the net proceeds from our financing facility with HCR and prior equity offerings and may not use them effectively. We are using the net proceeds of our financing facility with HCR, our ~~January~~ **September** 2024 ~~private placement, our December 2023~~ public equity offering **, the September 2024 Private Placement, the January 2024 Private Placement** and prior public and private equity offerings to support the development and commercialization of YUTREPIA, including the potential commercial launch of YUTREPIA in the event of final FDA approval, the commercialization of Treprostinil Injection, the development and servicing of pumps for the administration of

Treprostinil Injection, the development of L606, and for general corporate purposes. Our management has broad discretion in the application of such proceeds and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our equity. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, diminish cash flows available to service our obligations to HCR, cause the value of our equity to decline and delay the development of our product candidates. Pending their use, we may invest such proceeds in short- term, investment- grade, interest- bearing securities, which may not yield favorable returns. **We depend on skilled labor, and our business and prospects may be adversely affected if we lose the services of our skilled personnel, including those in senior management, or are unable to attract new skilled personnel. Our ability to continue our operations and manage our potential future growth depends on our ability to hire and retain suitably skilled and qualified employees, including those in senior management, in the long- term. Due to the specialized nature of our work, there is a limited supply of suitable candidates. We compete with other biotechnology and pharmaceutical companies, educational and research institutions and government entities, among others, for research, technical, clinical and sales and marketing personnel. In addition, in order to manage our potential future growth effectively, we will need to improve our financial controls and systems and, as necessary, recruit sales, marketing, managerial and finance personnel. The loss of the services of members of our sales team could seriously harm our ability to successfully implement our business strategy. If we are unable to attract and retain skilled personnel, including in particular Roger Jeffs, our Chief Executive Officer, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, our business and prospects may be materially and adversely affected.** Our ability to use our net operating loss carry forwards and certain other tax attributes may be limited. Under Section 382 of the Internal Revenue Code of 1986, as amended (the " ~~Code~~ **IRC** "), if a corporation undergoes an " ownership change ", generally defined as a greater than 50. 0 % change (by value) in its equity ownership over a three- year period, the corporation' s ability to use its pre- change net operating loss carryforwards and other pre- change tax attributes, such as research tax credits, to offset its post- change income may be limited. ~~With~~ **Given our many financings and other equity issuances, including our September 2024 public equity offering, our September 2024 Private Placement, our January 2024 Private Placement, our December 2023 public equity offering, our December 2023 private placement,** our April 2022 public equity offering, our 2021 private placement, the closing of the RareGen acquisition in November 2020, our July 2020 public equity offering, our December 2019 private placement, issuances under our prior at- the- market facility, our March 2019 follow- on equity offering and our July 2018 initial public offering, as well as other past transactions, we may have already triggered an " ownership change " limitation. We have not completed a formal study to determine if any " ownership changes " within the meaning of IRC Section 382 have occurred. If **such** " ownership changes " ~~within the meaning of Section 382 of the Code~~ have occurred, and if we earn net taxable income, our ability to use our net operating loss carryforwards and research and development tax credits generated since inception to offset U. S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us and could require us to pay U. S. federal income taxes earlier than would be required if such limitations were not in effect. Similar rules and limitations may apply for state income tax purposes. ~~Changes~~ **39Changes** to existing tax laws, or challenges to our tax positions could adversely affect our business and financial condition. The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. ~~The issuance of additional guidance~~ **Following the change in U. S. administration, there is uncertainty regarding future legislative and regulatory changes and policies** related to ~~existing or future tax laws~~ **matters such as taxation and importation** , **and any such proposed** or **enacted** ~~changes to tax laws or~~ regulations ~~proposed or implemented~~ by the current or a future U. S. ~~presidential~~ administration, Congress, or taxing authorities in other jurisdictions could materially affect our tax obligations **and operating results** . For example, beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures in the year incurred and instead requires taxpayers to capitalize and subsequently amortize such expenditures over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. In January 2024, the U. S. House of Representatives passed the Tax Relief for American Families and Workers Act, which would retroactively repeal for 2022 and 2023, and defer until 2026, the requirement to capitalize research and development expenditures for research activities conducted in the United States. Uncertainty exists as to whether the bill will be enacted into law. **In addition** ~~As another example~~ , ~~in August 2022,~~ the **IRA** ~~Inflation Reduction Act of 2022 was enacted, and~~ , among other things, included a new 15 % alternative minimum tax on the ~~34adjusted~~ -- **adjusted** financial statement income of certain large corporations for tax years beginning **in** ~~after December 31, 2022~~ **2023** . To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes could adversely impact our business, results of operations and financial position. In addition, U. S. federal, state and local tax laws are extremely complex and subject to various interpretations. Although we believe that our tax estimates and positions are reasonable, there can be no assurance that our tax positions will not be challenged by relevant tax authorities. If the relevant tax authorities assess additional taxes on us, this could result in adjustments to, or impact the timing or amount of, taxable income, deductions or other tax allocations, which may adversely affect our results of operations and financial position. We are a late- stage clinical biopharmaceutical company with no approved products and no historical revenue from the sale of our own products, which may make it difficult for you to evaluate our business, financial condition and prospects. We are a late- stage clinical biopharmaceutical company with no history of commercial operations upon which you can evaluate our prospects other than the activities we have undertaken with respect to the Promotion Agreement with Sandoz. Drug product development involves a substantial degree of uncertainty. Our operations to date have been limited to engaging in promotional and nonpromotional activities under the Promotion Agreement with Sandoz, developing our PRINT technology, undertaking preclinical studies and clinical trials for our product candidates and collaborating with pharmaceutical companies, including GSK, to expand the applications for our PRINT technology through licensing as well as joint product development arrangements. We have not

obtained final marketing approval for any of our product candidates and, accordingly, have not demonstrated an ability to generate revenue from our own pharmaceutical products or successfully overcome the risks and uncertainties frequently encountered by companies undertaking drug product development. Consequently, your ability to assess our business, financial condition and prospects may be significantly limited. Further, the net losses that we incur may fluctuate significantly from quarter- to- quarter and year- to- year, such that a period- to- period comparison of our results of operations may not be a good indication of our future performance. Other unanticipated costs may also arise **in connection with the development of our product candidates and commercialization of any approved products** . Liquidia PAH does not hold the FDA regulatory approval for Treprostinil Injection and is dependent on Sandoz to manufacture and supply Treprostinil Injection in compliance with FDA requirements, and is more broadly dependent on Sandoz' s FDA and healthcare compliance relative to Treprostinil Injection. Sandoz holds the ~~FDA approval, or the~~ ANDA ~~,~~ for ~~and controls~~ Treprostinil Injection and is responsible among other things for the compliant manufacture, distribution, labeling, and advertising of Treprostinil Injection. ~~Our role is one of a specialized service provider to Sandoz.~~ As a result, we are dependent on Sandoz to manufacture and supply Treprostinil Injection, and **are** dependent on Sandoz for the continued FDA compliance of Treprostinil Injection. We do not have control over Sandoz' s compliance with laws and regulations applicable to drug manufacturers and ANDA holders (for example, applicable current good manufacturing practices, or cGMPs; FDA labeling, promotional labeling, and advertising requirements; pharmacovigilance and adverse event reporting; and other ongoing ~~FDA~~ **40FDA** reporting and submission requirements), nor over its compliance with healthcare compliance and fraud, waste, and abuse laws, or similar regulatory requirements and other laws and regulations, such as those related to environmental health and safety matters. In addition, we have no control over the ability of Sandoz to maintain adequate quality control, quality assurance and qualified personnel, or other personnel with roles related to the regulatory compliance of Treprostinil Injection and its labeling, promotion, and advertising or of Sandoz' s activities in relation to government healthcare programs. If the FDA or a comparable foreign regulatory authority finds deficiencies with the manufacture or quality assurance of Treprostinil Injection or identifies safety or efficacy concerns related to Treprostinil Injection, or if Sandoz otherwise is unable to comply with applicable laws, regulations and standards, Sandoz' s ability to manufacture, sell and supply Treprostinil Injection could be limited. Sandoz' s ability to consistently manufacture and supply Treprostinil Injection in a timely manner may also be interrupted by production shortages or other supply interruptions ~~, including as a result of the ongoing COVID- 19 pandemic~~ . Our share of net profits under the Promotion Agreement is reduced by certain manufacturing costs and other write- offs related to Sandoz' s inability to sell Treprostinil Injection, including in the event that Treprostinil Injection expires prior to sale. Currently, Treprostinil Injection expires 24 months after the date of manufacture. ~~35Sales~~ -- **Sales** of Treprostinil Injection are dependent on market acceptance of generic treprostinil for parenteral administration by patients, health care providers and by third- party payors, while interactions with these persons and entities are subject to compliance requirements. The commercial success of Treprostinil Injection may also be impacted by increasing generic competition which may result in declining prices for Treprostinil Injection. Our ability to sell Treprostinil Injection is dependent on market acceptance of generic treprostinil for parenteral administration by patients, health care providers and by third- party payors. If Treprostinil Injection does not achieve an adequate level of acceptance, we may not generate sufficient revenue to offset our cost of revenue. At the same time, arrangements with healthcare providers, physicians, third- party payors and customers, and our sales, marketing and educational activities, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our business or financial arrangements and relationships. The degree of market acceptance of Treprostinil Injection will depend on a number of factors, including: ● the efficacy, safety and potential advantages compared to alternative treatments; ● our ability to offer Treprostinil Injection for sale at competitive prices (generic drug prices, after initial generic entry, have been observed to decline with the entrance of additional generic competition); ● the convenience and ease of administration compared to alternative treatments; ● product labeling or product insert requirements of the FDA or foreign regulatory authorities, including any limitations or warnings contained in a product' s approved labeling, including any black box warning; ● the willingness of the target patient population to try new treatments, including the generic version of a brand, and of physicians to prescribe such treatments; ● our ability to hire and retain sales and marketing personnel and their ability to support Sandoz under the Promotion Agreement; ● the strength of Sandoz' s manufacturing and distribution support; ● ~~the~~ **any** ~~requirement~~ **requirements** by third- party payors to use generic treprostinil for parenteral administration in place of **Remodulin; ● our ability to maintain availability of medical devices used to administer Treprostinil Injection and preferences of the target patient population and health care providers regarding the medical devices used to administer Treprostinil Injection versus medical devices used to administer** Remodulin; ● the availability of third- party coverage and adequate reimbursement for Treprostinil Injection; ● the prevalence and severity of any side effects; ● any restrictions on the use of Treprostinil Injection together with other medications; ● our and Sandoz' s ability to maintain relationships with the specialty pharmacies; and ● the services provided by specialty pharmacies related to use of Treprostinil Injection. ~~Our~~ **41Our** business may also be impacted by the need to maintain compliant operations (including oversight and monitoring of personnel and our activities) in relation to interactions with the persons and parties noted above, relative to FDA and healthcare law requirements, and with consideration of government and industry compliance best practices. Medical devices, which we do not control, are necessary for the administration of **YUTREPIA, L606 and** Treprostinil Injection. In order for **YUTREPIA, L606 or** Treprostinil Injection to be administered to patients, patients must use certain other medical equipment, including **dry powder inhalers (in the case of YUTREPIA), nebulizers (in the case of L606), and** pumps, cartridges and infusion sets **(in the case of Treprostinil Injection)** . We do not manufacture or control such medical equipment, which is manufactured by third parties **. In addition, while we will distribute the necessary medical devices used for YUTREPIA** and **L606 in kits with our product, the medical devices for Treprostinil Injection are** owned and dispensed by specialty pharmacies, hospitals or other third parties. Our ability to serve patients is dependent upon **our ability and** the ability of specialty pharmacies to maintain sufficient inventory of such medical equipment to provide to patients. If manufacturers

cease to manufacture or support medical equipment or if **we or** specialty pharmacies are unable to obtain or maintain sufficient inventories of such medical equipment, our sales may be adversely impacted. ~~We have worked with Chengdu to develop the RG Cartridge, which received FDA 510 (k) clearance in March 2021. The ability of patients to administer Treprostinil Injection through subcutaneous injection is dependent on the continued availability of the RG Cartridge. Our ability to sell the Treprostinil Injection for subcutaneous administration is dependent on market acceptance of the RG Cartridge by patients, health care providers and by third- party payors.~~ If ~~the RG Cartridge does not achieve an~~ **any manufacturers** ~~adequate level~~ of **such medical devices** ~~acceptance or if the RG Cartridge experiences~~ -- **experience** any quality problems, ~~36recalls~~ -- **recalls** or other adverse events, our ability to provide ~~Treprostinil Injection~~ **our products** to patients ~~who receive treprostinil through subcutaneous injection~~ will be limited. The ~~degree of market acceptance of~~ **nebulizers we plan to use with L606 are currently undergoing testing and review. If** ~~the~~ **those tests** ~~RG Cartridge will depend on a number of factors, including: ● the efficacy, safety, quality and potential advantages or disadvantages compared to alternative cartridges; ● Chengdu' s ability to offer the RG Cartridge for~~ - **or** ~~sale at competitive prices; ●~~ **reviews are delayed or do not yield satisfactory results,** the **nebulizers may require design changes** ~~strength of Chengdu' s manufacturing~~ and **/ or additional testing or we may need** ~~distribution support; and ● Chengdu' s ability~~ to **identify** ~~maintain regulatory approvals necessary to manufacture~~ and ~~sell~~ **develop a different nebulizer for use with L606, all of which may delay** the ~~RG Cartridge in the United States~~ **commencement of our planned pivotal trial for L606** . In addition, to administer Treprostinil Injection through subcutaneous injection, patients currently must use the CADD- MS 3 infusion pump manufactured by ~~Smiths~~ **ICU** Medical. ~~Smiths~~ **ICU** Medical no longer manufactures **or supports** the CADD- MS 3 infusion pump ~~and has indicated~~ **. Although we believe that the number of available CADD- MS 3 infusion pumps will be sufficient to serve patients through at least the end of 2025, it is possible that the availability of CADD- MS 3 infusion pumps could end earlier. Due to this limitation in the availability of pumps, specialty pharmacies will limit the number of patients** that they **place on subcutaneous Treprostinil Injection therapy in order to ensure that patients placed on subcutaneous administration of Treprostinil Injection** will ~~no~~ **not** ~~longer support~~ **have to discontinue such treatment due to the unavailability of CADD- MS3 infusion pumps. Until we are able to obtain a pump to replace** the CADD- MS 3 infusion pump ~~after January 1, 2025. Moreover, in the event components of the CADD- MS 3 infusion pump become unavailable prior to January 1, 2025, Smiths Medical may be unable to service pumps that require a replacement of such components. For instance, there is a shortage of a critical component of the CADD- MS 3 infusion pump that has caused the number of CADD- MS 3 infusion pumps available for the administration of Treprostinil Injection to be limited. Due to this limitation in the availability of pumps, specialty pharmacies are not currently placing new patients on subcutaneous Treprostinil Injection therapy in order to preserve the available pumps for those patients already receiving subcutaneous administration of Treprostinil Injection. Until we are able to obtain a pump to replace the CADD- MS 3~~ , the number of patients that can receive subcutaneous administration of Treprostinil Injection will continue to be constrained, which would continue to adversely affect sales of Treprostinil Injection. We are seeking to work with third parties to develop or procure other pumps that can be used to administer Treprostinil Injection in the future. For example, we have entered into ~~an~~ **a Pump Development** ~~agreement~~ **Agreement** with Sandoz and Mainbridge to develop a new pump that can be used to administer Treprostinil Injection in the future. Such pumps will require FDA 510 (k) clearance before they can be sold. There is no guarantee that we or our partners will receive FDA 510 (k) clearance for any such pumps or, even if they do receive FDA 510 (k) clearance for any such pumps, that they will do so in a timely manner. **For example, we have still not submitted a 510 (k) clearance application for a pump under our agreement with Sandoz and Mainbridge and are currently uncertain when, if ever, such a 510 (k) clearance application will be submitted.** If we are unable to identify, develop and obtain any required FDA clearance for new pumps for the subcutaneous ~~and intravenous~~ administration of Treprostinil Injection prior to the unavailability of the CADD- MS 3 **infusion pump** , we may no longer be able to serve patients with Treprostinil Injection through the subcutaneous route of administration. Failure by us or third parties to successfully develop or supply the medical equipment or to obtain or maintain regulatory approval or clearance of such medical equipment could negatively impact the market acceptance of and sales of Treprostinil Injection. We maintain our cash at financial institutions, often in balances that exceed federally insured limits. Our cash is held in non- interest- bearing and interest- bearing accounts at multiple ~~banking~~ **financial** institutions that may exceed the Federal Deposit Insurance Corporation ~~, or the FDIC~~ insurance limits. If such ~~banking~~ **financial** institutions were to fail, we could lose all or ~~a~~ **42a** portion of those amounts held in excess of such insurance limitations. **If financial institutions with whom we hold accounts enter receivership** ~~For~~ - **or** ~~example,~~ **become insolvent in** the **future in response to financial conditions affecting the banking system and financial markets** ~~FDIC took control of Silicon Valley Bank, where we previously held all of our~~ - **or otherwise, our ability to access our existing** cash **may be threatened** and ~~cash equivalents,~~ **could have a material adverse effect** on ~~March 10, 2023. The Federal Reserve subsequently announced that account holders would be made whole, and we were able to move substantially all of~~ our **business,** ~~cash and cash equivalents to another~~ financial **condition and results** ~~institution. However, the FDIC may not make all account holders whole in the event~~ of **operations** ~~future bank failures~~ . ~~In addition, even~~ **Even** if account holders are ultimately made whole with respect to a future bank failure, account holders' access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business. ~~37Risks~~ -- **Risks** Related to the Commercialization of our Product Candidates and Generic Treprostinil InjectionUnited Therapeutics has initiated lawsuits against us in which it claims that YUTREPIA is infringing its patents and that we have misappropriated its trade secrets and **confidential information and** has initiated a lawsuit against the FDA challenging the FDA' s acceptance of our amended NDA for YUTREPIA for review, which may result in our company being further delayed in its efforts to commercialize YUTREPIA **and may limit the indications for which YUTREPIA is approved** . We are developing YUTREPIA under the 505 (b) (2) regulatory pathway with Tyvaso as the reference listed drug.

Accordingly, under the Hatch- Waxman Amendments to the Food, Drug and Cosmetic Act, we were required to, in the NDA for YUTREPIA, certify that patents listed in the Orange Book for Tyvaso are invalid, unenforceable or will not be infringed by the manufacture, use or sale of YUTREPIA. ~~Two of these patents are U. S. Patent No. 9, 604, 901 (the " ' 901 Patent "), entitled " Process to Prepare Treprostinil, the Active Ingredient in Remodulin ® ", and U. S. Patent No. 9, 593, 066 (the " ' 066 Patent "), entitled " Process to Prepare Treprostinil, the Active Ingredient in Remodulin ® ", both of which are owned by United Therapeutics. A notice of the paragraph IV certification was required to be provided to United Therapeutics as the owner of the patents that are the subject of the certification to which the NDA for YUTREPIA refers. In June 2020, United Therapeutics, as the holder of such patents, asserted a patent challenge directed to the ' 901 Patent and the ' 066 Patent by filing a complaint against us in the U. S. District Court for the District of Delaware (Case No. 1: 20- cv- 00755- RGA) (the " Original Hatch- Waxman Litigation "). In July 2020, the U. S. Patent and Trademark Office (the " USPTO ") issued U. S. Patent No. 10, 716, 793 (the " ' 793 Patent "), entitled " Treprostinil Administration by Inhalation ", to United Therapeutics. In July 2020, United Therapeutics filed an amended complaint in the Original Hatch- Waxman Litigation asserting infringement of the ' 793 Patent by the practice of YUTREPIA. In June 2021, the Court held a claim construction hearing. Based on the Court' s construction of the claim terms, United Therapeutics filed a stipulation of partial judgment with respect to the ' 901 Patent in December 2021 under which United Therapeutics agreed to the entry of judgment of our non- infringement of the ' 901 Patent. United Therapeutics did not file an appeal with respect to the ' 901 Patent. Trial proceedings in the Original Hatch- Waxman Litigation were held in March 2022. In August 2022, Judge Andrews, who was presiding over the Original Hatch- Waxman Litigation, issued an opinion that claims 1, 2, 3, 6 and 9 of the ' 066 Patent were invalid, that the remaining asserted claims of the ' 066 Patent were not infringed by us, and that all of the asserted claims of the ' 793 Patent were both valid and infringed by us, based on the arguments we presented in the Original Hatch- Waxman Litigation. In September 2022, Judge Andrews entered a final judgment in the Original Hatch- Waxman Litigation that incorporated the findings from his opinion and ordered that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the' 793 Patent, which will be in 2027. Both we and United Therapeutics appealed Judge Andrews' decision to the United States Court of Appeals for the Federal Circuit. On July 24, 2023, the United States Court of Appeals for the Federal Circuit affirmed Judge Andrews' decision with respect to both the ' 066 Patent and the ' 793 Patent. In March 2020, we filed two petitions for inter partes review with the Patent Trial and Appeal Board, or the PTAB, of the USPTO. One petition was for inter partes review of the ' 901 Patent, seeking a determination that the claims in the ' 901 Patent are invalid, and a second petition is for inter partes review of the ' 066 Patent, seeking a determination that the claims in the ' 066 Patent are invalid. In October 2020, the PTAB instituted an inter partes review of the ' 901 Patent and concurrently denied institution on the ' 066 Patent, stating that the ' 066 petition has not established a reasonable likelihood that it would prevail in showing that at least one of the challenged claims is unpatentable. In October 2021, the PTAB issued a final written decision concluding that seven of the claims in the ' 901 patent were unpatentable, leaving only the narrower dependent claims 6 and 7, both of which require actual storage at ambient temperature of treprostinil sodium. In November 2021, United Therapeutics submitted a rehearing request with respect to the PTAB' s decision in the inter partes review of the ' 901 patent. The rehearing request was denied in June 2022. In August 2022, United Therapeutics appealed the decision of the PTAB with respect to the ' 901 Patent to the United States Court of Appeals for the Federal Circuit. Oral argument was held in February 2024, and the appeal remains pending. 38In January 2021, we filed a petition with the PTAB for inter partes review of the ' 793 Patent, seeking a determination that the claims in the ' 793 Patent are invalid. In August 2021, the PTAB instituted an inter partes review of the ' 793 Patent, finding that we had demonstrated a reasonable likelihood that we would prevail with respect to showing that at least one challenged claim of the ' 793 Patent is unpatentable as obvious over the combination of certain prior art cited by us in our petition to the PTAB. In July 2022, the PTAB ruled in our favor, concluding that based on the preponderance of the evidence, all the claims of the ' 793 Patent have been shown to be unpatentable. In August 2022, United Therapeutics submitted a rehearing request with respect to the PTAB' s decision in the inter partes review of the ' 793 Patent. The rehearing request was denied in February 2023. In April 2023, United Therapeutics appealed the decision of the PTAB with respect to the ' 793 Patent to the United States Court of Appeals for the Federal Circuit. In December 2023, the United States Court of Appeals for the Federal Circuit affirmed the earlier decision by the PTAB, which found all claims of the ' 793 Patent to be unpatentable due to the existence of prior art cited by us in inter partes review proceedings. As a result of this decision by the United States Court of Appeals for the Federal Circuit, in December 2023, we filed a motion for Judge Andrews to set aside the injunction he issued in the Original Hatch- Waxman Litigation. The motion has been fully briefed and remains pending. In January 2024, United Therapeutics filed a request for rehearing of the decision by the United States Court of Appeals for the Federal Circuit. The request for rehearing was denied on March 12, 2024. United Therapeutics has the right to file a petition for a writ of certiorari to seek an appeal with the United States Supreme Court, but no such petition has been filed to date.~~ In connection with an amendment to our NDA filed in July 2023 to add PH- ILD as an indication for YUTREPIA, we provided a new notice of the paragraph IV certification to United Therapeutics as the owner of the patents that are the subject of the certification to which the NDA for YUTREPIA refers. As a result, in September 2023, United Therapeutics filed a ~~second~~ complaint for patent infringement against us in the U. S. District Court for the District of Delaware (Case No. 1: 23- cv- 00975- RGA) (the " New Hatch- Waxman Litigation ") ~~, again asserting infringement by the Company of the ' 793 Patent~~ . In ~~November 2023, the U. S. Patent and Trademark Office (the USPTO) issued U. S. Patent No. 11, 826, 327, or the ' 327 Patent, entitled " Treatment for Interstitial Lung Disease ", to United Therapeutics. On November 30, 2023, United Therapeutics filed an amended complaint in~~ the New Hatch- Waxman Litigation **, United Therapeutics is** asserting **that the Company** ~~infringement~~ **infringes** ~~of~~ **U. S. Patent No. 11, 826, 327 (** the **"** ' 327 Patent **")** ~~by the practice of YUTREPIA based on the amended NDA. In January 2024~~ , **entitled " Treatment** ~~we filed an answer, counterclaims and a partial motion to dismiss the claims related to the ' 793 Patent as a result of the decision by the United States Court of Appeals~~ for **Interstitial Lung Disease** ~~the Federal Circuit to affirm the PTAB' s finding that the' 793~~

~~patent is unpatentable .~~ **"** In February 2024, United Therapeutics ~~stipulated to the dismissal of the claims in the New Hatch- Waxman Litigation related to the ' 793 Patent. In February 2024, United Therapeutics also~~ filed a motion seeking a preliminary injunction to prevent us from manufacturing, marketing, storing, importing, distributing, offering for sale, and / or selling YUTREPIA for the treatment of PH- ILD. **The** ~~Briefing on the~~ motion for **a** preliminary injunction **was denied in May 2024, and trial** is **currently scheduled for June 2025** ~~ongoing, and the motion remains pending .~~ Although we do not believe United Therapeutics is entitled to a new 30- month stay or a preliminary injunction in connection with the New Hatch- Waxman Litigation, it is possible that the Court could rule that a new mandatory 30- month delay has been triggered with respect to the approval of the 505 (b) (2) NDA application or that a preliminary injunction is warranted. In February 2024, United Therapeutics also filed a lawsuit against the FDA, challenging the FDA' s acceptance of our amended NDA for review (the " **Original** FDA Litigation "). ~~On~~ **In** March ~~4,~~ 2024, United Therapeutics filed a motion for a temporary restraining order in the **Original** FDA Litigation, seeking to enjoin the FDA from approving our NDA for YUTREPIA with respect to the indication to treat PH- ILD. ~~Briefing~~ **United Therapeutics' motion was denied in March 2024. In May 2024, both we and the FDA filed motions to dismiss United Therapeutics' complaint. Prior to the Court' s ruling** on the ~~motion~~ **motions** ~~for a temporary restraining order~~ **to dismiss, United Therapeutics voluntarily dismissed** ~~is~~ **its complaint in** ~~ongoing, and~~ the ~~motion remains pending~~ **Original FDA Litigation without prejudice. In September 2024, United Therapeutics re- asserted its challenge to FDA' s acceptance of our amended NDA for review as a cross claim in the lawsuit we instituted against the FDA in August 2024 (the " New FDA Litigation ")** . Although we do not believe the arguments of United Therapeutics have merit, it is possible that the Court could rule that the FDA must reject the amendment to the YUTREPIA NDA to add PH- ILD to the label, in which case we may be required to later file a supplement to our NDA to add PH- ILD to the label. ~~In~~ **If we are required to file a supplement to add PH- ILD to the label for YUTREPIA, although we do not believe United Therapeutics would be entitled to a new 30- month stay, it is possible that the FDA or a Court could rule that a new mandatory 30- month delay has been triggered with respect to the supplement. 43In** addition, United Therapeutics may seek to assert newly issued patents against us, including U. S. Patent Number 11, 723, 887, and may seek to enjoin the FDA from granting final approval to YUTREPIA or enjoin us from launching YUTREPIA through one or more additional legal proceedings. As a result of this litigation **instituted to date and potential litigation that may be instituted in the future, final FDA approval of YUTREPIA for PAH and / or PH- ILD may be further delayed even after Tyvaso DPI' s New Clinical Investigation exclusivity expires on May 23, 2025. Further, even if we receive FDA approval for YUTREPIA** , we may be subject to significant delay and incur substantial additional costs in litigation before we are able to commercialize YUTREPIA, if at all. In addition, if United Therapeutics is successful in any of its ~~39appeals or requests~~ **claims that it has brought to date** ~~for~~ **or** ~~rehearing~~ **any claims it may bring in the future** , we may be unable to commercialize YUTREPIA **for the treatment of one or more indications or at all** until the expiration of **the applicable** United Therapeutics ~~'~~ patents, which could materially harm our business. **For example, in the event United Therapeutics prevails with respect to its claims regarding the ' 327 Patent, it is possible that an injunction could be issued, preventing the FDA from granting final approval for YUTREPIA for PH- ILD or forcing the FDA to revoke any prior approval for YUTREPIA for PH- ILD.** Also **, although United Therapeutics' initial requests for injunctive relief have been denied** , if United Therapeutics is successful in obtaining a preliminary injunction or temporary restraining order in the New Hatch- Waxman Litigation or the **New** FDA Litigation, we could be limited to commercializing YUTREPIA only for the PAH indication for an extended time period. In December 2021, United Therapeutics filed a complaint in the Superior Court in Durham County, North Carolina, alleging that we and a former United Therapeutics employee ~~,~~ who later joined us as an employee many years after terminating his employment with United Therapeutics ~~,~~ **(the " Former Employee ")** conspired to misappropriate certain trade secrets of United Therapeutics and engaged in unfair or deceptive trade practices. In January 2024, **the Former Employee filed a motion for summary judgment on all claims, but the motion was denied in July 2024. In addition, in July 2024, the Company filed a motion for summary judgment with respect to all claims. Briefing on the Company' s motion is complete and a hearing was held in December 2024. The motion remains pending. In May 2024, United Therapeutics filed a second complaint in the Superior Court in Durham County, North Carolina, against the Former Employee, alleging that he breached prior employment agreements with United Therapeutics by failing to assign to United Therapeutics his interest in patents obtained by the Company that relied upon** ~~our~~ **or** ~~co-~~ **benefitted from certain inventions, discoveries, materials, authorship, derivatives and results developed by the Former Employee while he was employed by United Therapeutics. The Company was also named as a** defendant in ~~the~~ **this new** lawsuit **. As part of the lawsuit, United Therapeutics alleges that the Former Employee misappropriated certain intellectual property of United Therapeutics which led to the development of YUTREPIA. The complaint also seeks declaratory judgement such that all right, title and interest in and to any patentable or unpatentable inventions, discoveries, and ideas made or conceived by the Former Employee while employed by the Company should be assigned and transferred to United Therapeutics because they involved the use of United Therapeutics' confidential information. In July 2024, the Company** filed a motion to dismiss all claims. **Briefing on the motion is complete and a hearing was held in December 2024.** The motion ~~is being briefed and~~ remains pending. ~~Fact discovery in the case has concluded, and expert discovery is in process.~~ Success in ~~the~~ **a** ~~lawsuits~~ **lawsuit** ~~or inter partes review proceedings~~ **, including in any such lawsuit** with respect to some patents or some claims in a given patent **,** does not mean that we will be similarly successful upon appeal of those decisions. In addition, success **in one proceeding, including** with respect to a given patent ~~or~~ **,** patent claim ~~in one proceeding~~ **or trade secret,** does not mean we will be similarly successful with respect to that same **or a similar** patent ~~or~~ **,** patent claim **or trade secret** in another proceeding. If ~~, after the appeals process has been completed,~~ we are found to infringe, misappropriate or otherwise violate any **of** United Therapeutics' intellectual property rights, we could be required to obtain a license from United Therapeutics to continue developing and marketing YUTREPIA. However, we may not be able to obtain any required license on commercially reasonable terms or at all. We could be found

liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or to have misappropriated a trade secret of United Therapeutics. In addition, we may be forced to redesign YUTREPIA to avoid infringement. ~~We~~ **44We** face significant competition from large pharmaceutical companies, among others, in developing our products and in gaining regulatory approval to bring them to market in time to achieve commercial success, and our operating results will suffer if we are unable to compete effectively. We face significant competition from industry players worldwide, including large multi- national pharmaceutical companies, other emerging or smaller pharmaceutical companies, as well as universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as a larger research and development staff and more experience in manufacturing and marketing, than we do. As a result, these companies may obtain marketing approval for their product candidates more quickly than we are able to and / or be more successful in commercializing their products, including generic treprostinil products, than us. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaboration arrangements with large, established companies. We may also face competition as a result of advances in the commercial applicability of new technologies and greater availability of capital for investment in such technologies. Our competitors may also invest heavily in the discovery and development of novel drug products that could make our product candidates less competitive or may file FDA citizen petitions or other correspondence with the FDA **, as United Therapeutics has done,** which may delay the approval process for our product candidates. Furthermore, our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, pharmaceutical products that are easier to develop, more effective or less costly than any product candidates that we are currently developing or that we may develop. Our competitors may also succeed in asserting existing patents or developing new patents, including patents that may issue from patent applications that are currently being pursued by United Therapeutics, to which we do not have a license, in an attempt to prevent us from marketing our products. These competitors may also compete with us in recruiting and retaining qualified sales personnel. Any new drug product that competes with a prior approved drug product must demonstrate advantages in safety, efficacy, tolerability or convenience in order to overcome price competition and to be commercially successful. Our products, if and when approved, are expected to face competition from drug products that are already on the market, as well as those in our competitors' development pipelines. We expect that our lead program, YUTREPIA, an inhaled treprostinil therapy for the treatment of PAH and PH- ILD, and L606, a nebulized, liposomal formulation of treprostinil ~~40for~~ **for** treatment of PAH and PH- ILD, will face competition from the following inhaled prostacyclin analog therapies that are either currently marketed or in clinical development: ● Tyvaso (treprostinil), marketed by United Therapeutics, has been approved for the treatment of PAH in the United States since 2009 and for PH- ILD since 2021. Tyvaso is the reference listed drug in our NDA for YUTREPIA. Following patent litigation, United Therapeutics and Watson Pharmaceuticals reached a settlement whereby Watson Pharmaceuticals will be permitted to enter the market with a generic version of Tyvaso beginning on January 1, 2026. ● Tyvaso DPI (treprostinil), licensed from MannKind by United Therapeutics, is a dry- powder formulation of treprostinil that was approved for the treatment of PAH and PH- ILD in the United States in May 2022. ● ~~Treprostinil Palmitil Inhalation Powder (~~TPIP ~~),~~ is a dry- powder formulation of a treprostinil prodrug being developed by Insmed. Insmed announced the completion of an initial Phase 1 study in February 2021 which demonstrated that TPIP was generally safe and well tolerated, with a pharmacokinetic profile that supports once- daily dosing. Insmed ~~initiated~~ **has announced that it expects to complete a placebo- controlled** Phase 2 ~~trials~~ **trial in** ~~studying patients diagnosed with~~ PAH ~~and~~ **in 2025, having already concluded a smaller open- label Phase 2 study in** PH- ILD in ~~May 2021~~ **2024** ~~and December 2022~~ **. Based on these Phase 2 results** , ~~respectively~~ **Insmed has stated that it intends to pursue discussions with global regulatory authorities on the design of pivotal trials to support indications in PAH and PH- ILD** . If the TPIP clinical program is successful in demonstrating less frequent dosing with similar efficacy and safety to YUTREPIA and Tyvaso DPI, then TPIP has the potential to be viewed as a more attractive option and may take market share rapidly. ● Ventavis ® (iloprost), marketed by Actelion, a division of Johnson & Johnson, has been approved for the treatment of PAH in the United States since 2004. ~~In~~ **45In** addition to these other inhaled treprostinil therapies, we expect that YUTREPIA and L606 will also face competition from other treprostinil- based drugs, including Orenitram, which is administered orally, and Remodulin, which is administered parenterally, both of which are marketed by United Therapeutics. Branded pharmaceutical companies such as United Therapeutics continue to defend their products vigorously through, among other actions, life cycle management, marketing agreements with third- party payors, pharmacy benefits managers and generic manufacturers. These actions add increased competition in the generic pharmaceutical industry, including competition for Treprostinil Injection. Additionally, even though Sandoz launched the first- to- file fully substitutable generic treprostinil for parenteral administration in March 2019 that is sold primarily through ~~the~~ specialty pharmacies, Teva Pharmaceutical Industries Ltd. launched a generic treprostinil for parenteral administration in October 2019 that is sold primarily through ~~a~~ specialty ~~pharmacy~~ **pharmacies** and to hospitals, Par Pharmaceutical, Inc. launched a generic treprostinil for parenteral administration after receiving approval in September 2019 that is sold primarily to hospitals, Dr. Reddy' s Laboratories Inc. launched a generic treprostinil for parenteral administration in April 2023, and Alembic received approval in February 2021 for generic treprostinil for parenteral administration. Such increased competition may result in a smaller than expected commercial opportunity for us. Generic drug prices may, and often do, decline, sometimes dramatically, especially as additional generic pharmaceutical companies (including low- cost generic producers outside of the United States) receive approvals and enter the market for a given product. The goals established under the Generic Drug User Fee Act, and increased funding of the FDA' s Office of Generic Drugs, have led to more and faster generic approvals, and consequently increased competition for generic products. The FDA has stated that it has established new steps to enhance competition, promote access and lower drug prices and is approving record- breaking numbers of generic applications. The FDA' s changes may benefit our competitors. Our ability to sell Treprostinil Injection and earn revenue is affected by the number of companies selling competitive products, including new market entrants, and the timing of their approvals. In addition to treprostinil- based therapies, other classes of therapeutic agents for the treatment of PAH **and / or PH-**

ILD include the following: ● IP- agonists **to treat PAH** , such as selexipag, marketed by Actelion, and ralinepeg, licensed from Arena Pharmaceuticals, Inc. by United Therapeutics, which is currently in **Phase 3** clinical development **with initial results expected in 2025** . ~~41~~ ● Endothelin receptor antagonists **to treat PAH** , such as bosentan and macitentan, both marketed by Actelion, and ambrisentan, marketed by Gilead. Generic versions of bosentan and ambrisentan are currently available. ● PDE- 5 inhibitors **to treat PAH** , such as tadalafil, marketed by United Therapeutics, and sildenafil, marketed by Pfizer Inc. Generic versions of both tadalafil and sildenafil are currently available. ● ~~Soluble guanylate cyclase (~~ sGC ~~) stimulator~~ **stimulators** , such as **oral** riociguat marketed by Bayer ~~. We are also aware of several other agents in clinical development that are exploring mechanisms of action which, if approved, could impact the standard of care~~ for ~~treating~~ PAH **,** and ~~/~~ **inhaled mosliciguat being developed by Pulmovant** ~~or~~ **for** PH- ILD ~~in the United States~~ **. ● Activin signaling inhibitor to treat PAH** , ~~including programs from~~ **such as sotatercept marketed by** Merck & Co. ~~Inc., Gossamer Bio, Inc. and Acrovate Therapeutics, Inc., among others. For example,~~ Merck & Co' s injectable sotatercept **, with a brand name of Winrevair, was approved by the FDA in March 2024 and** is **a** ~~an investigational, potential~~ first- in- class molecule that targets the proliferation of cells in the pulmonary arterial wall ~~and~~ **. Its clinical use** is **developing** ~~being reviewed by the FDA for approval in 2024. If approved~~ , **and** it is possible that it may be used prior to prostacyclin therapies, which may have an adverse effect on the market potential for YUTREPIA and / or L606. **We are also aware of several other agents in clinical development that are exploring mechanisms of action which, if approved, could impact the standard of care for treating PAH and / or PH- ILD in the United States, including programs from Gossamer Bio, Inc., Cereno Scientific, Novartis AG, and Forsee Pharmaceuticals among others.** ~~There~~ **46There** are a number of competitors seeking marketing approval and / or regulatory exclusivity with respect to products that are or would be competitive to our product candidate. Thus, we face the risk that one of our competitors will be granted marketing approval and / or regulatory exclusivity before we are able to obtain FDA approval for our product candidate. In that case, as stated above, there is the possibility that such a competitor would be able to prevent us from obtaining approval of and marketing our product candidate until the expiration of the competitor' s term of FDA regulatory exclusivity, which could be a term of three years for so- called New Clinical Investigation exclusivity, or could conceivably be for longer periods of time if the competitor is successful in being granted other forms of FDA regulatory exclusivity which might include, for example, Orphan Disease Designation exclusivity (seven years), New Chemical Entity exclusivity (five years), or Pediatric exclusivity (six months beyond other existing exclusivities or patent terms). **For example,** United Therapeutics ~~has been granted~~ **was recently awarded** New Clinical Investigation exclusivity for Tyvaso **DPI** ~~through March 31~~ , **which will expire in May** ~~2024~~ **2025** ~~for the indication of treatment of PH- ILD to improve exercise ability~~ . **As a result** ~~Until the expiration of this exclusivity~~ , ~~we~~ **the FDA** will be unable to ~~receive FDA approval~~ **approve** ~~for~~ YUTREPIA ~~for~~ **until after** the **exclusivity expires in May 2025** ~~indication of treatment of PH- ILD to improve exercise ability~~ . In the event United Therapeutics sought and was able to obtain one or more **other** regulatory exclusivities with respect to Tyvaso DPI, it could **further** significantly delay our ability to obtain final approval for YUTREPIA. Even if the FDA does not recognize any new regulatory exclusivity for United Therapeutics, United Therapeutics could challenge the FDA' s decision and seek an injunction to prevent approval of YUTREPIA in ~~on~~ **one** or more indications until such challenge has been decided. In addition, if one of our competitors is granted marketing approval before we are able to obtain FDA approval for our product candidates, as was the case with respect to the approval of United Therapeutics' Tyvaso DPI product, such competitors will be able to ~~detail~~ **promote** and market their products before we are able to do so, which may place us at a competitive disadvantage in the marketplace. One or more products that are competitive with YUTREPIA could also obtain approval for additional indications or broader conditions of use. These additional indications and broader conditions of use could be protected by one or more **patents or** regulatory exclusivities, preventing YUTREPIA from obtaining approval for the same indications or conditions of use. For instance **, if Liquidia is prevented from launching or selling YUTREPIA for the treatment of PH- ILD in connection with the patent litigation related to the ' 327 patent or the lawsuit that United Therapeutics filed against the FDA, Tyvaso and Tyvaso DPI would have broader labels than YUTREPIA. In addition** , United Therapeutics is currently studying Tyvaso for the treatment of idiopathic pulmonary fibrosis, an indication for which it has received an orphan drug designation. Thus, even if YUTREPIA is approved, such competitive products could have a broader label than the initial label for YUTREPIA. If YUTREPIA has a narrower label than other competitive products, it may affect our ability to compete with such products. The ability of competitors to utilize other regulatory incentive programs could also expedite their FDA review and approval timeline, which could result in their products reaching the market before our product candidate, and which could create further potential implications on exclusivity as noted above. For example, when a Priority Review Voucher is redeemed in connection with an NDA, the FDA' s goal review period would generally be expedited to six months, although this timeframe is not guaranteed. ~~42If~~ **If** we are unable to maintain our competitive position, our business and prospects will be materially and adversely affected. **If the FDA or comparable regulatory authorities in other countries approve generic versions of our product candidates, or do not grant our product candidates a sufficient period of market exclusivity before approving their generic versions, our ability to generate revenue may be adversely affected. Once an NDA is approved, the drug product covered will be listed as a reference listed drug in the FDA' s Orange Book. In the United States, manufacturers of drug products may seek approval of generic versions of reference listed drugs through the submission of ANDAs. In support of an ANDA, a generic manufacturer is generally required to show that its product has the same active pharmaceutical ingredient (s), dosage form, strength, route of administration and conditions of use or labeling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug. Generic drug products may be significantly less expensive to bring to market than the reference listed drug, and companies that produce generic drug products are generally able to offer them at lower prices. Thus, following the 47introduction of a generic drug product, a significant percentage of the sales of any reference listed drug may be lost to the generic drug product. The FDA will not approve an ANDA for a generic drug product until the applicable period of market exclusivity for the reference listed drug has expired. The**

applicable period of market exclusivity varies depending on the type of exclusivity granted. A grant of market exclusivity is separate from the existence of patent protection and manufacturers may seek to launch generic versions of our drug products following the expiration of their respective marketing exclusivity periods, even if our drug products are still under patent protection at the relevant time. Any competition that our product candidates may face, if and when such product candidates are approved for marketing and commercialized, from generic versions could substantially limit our ability to realize a return on our investment in the development of our product candidates and have a material and adverse effect on our business and prospects. Our products may not achieve market acceptance **or adequate third- party payor coverage** . We are currently focused on developing drug products that can be approved under abbreviated regulatory pathways in the United States, such as the 505 (b) (2) regulatory pathway, which allows us to rely on existing knowledge of the safety and efficacy of the relevant reference listed drugs to support our applications for approval in the United States. While we believe that it will be less difficult for us to convince physicians, patients and other members of the medical community to accept and use our drug products as compared to entirely new drugs, our drug products may nonetheless fail to gain sufficient market acceptance by physicians, patients, other healthcare providers and third- party payors. If any of our drug products fail to achieve sufficient market acceptance **or third- party payor coverage** , we may not be able to generate sufficient revenue to become profitable. The degree of market acceptance **and third- party payor coverage** of our drug products, if and when they are approved for commercial sale, will depend on a number of factors, including but not limited to: ● the timing of our receipt of marketing approvals, the terms of such approvals and the countries in which such approvals are obtained; ● the safety, efficacy, reliability and ease of administration of our drug products; ● the prevalence and severity of undesirable side effects and adverse events; ● the extent of the limitations or warnings required by the FDA or comparable regulatory authorities in other countries to be contained in the labeling of our drug products; ● the clinical indications for which our drug products are approved; ● the availability and perceived advantages of alternative therapies; ● any publicity related to our drug products or those of our competitors; ● the quality and price of competing drug products; ● our ability to obtain third- party payor coverage and sufficient reimbursement; ● the willingness of patients to pay out of pocket in the absence of third- party payor coverage; and ● the selling efforts and commitment of our commercialization collaborators. If our drug products, if and when approved, fail to receive a sufficient level of market acceptance **or sufficient third- party payor coverage** , our ability to generate revenue from sales of our drug products will be limited, and our business and results of operations may be materially and adversely affected. We may not be able to build a commercial operation, including establishing and maintaining marketing and sales capabilities or entering into agreements with third parties to market and sell our drug products. In order to market and sell any of our drug products, if and when approved, we will be required to build our marketing and sales capabilities with respect to such products. With the acquisition of Liquidia PAH, we acquired a sales force to market generic treprostinil in accordance with the Promotion Agreement. In addition, **during 2023,** we ~~have recently~~ significantly increased the size of our sales force in anticipation of a potential launch of YUTREPIA. ~~We~~ **However, if we experience continued delays in the approval of YUTREPIA, we may be unable to retain our sales force. Moreover, we** cannot assure you that we will be successful in further building or effectively managing our marketing and sales capabilities or be able ~~to~~ **48to** do so in a cost- effective manner. In addition, we may enter into collaboration arrangements with third parties to market our drug products. We may face significant competition for collaborators. In addition, collaboration arrangements may be time- consuming to negotiate and document. We cannot assure you that we will be able to negotiate collaborations for the marketing and sales of our drug products on acceptable terms, or at all. Even if we do enter into such collaborations, we cannot assure you that our collaborators will be successful in commercializing our products. If we or our collaborators are unable to successfully commercialize our drug products, whether in the United States or elsewhere, our business and results of operations may be materially and adversely affected. As we seek to establish a commercial operation with respect to YUTREPIA in anticipation of potential approval from the FDA, we also continue to evaluate and develop additional drug candidates, including L606. There can be no assurance that we will be able to successfully manage the balance of our research and development operations with our commercial activities. Potential investors should be aware of the problems, delays, expenses and difficulties frequently ~~43encountered~~ -- **encountered** by companies balancing development of product candidates, which can include problems such as unanticipated issues relating to clinical trials and receipt of approvals from the FDA and foreign regulatory bodies, with commercialization efforts, which include problems relating to managing manufacturing and supply, reimbursement, marketing problems, and other additional costs. There are risks involved with building and expanding our sales, marketing, and other commercialization capabilities. For example, recruiting and training a sales force is expensive and time- consuming. If the commercial launch of a drug candidate for which we recruit or have recruited 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 impact our efforts to commercialize our drug candidates on our own and generate product revenues include: ● our inability to recruit and retain adequate numbers of effective sales and marketing personnel over a large geographic area; ● the costs and time associated with the initial and ongoing training of sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions; ● understanding and training relevant personnel on the limitations on, and the transparency and reporting requirements applicable to, remuneration provided to actual and potential referral sources; ● the clinical indications for which the products are approved and the claims that we may make for the products; ● limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling; ● the inability of sales personnel to obtain access to physicians or to effectively promote any future drugs ~~; ● our ability to appropriately market, detail and distribute products in light of any healthcare provider facility closures, quarantine, travel restrictions and other governmental restrictions caused by COVID- 19~~ ; ● the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; ● any distribution and use restrictions imposed by the FDA or to which we agree; ● liability

for sales and marketing personnel who fail to comply with the applicable legal and regulatory requirements; ● our ability to maintain a healthcare compliance program including effective mechanisms for compliance monitoring; and ● unforeseen costs and expenses associated with creating a sales and marketing organization. In the future, we may choose to participate in sales activities with collaborators for some of our drug candidates. However, there are also risks with entering into these types of arrangements with third parties to perform sales, marketing and distribution services. For example, we may not be able to enter into such arrangements on terms that are favorable to us. Our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any drug candidates that we develop ourselves. In addition, we likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our drug candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our drug candidates. Further, our business, results of operations, financial condition and prospects will be materially adversely affected. ~~We~~ **49We** may be exposed to claims and may not be able to obtain or maintain adequate product liability insurance. Our business is exposed to the risk of product liability and other liability risks that are inherent in the development, manufacture, clinical testing **, commercialization** and marketing of pharmaceutical products. These risks exist even if a product is approved for commercial sale by the FDA or comparable regulatory authorities in other countries and manufactured in licensed facilities. Our current product candidates, YUTREPIA and L606, and Treprostinil Injection are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our products could result in injury to a patient or even death. ~~44Claims~~ -- **Claims** that are successfully brought against us could have a material and adverse effect on our financial condition and results of operations. Further, even if we are successful in defending claims brought against us, our reputation could suffer. Regardless of merit or eventual outcome, product liability claims may also result in, among others: ● a decreased demand for our products; ● a withdrawal or recall of our products from the market; ● a withdrawal of participants from our ongoing clinical trials; ● the distraction of our management' s attention from our core business activities to defend such claims; ● additional costs to us; and ● a loss of revenue. Our insurance may not provide adequate coverage against our potential liabilities. Furthermore, we, our collaborators or our licensees may not be able to obtain or maintain insurance on acceptable terms, or at all. **Our inability to obtain sufficient product liability insurance at an acceptable cost and / or scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with our collaborators. The market for insurance coverage is increasingly expensive, and the costs of insurance coverage will increase as our clinical programs and commercialization efforts increase in size.** In addition, our collaborators or licensees may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have sufficient assets to satisfy any product liability claims. To the extent that they are uninsured or uninsurable, claims or losses that may be suffered by us, our collaborators or our licensees may have a material and adverse effect on our **financial condition and results of operations. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources, adversely affect or eliminate the prospects for commercialization or sales of a product that is the subject of any such claim, and could have a material adverse effect on our business, financial condition, results of operations, and growth prospects. Our business and operations may be adversely affected by the effects of public health emergencies, including pandemics and epidemics. Our business and operations could be adversely affected by public health emergencies, including pandemics and epidemics, in regions where we have offices, manufacturing facilities, clinical trial sites or other business operations, and could cause significant disruption in the operations of clinical trial sites, contract manufacturers or suppliers and contract research organizations upon whom we rely. The extent to which such public health emergencies impact our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence at the time of this Annual Report on Form 10- K, such as the severity and duration of outbreaks, the duration and effect of business disruptions and the administration, availability and efficacy of vaccination programs or other treatments and the effects of any travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat any such public health emergencies. These impacts could adversely affect our business, financial condition, results of operations and growth prospects. 50In addition, to the extent any public health emergencies adversely affect our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this " Risk Factors " section and the " Risk Factors " sections of the documents incorporated by reference herein. We are currently operating in a period of global economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability. Changes and instability in global economic conditions and geopolitical matters could have a material adverse effect on our business, financial condition and results of operations. The United States and global markets are experiencing volatility and disruption, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation and interest rates, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of geopolitical conflicts, including in Russia and Ukraine, the Middle East and other areas, terrorism or other events. Sanctions and enhanced export controls imposed by the United States and other countries in response to such conflicts may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. Changes in regulations and policies by the new U. S. administration and the resulting political and economic uncertainty in the United States may also impact us, the financial markets and the global economy. For example, we procure APIs, medical devices and other raw materials from suppliers in South Korea, Taiwan, China, Italy and elsewhere. In addition, Sandoz currently procures treprostinil from a production facility in Canada. Tariffs imposed on or by one or**

more of these jurisdictions may increase our costs. The new U. S. administration may also enact other new regulations or policies that affect trade with China or otherwise impact the pharmaceutical industry by enacting laws to restrict U. S. pharmaceutical companies from contracting with Chinese companies on the development, research or manufacturing of pharmaceutical products. Any executive orders, legislative action or potential sanctions on China could materially impact our current manufacturing partners. See Item 1A. Risk Factors – We depend on third parties for clinical and commercial supplies, including single suppliers for the active ingredient, the device, encapsulation and packaging of YUTREPIA and single suppliers for the active ingredient, the device, bulk product manufacturing and packaging of L606. In addition, natural and man- made disasters and global health emergencies, including pandemics and epidemics, may also adversely affect the financial markets and the global economy and result in significant business disruption. See Item 1A. Risk Factors – Our operations are concentrated in Morrisville, North Carolina and interruptions affecting us or our suppliers due to natural or man- made disasters or other unforeseen events could materially and adversely affect our operations and result in losses that may not be covered by insurance. The volatile business environment or continued unpredictable and unstable market conditions may result in further deterioration of the equity and credit markets, significant volatility in commodity prices, as well as supply chain interruptions and result in an economic downturn, which would make any equity or debt financing more difficult, costly and dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, limit, reduce, or terminate our product development or future commercialization efforts. Although our business has not been materially impacted by the adverse effects of geopolitical events, natural or man- made disasters or other business disruptions to date, such matters may affect our business in the future and it is impossible to predict the extent to which our operations, or those of our suppliers and manufacturers, will be impacted in the short and long term, or the ways in which such matters may impact our business. The extent and duration of such adverse geopolitical events, natural or man- made disasters or other business disruptions and actual or perceived political or economic instability and resulting market disruptions are impossible to predict but could be substantial. Any such disruptions may also magnify the impact of other risks described herein. 51The political and economic environment in the United States could materially impact our business operations and financial performance, and uncertainty surrounding the potential legal, regulatory and policy changes by a new U. S. presidential administration may directly affect us and the global economy. The political and economic environment in the United States and elsewhere has resulted in and will continue to result in some uncertainty. Changing regulatory policies because of the changing political environment could impact our regulatory and compliance costs and future revenues, all of which could materially and adversely affect our business, financial condition and operating results. Failure to adapt to or comply with evolving regulatory requirements or investor or stakeholder expectations and standards could negatively impact our reputation, ability to do business with certain partners, access to capital and our stock price. Further, the new U. S. administration and recent congressional seat turnover may result in increased regulatory and economic uncertainty. Changes in federal policy by the executive branch and regulatory agencies may occur over time through the new presidential administration' s and / or Congress' s policy and personnel changes, which could lead to changes involving the level of oversight and focus on the pharmaceutical industry; however, the nature, timing and economic and political effects of such potential changes remain highly uncertain. Any future changes in federal and state laws and regulations, as well as the interpretation and implementation of such laws and regulations, could affect us in substantial and unpredictable ways. At this time, it is unclear what laws, regulations and policies may change and whether future changes or uncertainty surrounding future changes will adversely affect our operating environment and therefore our business, financial condition and results of operations. Risks Related to the Development and Regulatory Approval of our Product CandidatesWe are primarily dependent on the success of our product candidate, YUTREPIA, for which we received tentative approval from the FDA, and this product candidate may fail to receive final marketing approval (in a timely manner or at all) **, may fail to receive approval for one or more indications for which we have sought approval** or may not be commercialized successfully. We do not have any products approved for marketing in any jurisdiction and we have never generated any revenue from sales of our own products. Our ability to generate revenue from sales of our own products and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, one or more of our product candidates. We expect that a substantial portion of our efforts and expenditure over the next few years will be devoted to our product candidate, YUTREPIA, a proprietary inhaled dry powder formulation of treprostinil for the treatment of PAH and PH- ILD, and L606, a nebulized, liposomal formulation of treprostinil for treatment of PAH and PH- ILD. We received tentative approval of our NDA for YUTREPIA for the treatment of PAH **and PH- ILD** in ~~November~~ **August** ~~2021~~ **2024** . ~~However~~ **The final approval of YUTREPIA for PAH and PH- ILD is delayed until after expiration of the three- year New Clinical Investigation exclusivity for Tyvaso DPI on May 23** , **2025. Although the exclusivity period will expire on such date, the FDA may need more time after the expiration of the exclusivity period to review and approve** our **NDA. Our** receipt of tentative approval does not mean that we will receive final approval of our NDA for YUTREPIA in a timely manner or at all or that we will receive **final** approval for ~~other~~ **both** indications ~~, such~~ **. United Therapeutics** ~~as~~ **has** ~~PH- ILD.~~ **invested considerable time and resources in an effort to block final approval of YUTREPIA, and** ~~Expectations~~ **expectations** related to final FDA approval and projected product launch timelines are impacted by ongoing litigation following lawsuits filed by United Therapeutics. **For instance** ~~Judge Andrews issued an order in the Original Hatch- Waxman Litigation enjoining the FDA from issuing a final approval for the YUTREPIA NDA until the expiration of the ' 793 Patent in 2027. In December 2023~~ , ~~the United States Court of Appeals for the Federal Circuit affirmed the earlier decision by the PTAB, which found all claims of the ' 793 Patent to be unpatentable due to the existence of prior art cited by us~~ in ~~inter partes review~~

~~proceedings. Although the PTAB' s decision has now been affirmed on appeal, Judge Andrews may need to lift his injunction before we are able to obtain final FDA approval for YUTREPIA. In December 2023, we filed a motion with Judge Andrews to set aside his injunction as a result of the decision by the United States Court of Appeals for the Federal Circuit. However, there are no assurances whether and when Judge Andrews would do so. In~~ connection with an amendment to our NDA filed on July 24, 2023 to add PH- ILD as an indication for YUTREPIA, we provided a new notice of the paragraph IV certification to United Therapeutics as the owner of the patents that are the subject of the certification to which the NDA for YUTREPIA refers. As a result, in September 2023, United Therapeutics filed the New Hatch- Waxman Litigation, again asserting infringement by the Company of **U. S. Patent No. 10, 716, 793, entitled " Treprostinil Administration by Inhalation " (** the **"** ' 793 Patent **")** , which lawsuit was amended on November 30, 2023, to add claims asserting infringement of the ' 327 Patent. Although the claims related to the ' 793 Patent were subsequently withdrawn **, in February 2024, United Therapeutics also filed a motion seeking a preliminary injunction to prevent us from manufacturing, marketing, storing, importing, distributing, offering for sale,** and **/ or selling YUTREPIA for the treatment of PH- ILD. That motion for preliminary injunction was denied, but United Therapeutics may still seek injunctive relief in the future. In September 2024, United Therapeutics also filed a cross 52claim in the New FDA Litigation, seeking to enjoin the FDA from approving our NDA for YUTREPIA with respect to the indication to treat PH- ILD. Although** we do not believe United Therapeutics is entitled to **any** ~~a new 30- month stay or preliminary~~ injunction **or temporary restraining order** in ~~connection with~~ the New Hatch- Waxman Litigation **or the New FDA Litigation** , it is possible that the Court could rule that ~~a new mandatory 30- month delay has been triggered with respect to the approval of the 505 (b) (2) NDA application or that we are enjoined from launching YUTREPIA for the treatment of PH- ILD. In February 2024, United Therapeutics also commenced the FDA Litigation, seeking to enjoin the FDA from approving our NDA for YUTREPIA with respect 45to the indication to treat PH- ILD. Although we do not believe United Therapeutics is entitled to any injunction or temporary restraining order in the FDA Litigation, it is possible that the Court could rule that~~ the FDA must reject the amendment to the YUTREPIA NDA to add PH- ILD to the label ~~, in which case we may be required to later file a supplement to our~~ **or** ~~NDA to add~~ **that, even if YUTREPIA has launched for both PAH and** PH- ILD ~~to~~ **, the Company must remove PH- ILD from** the label **for YUTREPIA** . In addition, a drug product that is granted tentative approval, like YUTREPIA, may be subject to additional review before final approval, particularly if tentative approval was granted more than three years before the earliest lawful approval date. The FDA' s tentative approval of YUTREPIA for the treatment of PAH **and PH- ILD** was based on information available to FDA at the time of the tentative approval letter (i. e., information in the application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to FDA' s attention. ~~In addition, the FDA has not yet issued any approval for YUTREPIA for the treatment of PH- ILD, which remains under review.~~ A new drug product may not be marketed until the date of final approval. Expectations for YUTREPIA and / or L606 also may be impacted by competing products, including Tyvaso ® DPI. See Item 1A. Risk Factors ~~- —~~ We face significant competition from large pharmaceutical companies, among others, in developing our products and in gaining regulatory approval to bring them to market in time to achieve commercial success, and our operating results will suffer if we are unable to compete effectively. We cannot assure you that we will receive final marketing approval for YUTREPIA or L606 or, even if we do receive final marketing approval, the indications for which they will be approved. The FDA or comparable regulatory authorities in other countries may delay, limit or deny final approval of our product candidate for various reasons. For example, such authorities may disagree with the design, scope or implementation of our clinical trials, or with our interpretation of data from our preclinical studies or clinical trials. Further, there are numerous FDA personnel assigned to review different aspects of an NDA ~~,~~ and **there may be turnover and / or vacancies at the FDA, which may delay review of our NDA. In addition,** uncertainties can be presented by ~~their~~ -- **the** ability **of FDA personnel, including any new FDA personnel who have not previously reviewed our NDA,** to exercise judgment and discretion during the review process. During the course of review prior to final approval, the FDA may request or require additional preclinical, clinical, ~~chemistry, manufacturing, and control (~~ CMC ~~)~~ or other data and information or conduct additional inspections. If any additional issues were identified in such information requests or inspections **or if FDA determines that we failed to include required CMC information in the NDA for our products, including YUTREPIA** , we may be delayed in obtaining final approval or may be unable to obtain final approval. Furthermore, responses to FDA' s requests may be time- consuming and expensive. Status as a combination product, as is the case for YUTREPIA and L606, may complicate or delay the FDA review process. Product candidates that the FDA deems to be combination products, such as YUTREPIA and L606, or that otherwise rely on innovative drug delivery systems, may face additional challenges, risks and delays in the product development and regulatory approval process. Additionally, the FDA could delay approval of YUTREPIA and / or L606 even if approvable after completing its review. For example, ~~if~~ **Tyvaso DPI was granted regulatory exclusivity that will delay final approval of YUTREPIA until after the exclusivity expires in May 2025. If** a competing product comprised of an inhaled dry- powder formulation of treprostinil, such as Tyvaso DPI, is granted **additional** regulatory exclusivity, that could delay the final approval of YUTREPIA until said exclusivity expires. Moreover, the applicable requirements for approval may differ from country to country **. It is also possible that recent decisions by the United States Supreme Court, eliminating court deference to decisions by administrative agencies, may delay any final decisions from the FDA as it considers how to implement this new ruling into its decision- making process** . If we successfully obtain marketing approvals for YUTREPIA and / or L606, we cannot assure you that they will be commercialized in a timely manner or successfully, or at all. For example, **even if such products are approved by the FDA,** they may not achieve a sufficient level of market acceptance **or third- party payor coverage** , or we may not be able to effectively build our marketing and sales capabilities or scale our manufacturing operations to meet commercial demand. The successful commercialization of YUTREPIA and L606 will also, in part, depend on factors that are beyond our control. Therefore, we may not generate significant revenue from the sale of such products, even if approved. Any delay or setback we

face in the commercialization of YUTREPIA and / or L606 may have a material and adverse effect on our business and prospects, which will adversely affect your investment in our company. ~~Our~~ **53Our** preclinical studies and clinical trials may not be successful and delays in such preclinical studies or clinical trials may cause our costs to increase and significantly impair our ability to commercialize our product candidates. Results of previous clinical trials or interim results of ongoing clinical trials may not be predictive of future results. Before we are able to commercialize our drug products, we are required to undertake extensive preclinical studies and clinical trials to demonstrate that our drug products are safe and effective for their intended uses. However, we cannot assure you that our drug products will, in preclinical studies and clinical trials, demonstrate safety and efficacy as ~~46necessary~~ -- **necessary** to obtain marketing approval. Due to the nature of drug product development, many product candidates, especially those in early stages of development, may be terminated during development. Although we believe we have completed clinical development for YUTREPIA **and believe we have completed preclinical development of L606** , we have not yet obtained final approval for or commercialized any of our own product candidates and as a result do not have a track record of successfully bringing our own product candidates to market. Furthermore, YUTREPIA and L606 have, to date, been tested only in relatively small study populations and, accordingly, the results from our earlier clinical trials may be less reliable than results achieved in larger clinical trials, if required. Additionally, the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and preliminary and interim results of a clinical trial do not necessarily predict final results. Preclinical studies and clinical trials may fail due to factors such as flaws in trial design, dose selection and patient enrollment criteria. The results of preclinical studies and early clinical trials may not be indicative of the results of subsequent clinical trials. Product candidates may, in later stages of clinical testing, fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and earlier clinical trials. Moreover, there may be significant variability in safety or efficacy results between different trials of the same product candidate due to factors including, but not limited to, changes in trial protocols, differences in the composition of the patient population, adherence to the dosing regimen and other trial protocols and amendments to protocols and the rate of drop- out among patients in a clinical trial. If our preclinical studies or clinical trials are not successful and we are unable to bring our product candidates to market as a result, our business and prospects may be materially and adversely affected. Furthermore, conducting preclinical studies and clinical trials is a costly and time- consuming process. The length of time required to **prepare for and** conduct the required studies and trials may vary substantially according to the type, complexity, novelty and intended use of the product candidate. A single clinical trial may take up to several years to complete. Moreover, our preclinical studies and clinical trials may be delayed or halted due to various factors, including, among others: ● delays in raising the funding necessary to initiate or continue a clinical trial; ● delays in manufacturing sufficient quantities of product candidates for clinical trials **; ● delays in obtaining suitable medical devices for the conduct of a clinical trial** ; ● delays in reaching agreement on acceptable terms with prospective contract research organizations (**“** CROs **”**) and clinical trial sites; ● delays in obtaining ~~institutional review board approval~~ **approvals from IRBs, DSMBs, and ECs** at clinical trial sites; ● delays in recruiting suitable patients to participate in a clinical trial; ● delays in patients’ completion of clinical trials or their post- treatment follow- up; ● regulatory authorities’ interpretation of our preclinical and clinical data; **● delays in regulatory authorities’ review and approval of products caused by government funding shortages, government shutdowns, government personnel shortages, global health emergencies or other disruptions;** and ● unforeseen safety issues, including a high and unacceptable severity, or prevalence, of undesirable side effects or adverse events caused by our product candidates or similar drug products or product candidates. If our preclinical studies or clinical trials are delayed, the commercialization of our product candidates will be delayed and, as a result, we may incur substantial additional costs or not be able to recoup our investment in the development of our product candidates, which would have a material and adverse effect on our business. ~~Clinical~~ **54Clinical** trials and data analysis can be expensive, time-consuming and difficult to design and implement. If we are unsuccessful in obtaining regulatory approval for our products, or any required clinical studies of our products do not provide positive results, we may be required to delay or abandon development of such products, which would have a material adverse impact on our business. Continuing product development requires additional and extensive clinical testing. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time- consuming. We cannot provide any assurance or certainty regarding when we might receive regulatory approval for our products, including YUTREPIA and L606. Furthermore, failure can occur at any stage of the process, and we could encounter problems that cause us to abandon an NDA filed with the FDA or ~~47repeat~~ -- **repeat** clinical trials. The commencement and completion of clinical trials for any current or future development product candidate may be delayed by several factors, including: ● unforeseen safety issues; ● determination of dosing issues; ● lack of effectiveness during clinical trials; ● slower than expected rates of patient recruitment; ● inability to monitor patients adequately during or after treatment; and ● inability or unwillingness of medical investigators to follow our clinical protocols or amendments to our protocols. In addition, the FDA or ~~an independent IRB~~ **IRBs , DSMBs, or ECs** may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submissions or the conduct of these trials. Therefore, we cannot provide any assurance or predict with certainty the schedule for future clinical trials. Although clinical data is an essential part of NDA filings, NDAs must also contain a range of additional data including CMC data to meet FDA standards for approval. In the event we do not ultimately receive final regulatory approval for YUTREPIA and / or L606, we may be required to terminate development of these product candidates. The marketing approval processes of the FDA and comparable regulatory authorities in other countries are unpredictable and our product candidates may be subject to multiple rounds of review or may not receive marketing approval. Pursuing marketing approval for a pharmaceutical product candidate (for example, through the NDA process) is an extensive, lengthy, expensive and inherently uncertain process. We cannot assure you that any of our product candidates will receive marketing approval. Regulatory authorities may delay, limit or deny approval of our product candidates for many reasons, including, but not limited to, the following: ● the FDA or comparable regulatory authorities may, for a variety

of reasons, take the view that the data collected from our preclinical and clinical trials and human factors testing, or data that we otherwise submit or reference to support an application, are not sufficient to support approval of a product candidate; ● the FDA or comparable regulatory authorities in other countries may ultimately conclude that our manufacturing processes or facilities or those of our third- party manufacturers do not sufficiently demonstrate compliance with cGMP to support approval of a product candidate, ~~or~~ that the drug CMC data or device biocompatibility data for our product candidates otherwise do not support approval **or that additional CMC data or information for our product candidates must be submitted for review** ; ● we may be unable to demonstrate to the satisfaction of the FDA or comparable regulatory authorities in other countries that our product candidate is safe and effective for its proposed indication, or that its clinical and other benefits outweigh its safety risks; ● the approval policies of the FDA or comparable regulatory authorities in other countries may change in a manner that renders our data insufficient for approval. ~~Even~~ **55Even** if we obtain marketing approval, the FDA or comparable regulatory authorities in other countries may approve our product candidates for fewer or more limited indications than those for which we requested approval or may include safety warnings or other restrictions that may negatively impact the commercial viability of our product candidates. Likewise, regulatory authorities may grant approval contingent on the performance of costly post- marketing clinical trials or other studies or the conduct of an expensive risk evaluation and mitigation strategies, or REMS, which could significantly reduce the potential for commercial success or viability of our product candidates. We also may not be able to find acceptable collaborators to manufacture our drug products, if and when approved, in commercial quantities and at acceptable prices, or at all. ~~48We~~ **We** may encounter difficulties in enrolling patients in our clinical trials. We may not be able to commence or complete 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. Patient enrollment may be affected by **a variety of factors, including** , among others: ● the severity of the disease under investigation; ● the design of the clinical trial protocol and amendments to a protocol; ● the size and nature of the patient population; ● eligibility criteria for the clinical trial in question; ● the perceived risks and benefits of the product candidate under clinical testing, including a high and unacceptable severity, or prevalence, of undesirable side effects or adverse events caused by our product candidates or similar products or product candidates; ● the existing body of safety and efficacy data in respect of the product candidate under clinical testing; ● the proximity of patients to clinical trial sites; ● the number and nature of competing therapies and clinical trials; and ● other environmental factors such as ~~the ongoing COVID~~ **natural and man - made** ~~19 pandemic or other natural or unforeseen~~ disasters **and global health emergencies, such as pandemics and epidemics** . Any negative results we may report in clinical trials of our product candidates may also make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. We expect that if we initiate, as we are currently contemplating, a clinical trial of YUTREPIA in pediatric patients, we may encounter difficulties enrolling patients in such a trial because of the limited number of pediatric patients with this disease. Furthermore, we are aware of a number of therapies for PAH that are being developed or that are already available on the market, and we expect to face competition from these investigational drugs or approved drugs for potential subjects in our clinical trials, including planned clinical trials for YUTREPIA and L606, which may delay enrollment in our planned clinical trials. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays, or both. We may, as a result of such delays or failures, be unable to carry out our clinical trials as planned or within the timeframe that we expect or at all, and our business and prospects may be materially and adversely affected as a result. Product candidates that the FDA deems to be combination products, such as YUTREPIA and L606, or that otherwise rely on innovative drug delivery systems, may face additional challenges, risks and delays in the product development and regulatory approval process. The FDA has indicated that it considers YUTREPIA, which is delivered by a DPI, and L606, which is delivered by a next generation nebulizer, to be drug-device combination products **, with the primary mode of action determined to be a drug** . Accordingly, the medical devices used to administer the products were, or in the case of L606 will be, evaluated as part of our NDA filing. When evaluating products that utilize a specific drug delivery system or device, the FDA will evaluate the characteristics of that delivery system and its functionality, as well as the potential for undesirable interactions between the drug and the delivery system, including the potential to negatively impact the safety or ~~effectiveness~~ **56effectiveness** of the drug. The FDA review process can be more complicated for combination products, and may result in delays, particularly if novel delivery systems are involved. We rely on third parties for the design and manufacture of the delivery systems for our products, including the DPI for YUTREPIA and the nebulizer for L606, and in some cases for the right to refer to their data on file with the FDA or other regulators. Quality or design concerns with the delivery system, or commercial disputes with these third parties, could delay or prevent regulatory approval and commercialization of our product candidates. ~~49We~~ **We** are pursuing the FDA 505 (b) (2) pathway for our current product candidates. If we are unable to rely on the 505 (b) (2) regulatory pathway to apply for marketing approval of our product candidates in the United States, seeking approval of these product candidates through the 505 (b) (1) NDA pathway would require full reports of investigations of safety and effectiveness, and the process of obtaining marketing approval for our product candidates would likely be significantly longer and more costly. We are currently focused on developing drug products that can be approved under abbreviated regulatory pathways in the United States, such as the 505 (b) (2) regulatory pathway, which permits the filing of an NDA where at least some of the information required for approval comes from studies 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 for a particular product candidate, 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 compounds, which could expedite the development program for a product candidate by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. We have pursued this pathway for our current product candidate, YUTREPIA, and are pursuing this pathway for L606. Even if the FDA allows us to rely on the 505 (b) (2) regulatory pathway for a given product candidate, we cannot assure you that marketing approval will be obtained in a timely manner, or at all. The FDA may require us to perform additional clinical trials to support any change from the reference listed drug, which could be time-

consuming and substantially delay our receipt of marketing approval. Also, as has been the experience of others in our industry, our competitors may file ~~citizens~~ **citizen** ' petitions or other correspondence with **the FDA or lawsuits against** the FDA to contest approval of our NDA, which may delay or even prevent the FDA from approving any NDA that we submit under the 505 (b) (2) regulatory pathway **. For instance, United Therapeutics has a lawsuit against the FDA and previously filed a citizen petition in an attempt to prevent or delay the approval of YUTREPIA** . If an FDA decision or action relative to our product candidate, or the FDA' s interpretation of Section 505 (b) (2) more generally, is successfully challenged, it could result in delays or even prevent the FDA from approving a 505 (b) (2) application for our product candidates **or for certain indications for our product candidates** . Even if we are able to utilize the 505 (b) (2) regulatory pathway **, the approval of a drug developed under the 505 (b) (2) regulatory pathway may be delayed by one or more regulatory exclusivities. For example, Tyvaso DPI was recently granted New Clinical Investigation exclusivity, which has delayed final approval of YUTREPIA until after the exclusivity expires in May 2025. Also** , a drug approved via this pathway may be subject to the same post- approval limitations, conditions and requirements as any other drug. In addition, we may face Hatch- Waxman litigation in relation to our NDAs submitted under the 505 (b) (2) regulatory pathway, which may further delay or prevent the approval of our product candidates. The pharmaceutical industry is highly competitive, and 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 505 (b) (2) NDA. If the previously approved drugs referenced in an applicant' s 505 (b) (2) NDA are protected by patent (s) listed in the Orange Book, the 505 (b) (2) applicant is required to make a claim after filing its NDA or certain types of amendments to its NDA that each such patent is invalid, unenforceable or will not be infringed. The patent holder may thereafter bring suit for patent infringement, which will trigger a mandatory 30- month delay (or the shorter of dismissal of the lawsuit or expiration of the patent (s)) in approval of the 505 (b) (2) NDA application. In addition, in the event the court in any such lawsuit finds that any claims of any of the asserted patents are both valid and infringed, the court would likely issue an injunction prohibiting approval of the product at issue until the expiration of the patent (s) found to have been infringed. For example, the YUTREPIA NDA was filed under the 505 (b) (2) regulatory pathway with Tyvaso as the reference listed drug. Under the Hatch- Waxman Act, as a result of the litigation commenced by United Therapeutics in June 2020, the FDA was automatically precluded from approving the YUTREPIA NDA for up to 30 months. **Also** ~~In August 2022 , prior to the expiration of the 30- month stay, the Court found that the asserted claims of one of the patents, the ' 793 Patent, were both valid and infringed by the Company and ordered that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the ' 793 Patent. In December 2023, the United States Court of Appeals for the Federal Circuit affirmed the earlier decision by the PTAB, which found all claims of the ' 793 Patent to be unpatentable due to the existence of prior art cited by us~~ in ~~inter partes review proceedings. As a result of this decision by the United States Court of Appeals for the Federal Circuit, we have filed a motion with Judge Andrews seeking to set aside his injunction blocking final regulatory approval of YUTREPIA by the FDA. However, there are no assurances whether and when Judge Andrews would do so. In~~ connection with an amendment to our NDA filed in July 2023 to add PH- ILD as an indication for YUTREPIA, we provided a new notice ~~of~~ **57of** the paragraph IV certification to United Therapeutics as the owner of the patents that are the subject of the certification to which the NDA for YUTREPIA refers. As a result, in September 2023, United Therapeutics filed the New Hatch- Waxman Litigation, again asserting infringement by the Company of the ' 793 Patent, ~~50which~~ -- **which** lawsuit was amended on November 30, 2023, to add claims asserting infringement of the ' 327 Patent. **In February 2024,** ~~Although the claims related to the ' 793 Patent were subsequently withdrawn and we do not believe~~ United Therapeutics **filed** ~~is entitled to~~ a ~~new 30~~ **motion seeking a preliminary injunction to prevent us from manufacturing, marketing, storing, importing, distributing, offering for sale, and / or selling YUTREPIA for the treatment of PH** ~~month stay in connection with~~ **ILD. Although the motion for preliminary injunction was denied, United Therapeutics may still seek injunctive relief and** ~~the~~ **other remedies** ~~New Hatch- Waxman Litigation, it is possible that the Court could rule that a new mandatory 30- month delay has been triggered with respect to the approval of the 505 (b) (2) NDA application~~ . In addition, United Therapeutics may seek to assert newly issued patents against us, including U. S. Patent Number 11, 723, 887, and may seek to enjoin the FDA from granting final approval to YUTREPIA or enjoin us from launching YUTREPIA. It is also not uncommon for a manufacturer of an approved product, such as United Therapeutics, to file a citizen petition or other correspondence with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products or to take other actions, such as engaging in litigation with the FDA to enjoin approval of a competing product. If successful, such petitions, correspondence or litigation can significantly delay, or even prevent, the approval of the new product. For example, United Therapeutics is currently pursuing litigation under the Administrative Procedures Act, seeking to require the FDA to reject our amendment to the YUTREPIA NDA to add PH- ILD to the label. Even if the FDA ultimately ~~denies~~ **prevails in** such ~~a petition or the actions requested in such correspondence and prevails in any related~~ litigation, the FDA may substantially delay approval while it ~~considers and responds to the petition or correspondence and~~ is engaged in litigation or the FDA may be temporarily enjoined by a court from granting approval until the court has ruled on United Therapeutics' ~~requests~~ - **request** . If the FDA determines that any of our product candidates do not qualify for the 505 (b) (2) regulatory pathway, we would need to reconsider our plans and might not be able to commercialize our product candidates in a cost- efficient manner, or at all. If we were to pursue approval under the 505 (b) (1) NDA pathway, we would be subject to more extensive requirements and risks such as conducting additional clinical trials, providing additional data and information or meeting additional standards for marketing approval. As a result, the time and financial resources required to obtain marketing approval for our product candidates would likely increase substantially and further complications and risks associated with our product candidates may arise. Also, new competing products may reach the market faster than ours, which may materially and adversely affect our competitive position, business and prospects. We may be unable to continually develop a pipeline of product candidates, which could affect our business and prospects. A key element of our long- term strategy is to continually develop a pipeline of product candidates by developing products for the treatment of

pulmonary hypertension and proprietary innovations to ~~FDA- approved~~ drug products using our PRINT technology. If we are unable to identify suitable product candidates for the treatment of pulmonary hypertension or off- patent drug products for which we can develop proprietary innovations using our PRINT technology or are otherwise unable to expand our product candidate pipeline, whether through licensed or co- development opportunities, and obtain marketing approval for such product candidates within the timeframes that we anticipate, or at all, our business and prospects may be materially and adversely affected **. Disruptions at the FDA, the SEC and other government agencies caused by funding shortages, government shutdowns or global health emergencies or their inability to hire, retain or deploy key leadership and other personnel, could prevent new or modified products from being developed, approved or commercialized in a timely manner or at all or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our operations. The ability of the FDA and other government agencies to review and approve new or modified products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, a government agency' s ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency' s ability to perform routine functions. Average review times at the FDA and other government agencies have fluctuated in recent years as a result. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and SEC, have had to 58furlough critical employees and stop critical activities. In addition, government funding of agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Such disruptions at the FDA and other agencies may also increase the time necessary for new drugs or modifications to approved drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. If prolonged government shutdowns, inadequate funding, loss of employees (including those employees who were previously involved in the review of the NDA for YUTREPIA), changes in regulations or policies by the new U. S. administration or other disruptions were to occur at the FDA, a final FDA decision with respect to the NDA for YUTREPIA for PAH and PH-ILD may be further delayed even after Tyvaso DPI' s New Clinical Investigation exclusivity expires on May 23, 2025** . We have conducted, and may in the future conduct, clinical trials for our product candidates outside the United States and the FDA may not accept data from such trials. Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for our product candidates, if not conducted under an IND, this is subject to certain conditions set out in 21 C. F. R. § 312. 120. For example, **we plan to conduct our Phase 3 pivotal clinical trial for L606** in **multiple sites in China and we plan to use such data to support our NDA in the United States for the approval of L606. In** order for the FDA to accept data from ~~such~~ a foreign clinical trial, the study must have been conducted in accordance with ~~Good Clinical Practice (~~ GCP ~~)~~ including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. The FDA must also be able to validate the data from the study through an onsite inspection if the agency deems it necessary. In addition, foreign clinical data submitted to support FDA applications should be applicable to the U. S. population and U. S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country. ~~51Risks~~ **Even if we obtain regulatory approval for a product candidate, our products and business will remain subject to ongoing regulatory obligations and review. If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, drug supply chain security surveillance and tracking, advertising, promotion, sampling, record- keeping, conduct of post- marketing studies and submission of safety, efficacy and other post- market information, including both federal and state requirements in the United States and comparable requirements outside of the United States. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Any regulatory approvals that we may receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our product candidates, 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 minimization tools. We will also be required to report certain adverse reactions and production problems, if any, to the FDA or other regulatory agencies and to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product' s approved label. As such, we may not promote our products for indications or uses for which they do not have FDA or other regulatory agency approval. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post- marketing clinical studies to verify the safety and efficacy of our product candidates in general or in specific patient subsets. An unsuccessful post- marketing study or failure to complete such a clinical study could result in the withdrawal of marketing approval. Furthermore, any new legislation addressing drug safety issues could result in delays in product development or commercialization or increased costs to assure compliance. Foreign regulatory authorities impose similar requirements. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, 59including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or**

enforcement authority may, among other things: ● issue warning letters asserting that we are in violation of the law; ● seek an injunction or impose civil or criminal penalties or monetary fines; ● suspend or withdraw regulatory approval; ● suspend any of our ongoing clinical trials; ● refuse to approve pending applications or supplements to approved applications submitted by us or our strategic partners; ● restrict the marketing or manufacturing of our products; ● seize or detain products, or require a product recall; ● refuse to permit the import or export of our product candidates; or ● refuse to allow us to enter into government contracts. 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 revenue from our product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. 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. 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 and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. Even if we obtain marketing approval for our product candidates in the United States, we or our collaborators may not obtain marketing approval for the same product candidates elsewhere. We may enter into strategic collaboration arrangements with third parties to commercialize our product candidates outside of the United States. In order to market any product candidate outside of the United States, we or our collaborators will be required to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be recognized or accepted by regulatory authorities in other countries, and obtaining marketing approval in one country does not mean that marketing approval will be obtained in any other country. Approval processes vary among countries and additional product testing and validation, or additional administrative review periods, may be required from one country to the next. Seeking marketing approval in countries other than the United States could be costly and time-consuming, especially if additional preclinical studies or clinical trials are required to be conducted. We currently do not have any product candidates approved for sale in any jurisdiction, including non- U. S. markets, and we do not have experience in obtaining marketing approval in non- U. S. markets. We currently also have not identified any collaborators to market our products outside of the United States and cannot assure you that such collaborators, even if identified, will be able to successfully obtain marketing approval for our product candidates outside of the United States. If we or our collaborators fail to obtain marketing approval in non- U. S. markets, or if such approval is delayed, our target market may be reduced, and our ability to realize the full market potential of our products will be adversely affected. 60Risks Related to Government RegulationThe pharmaceutical industry is subject to a range of laws and regulations in areas including healthcare program requirements and fraud, waste, and abuse; healthcare and related marketing compliance and transparency; and privacy and data security. Our failure to comply with these laws and regulations as they are, or in the future become, applicable to us may have an adverse effect on our business. Healthcare providers, physicians and third- party payors often play a primary role in the recommendation and prescription of any drug products for which we may obtain marketing approval, or for which we may provide contracted promotional services to third parties. Our current and future arrangements with healthcare providers, physicians, third- party payors and customers, and our sales, marketing and educational activities, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations (at the federal and state level) that may constrain our business or financial arrangements and relationships through which we market, sell, or distribute drug products. In addition, we may be subject to transparency laws and patient privacy regulation by both the federal government and the states in which we conduct our business. We also plan to conduct clinical trials and may in the future conduct business in jurisdictions outside of the United States, which may cause us to become subject to transparency law and privacy regulations in those jurisdictions as well. The laws that may affect our ability to operate include, but are not limited to, the following examples: ● The federal Anti- Kickback Statute (“ AKS ”) prohibits, among other things, persons and entities including pharmaceutical manufacturers from, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, 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, or order of, or the arranging for an item or service for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, they are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending or arranging for the prescription or purchase of any drug product may be subject to scrutiny if they do not qualify for an exception or safe harbor. This law applies to our marketing practices, educational programs, pricing policies and relationships with healthcare providers. We continue to evaluate what effect, if any, these rules will have on our business. ● The federal civil and criminal false claims laws and civil monetary penalty laws impose a range of prohibitions and compliance considerations. For example, the False Claims Act (“ FCA ”) prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to, or approval by, the federal government that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. Claims resulting from a violation of the federal AKS or the FDCA constitute a false or

fraudulent claim for purposes of the FCA. Promotion that is deemed to be " off label " can also be the basis of FCA exposure. ● Federal law includes provisions established under the Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (" HITECH ") and its implementing regulations addressing healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Violations of these statutes is a felony and may result in fines, imprisonment or exclusion from governmental programs. Similar to the federal AKS, 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. 61 ● Privacy and data security laws may apply to our business. Under Section 5 (a) of the Federal Trade Commission Act, the Federal Trade Commission expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. States may also impose requirements, for example the California Consumer Privacy Act created data privacy obligations for covered companies and providing privacy rights to California residents, including the right to opt out of certain disclosures of their information. In addition, if we engage in business activities outside of the United States, including clinical trials that we plan to conduct outside of the United States, we may become subject to privacy and data security laws in those additional jurisdictions in which we operate or conduct clinical trials. HIPAA, as amended by HITECH and its implementing regulations, also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH created new tiers of civil monetary penalties, made civil and criminal penalties directly applicable to business associates, and gave state attorneys authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA laws and seek attorneys' fees and costs. While we are not currently a covered entity or a business associate under HIPAA, our future operations could subject us to HIPAA as a business associate or covered entity, depending on the scope of such operations. ● The federal physician payment transparency requirements, sometimes referred to as the " Physician Payments Sunshine Act, " requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under government healthcare programs to annually report to the Centers for Medicare and Medicaid Services (" CMS ") information related to certain payments or other transfers of value made or distributed to physicians, certain non-physician practitioners and teaching hospitals, as well as ownership and investment interests held by such healthcare professionals and their immediate family members. ● For both investigational and commercialized products, interactions with or communications directed to healthcare professionals, patients or patient- or disease- advocates or advocacy groups, and payors, are subject to heightened scrutiny by the FDA. Relative to nonpromotional communications, for example, there are specific and limited FDA accommodations for nonpromotional, truthful and non- misleading sharing of information regarding products in development and off- label uses including dissemination of peer- reviewed reprints, support of independent continuing medical education, and healthcare economic discussions with payors. In a competitive environment, a company' s communications about products in development may also be subject to heightened scrutiny. ● Analogous state laws and regulations, such as state anti- kickback and false claims laws, may apply to items or services reimbursed by any third- party payor, including commercial insurers, and in some cases may apply regardless of payor (i. e., even for self- pay scenarios). Some state laws require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report pricing and marketing information, including, among other things, information related to payments to physicians and other healthcare providers or marketing expenditures, state and local laws that require the registration of pharmaceutical sales representatives. Many of these state laws differ from each other in significant ways and may not have the same effect, and may apply more broadly or be stricter than their federal counterparts, thus complicating compliance efforts; and ● Price reporting laws require the calculation and reporting of complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursements or discounts on our drug products. Participation in such programs and compliance with their requirements may subject us to increased infrastructure costs and potentially limit our ability to price our drug products. 62Ensuring that our business and business arrangements with third parties comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource- consuming and can divert management' s attention from the business, even if the government ultimately finds that no violation has occurred. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. A government investigation, regardless of its outcome, could impact our business practices, harm our reputation, divert attention of management, increase our expenses and reduce availability of assistance to patients. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual

damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time- consuming and may require significant financial and 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. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws or regulations, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government- funded healthcare programs. Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations involves substantial costs. The compliance and enforcement landscape, and related risk, is informed by government enforcement precedent and settlement history, Office of Inspector General advisory opinions, and special fraud alerts. Our approach to compliance may evolve over time in light of these types of developments. Additionally, the potential safe harbors available under the federal AKS are subject to change through legislative and regulatory action, and we may decide to adjust our business practices or be subject to heightened scrutiny as a result. If our operations, including activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government- funded healthcare programs, such as Medicare and Medicaid, qui tam actions brought by individual whistleblowers in the name of the government, and the curtailment or restructuring of our operations. Recently enacted and future legislation and other legal developments may increase the difficulty and cost for us to obtain marketing approval of and commercialize our products and product candidates and affect the prices we may obtain. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In the United States, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the " ACA "), is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our product candidates are the following: ● establishment of a new pathway for approval of lower- cost biosimilars to compete with biologic products; ● an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents; ● an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; 63 ● a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point- of- sale discounts off negotiated prices, now reformed as a result of the IRA; ● expansion of manufacturers' Medicaid rebate liability; and ● expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. The ACA marketplace subsidies are set to expire in 2025, and without an extension, premiums will increase for the millions of enrollees. We cannot project the implications or if the subsidies will be renewed. Further, in March 2021, the American Rescue Plan Act of 2021 was signed into law, which, among other things, eliminated the statutory cap on drug manufacturers' Medicaid Drug Rebate Program rebate liability, effective January 1, 2024, removing the 100 % cap that was established in the ACA. In addition, on September 20, 2024, the Centers for Medicare & Medicaid Services issued a final rule titled " Medicaid Program; Misclassification of Drugs, Program Integrity Updates Under the Medicaid Drug Rebate Program " which may impact our reimbursement and rebate strategy. We expect that other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to price our products at what we consider to be a fair or competitive price, generate revenue, attain profitability, or commercialize our product candidates, if approved. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Individual states in the United States have become increasingly active in implementing regulations designed to contain pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Most significantly, the IRA, among other things, requires manufacturers of certain drugs to engage in the drug price negotiation program with Medicare (beginning in 2026) or face steep penalties if they don' t agree to provide their drug at the government- set price subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (beginning in 2022); establishes an out- of- pocket maximum for beneficiaries in Part D; and replaces the Part D coverage gap discount program with a new discounting program (the last two both beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, and HHS announced another 15 drugs subject to negotiations in January 2025. The Medicare drug price negotiation program is currently subject to legal challenges. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our ability to price our products appropriately, which could

negatively impact 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, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects. 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 or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. There is also a great degree of uncertainty regarding how the recent U. S. Supreme Court decisions, including Loper Bright Enterprises v. Raimondo and Corner Post, Inc. v. Board of Governors of the Federal Reserve System, will impact FDA' s enforcement and decision- making authority. Loper Bright explicitly overturned Chevron deference, which 64previously gave judicial deference to administrative action by agencies in the executive branch. Further, the Supreme Court' s decision in Corner Post may result in challenges to FDA decisions by new litigants long into the future, resulting in greater uncertainty about our continued operations. We and the third parties with whom we work are subject to stringent and evolving U. S. and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Any actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation (including class claims), negative publicity or other adverse consequences that could negatively affect our operating results and business. In the ordinary course of business, we and our partners process sensitive data, including personal data. As a result, we and our partners may be subject to numerous data privacy and security obligations, such as various federal, state and foreign laws and regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to data privacy and security. In the United States, numerous federal, state and local governments have enacted laws and regulations, including state data breach notification laws, state health information privacy laws, federal and state consumer protection laws and other similar regulations that govern the processing of sensitive data, including health- related information. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable protected health information. There are additional federal and state privacy and security- related laws that may be more restrictive than HIPAA and could impose additional penalties. For example, even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of the Federal Tort Claims Act. The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. In addition, numerous U. S. states — including California, Virginia, Colorado, Connecticut and Utah — have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including, without limitation, providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct or delete certain personal data, and to opt- out of certain data processing activities, such as targeted advertising, profiling and automated decision- making. Failure to comply with these laws, where applicable, can result in significant statutory fines. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act of 2020, or CPRA, collectively the CCPA, applies to personal data of consumers, business representatives and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA and other comprehensive U. S. state privacy laws provide exceptions for some data processed in the context of clinical trials, but these developments may further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties with whom we work. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. Outside the United States, an increasing number of laws and regulations, including the General Data Protection Regulation in the EU and UK (collectively, the " GDPR ") may also apply to our processing of sensitive data, including health- related and other personal data. The GDPR imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern, when required, the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EU or the United Kingdom, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. In addition, the EU and other jurisdictions have enacted laws restricting the transfer of personal data from the EU and other jurisdictions to the United States due to data localization requirements or limitations on cross- border data flows. Although there are currently various mechanisms that may be used to transfer personal data from the EU and United Kingdom to the United States in compliance with law, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. 65Obligations related to data privacy and security (and consumers' data privacy expectations) are rapidly evolving, becoming increasingly stringent and creating uncertainty. Additionally, these obligations may be subject to differing

applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with U. S. and foreign data privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose sensitive data, or, in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Any actual or perceived failure to comply with U. S. and foreign data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation or adverse publicity and could negatively affect our operating results and business. In particular, plaintiffs have become increasingly more active in bringing privacy- related claims against companies, including class claims and mass arbitration demands. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws 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. We, directly or through our third- party service providers, may adopt, use or incorporate artificial intelligence (" AI ") technology and capabilities into the information technology systems or software that we use in our business and operations. Defects in such AI technology or related security breaches, loss of data and other disruptions as well as changes in implementation standards and enforcement practices under a rapidly evolving regulatory framework for AI technology may adversely affect our business and operations and potentially expose us to increasing liability. We, directly or through our third- party service providers, may adopt, use or incorporate AI technology and capabilities into information technology systems or software to help us operate our business more efficiently than existing industry tools. The regulatory framework for AI technologies is rapidly evolving as many federal, state and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations. In addition, existing laws and regulations may be interpreted in ways that would affect the use of AI in our business. As a result, implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or market perception of such requirements may have on our business and may not always be able to anticipate how to respond to these laws or regulations. Several governmental agencies in the U. S. and non- U. S. jurisdictions have proposed or enacted laws regulating AI technologies by setting out principles intended to guide AI design and deployment for the public and private sectors and signaling the increase in governmental involvement and regulation over AI technologies. In May 2024, the European Union legislators approved the EU Artificial Intelligence Act (the " EU AI Act "), which establishes a comprehensive, risk- based governance framework for AI in the EU market. The EU AI Act, and developing interpretation and application of the GDPR in respect of automated decision making, together with developing guidance and / or decisions in the impact of AI technology on data privacy, may affect our use of AI technologies and our ability to provide, improve or commercialize our business, require additional compliance measures and changes to our operations and processes, and result in increased compliance costs and potential increases in civil claims against us, and could adversely affect our business, operations and financial condition. Further, interpretation and implementation of intellectual property protection in the field of AI are rapidly evolving and there is uncertainty and ongoing litigation in different jurisdictions as to the degree and extent of protection warranted for AI and relevant system inputs and outputs. If we fail to obtain protection for intellectual property rights for any of our intellectual property that may incorporate or be developed using AI technologies, or later have our intellectual property rights invalidated or otherwise diminished, our competitors may be able to take advantage of our research and development efforts to develop competing products that could adversely affect our business, reputation and financial condition. Further, other parties may have, or in the future may obtain, patents or other proprietary rights that would prevent, limit or interfere with our ability to use any AI technologies that we may develop or use in our business. It is possible that further new laws and regulations will be adopted in the United States and in other non- U. S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI technologies for our business, or require us to change the way we use AI 66technologies in a manner that negatively affects the performance of our system and business and the way in which we use AI technologies. We may need to expend resources to adjust our system in certain jurisdictions if the laws, regulations, or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations or decisions and / or guidance interpreting existing laws, could be significant and would increase our operating expenses. Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could materially and adversely affect our business, financial condition, results of operations, and prospects. Environmental, social and governance matters may impact our business and reputation. Compliance with environmental, social and governance (collectively, " ESG ") regulations and policies, including diversity and inclusion, climate change, water use, recyclability or recoverability of packaging, and plastic waste, which have recently been the focus of governmental authorities, non-governmental organizations, customers, employees and other external stakeholders, may result in increased costs associated with developing, manufacturing and distributing our products. Our ability to compete could also be affected by changing customer preferences and requirements, such as growing demand for more environmentally friendly products, packaging or supplier practices, or by failure to meet such customer expectations or demand. Changes in regulations and policies of the new U. S. administration may have the effect of scaling back or halting the progress of proposed or enacted ESG- related regulations, which may also have an effect on requirements and preferences of various government agencies and external stakeholders. While we strive to improve our ESG performance, to the extent such ESG- related regulations and policies remain in place, we risk negative stockholder reaction, including from proxy

advisory services, as well as damage to our brand and reputation, if we do not act responsibly, or if we are perceived to not be acting responsibly in key ESG areas, including equitable access to medicines and vaccines, product quality and safety, diversity and inclusion, environmental stewardship, support for local communities, corporate governance and transparency, and addressing human capital factors in our operations. If we do not meet the ESG expectations of our investors, customers and other stakeholders, we could experience reduced demand for our products, loss of customers, and other negative impacts on our business and results of operations. Climate change or legal, regulatory or market measures to address climate change may negatively affect our business, results of operations, cash flows and prospects. We believe that climate change has the potential to negatively affect our business and results of operations, cash flows and prospects. We are exposed to physical risks (such as extreme weather conditions or rising sea levels), risks in transitioning to a low- carbon economy (such as additional legal or regulatory requirements, changes in technology, market risk and reputational risk) and social and human effects (such as population dislocations and harm to health and well- being) associated with climate change. These risks can be either acute (short- term) or chronic (long- term). The adverse impacts of climate change include increased frequency and severity of natural and man- made disasters and extreme weather events such as hurricanes, flooding, typhoons, tornados, wildfires and fires, drought, extreme heat, earthquakes, water shortages, blizzards and other extreme weather conditions. Extreme weather and sea- level rise pose physical risks to our facilities as well as those of our suppliers. Such risks include losses incurred as a result of physical damage to facilities, loss or spoilage of inventory, power outages, telecommunications, transportation or other infrastructure failure, cybersecurity incidents and other business interruption caused by such natural and man- made disasters and extreme weather events. Other potential physical impacts due to climate change include reduced access to high- quality water in certain regions and the loss of biodiversity, which could impact future product development. These risks could disrupt our operations and its supply chain, which may result in increased costs. New legal or regulatory requirements may be enacted to prevent, mitigate, or adapt to the implications of a changing climate and its effects on the environment. These regulations, which may differ across jurisdictions, could result in us being subject to new or expanded carbon pricing or taxes, increased compliance costs, restrictions on greenhouse gas emissions, investment in new technologies, increased carbon disclosure and transparency, upgrade of facilities to meet new building codes, and the redesign of utility systems, which could increase our operating costs, including the cost of electricity and energy used by us. Our supply chain would likely be subject to these same transitional risks and would likely pass along any increased costs to us. 67Risks Related to Our Dependence on Third PartiesWe **rely on third parties to conduct our preclinical studies and clinical trials. We currently rely on, and plan to continue to rely on, third- party contract research organizations, or CROs, to monitor and manage data for our preclinical studies and clinical trials. However, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable regulatory standards and our reliance on CROs does not relieve us of our regulatory responsibilities. The CROs on which we rely are required to comply with FDA regulations (and the regulations of comparable regulatory authorities in other countries) regarding GCP. Regulatory authorities enforce GCP standards through periodic inspections. If any of the CROs on which we rely fail to comply with the applicable GCP standards, the clinical data generated in our clinical trials may be deemed unreliable. While we have contractual agreements with these CROs, we have limited influence over their actual performance and cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical trials. A failure to comply with the applicable regulations in the conduct of the preclinical studies and clinical trials for our product candidates may require us to repeat such studies or trials, which would delay the process of obtaining marketing approval for our product candidates and have a material and adverse effect on our business and prospects. Some of our CROs have the ability to terminate their respective agreements with us if, among others, it can be reasonably demonstrated that the safety of the patients participating in our clinical trials warrants such termination. If any of our agreements with our CROs is terminated, and if we are not able to enter into agreements with alternative CROs on acceptable terms or in a timely manner, or at all, the clinical development of our product candidates may be delayed and our development expenses could be increased. We** depend on third parties for clinical and commercial supplies, including single suppliers for the active ingredient, the device, encapsulation and packaging of YUTREPIA and single suppliers for the active ingredient **, the device** , bulk product manufacturing and packaging of L606. We depend on third- party suppliers for clinical and commercial supplies for the supply of materials and components necessary for clinical and commercial production of YUTREPIA and L606, including the active pharmaceutical ingredients which are used in our product candidates. These supplies may not always be available to us at the standards we require or on terms acceptable to us, or at all, and we may not be able to locate alternative suppliers in a timely manner, or at all. If we are unable to obtain necessary clinical or commercial supplies, our manufacturing operations and clinical trials and the clinical trials of our collaborators may be delayed or disrupted and our business and prospects may be materially and adversely affected as a result. For example, we currently rely on a sole supplier for treprostinil, the active pharmaceutical ingredient of YUTREPIA, which sources treprostinil from a manufacturer in South Korea, with whom we have a long- term supply agreement. If our supplier is unable to supply treprostinil to us in the quantities we require, or at all, or otherwise defaults on its supply obligations to us, or if it ceases its relationship with us, we may not be able to obtain alternative supplies of treprostinil from other suppliers on acceptable terms, in a timely manner, or at all. We also rely on a sole supplier **located in Tampa, Florida** for encapsulation and packaging services, with whom we have a long- term contract. Furthermore, YUTREPIA is administered using the RS00 Model 8 DPI, which is manufactured by Plastiape, which is located in Italy. In the event of any prolonged disruption to our supply of treprostinil, the encapsulation and packaging services, or the manufacture and supply of RS00 Model 8 DPI, our ability to develop and commercialize, and the timeline for commercialization of, YUTREPIA may be adversely affected. We ~~also rely~~ **have relied** upon ~~Chengdu~~ **ICU Medical** for **servicing** ~~the manufacture~~ and ~~supply~~ **support** of ~~RG Cartridges for the subcutaneous~~ **CADD**

MS- 3 infusion pumps that patients currently use to ~~administration ----- **administer** of~~ Treprostinil Injection ~~and upon Smiths **through subcutaneous injection. ICU** Medical **no longer manufactures** for ~~- **or** ongoing servicing and support~~ **supports** ~~of~~ the **CADD MS- 3 infusion pumps. Although we believe that the number of available** CADD- MS 3 ~~, CADD Legacy and CADD- Solis~~ infusion pumps **will be sufficient** ~~. In the event of any disruption~~ to **continue** ~~our supply of RG Cartridges or any disruption in the availability of parts or servicing~~ -- **serving** ~~for~~ **patients through at least** the **end of 2025** ~~CADD- MS 3~~ , **we are working to develop new** ~~CADD Legacy and CADD- Solis infusion~~ pumps ~~, sales~~ **for the subcutaneous administration** of Treprostinil Injection **to replace** ~~may be adversely affected. In addition, Smiths Medical has indicated that they will no longer support~~ the CADD MS- 3 **infusion pumps** ~~after January 1, 2025~~ . **Prior to using any such** ~~We are relying upon Mainbridge for the development of~~ new pumps **, we** ~~for - **or** the subcutaneous administration of Treprostinil Injection~~ **our development partners will be required** to ~~replace~~ **obtain FDA clearance. To date, we have not 68submitted a 510 (k) clearance application for any such new pumps, and we are currently uncertain when, if ever, such a 510 (k) clearance application will be submitted. If** the **existing supply of** CADD MS- 3 **infusion** ~~. In the event of any failure of Mainbridge to successfully develop such a pump~~ **pumps become unavailable before the new pumps are cleared by the FDA** , sales of Treprostinil Injection may be adversely affected **. We also rely upon manufacturers with operations or suppliers in China and Taiwan. Chengdu, which manufactures and supplies RG Cartridges for the subcutaneous administration of Treprostinil Injection, has facilities and suppliers located in China** . For L606, we rely upon single sources of supply for the active pharmaceutical ingredient, **the device,** manufacture of bulk drug product and packaging ~~.~~ **, ~~Some~~ some** of **which** ~~these suppliers~~ are located in Taiwan. ~~Although~~ **The operations of our current manufacturing partners and those of its suppliers may be materially disrupted by changes in regulations or policies by the new U. S. administration to increase tariffs or otherwise affect trade with China or restrict U. S. pharmaceutical companies from contracting with Chinese companies on the development, research or manufacturing of pharmaceutical products. Any such executive orders, legislative action or potential sanctions on China could result in trade wars, supply chain disruptions and heighten geopolitical tensions and instability in China and Taiwan and we may be unable to secure an adequate supply of RG Cartridges or L606 at a reasonable cost or in a timely manner, if at all. In addition,** we are **currently** working to establish a secondary supply chain outside of Taiwan ~~, if hostilities were to break out between Taiwan~~ and ~~China, we may be unable to secure a supply of L606. Also, we are currently evaluating~~ **evaluate** devices to use for the administration of L606. If we are unable to identify a device to use for our L606 program, establish an agreement with the manufacturer of that device for the supply of such devices or obtain adequate quantities of that device in a timely manner or at all, we may be unable to successfully develop L606 or to do so in a timely manner **. If any of our limited source suppliers are adversely affected by geopolitical events, natural or man- made disasters, public health emergencies or other events that disrupt or adversely affect their operations or their ability to supply us, our business may be adversely affected** . If we are unable to establish or maintain licensing and collaboration arrangements with other pharmaceutical companies on acceptable terms, or at all, we may not be able to develop and commercialize additional product candidates using our PRINT technology. We have collaborated, and may consider collaborating, with, among others, pharmaceutical companies to expand the applications for our PRINT technology through licensing as well as joint product development arrangements. In addition, if we are able to obtain marketing approval for our product candidates from regulatory authorities, we may enter into strategic relationships with collaborators for the commercialization of such products. ~~52Collaboration~~ -- **Collaboration** and licensing arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish collaboration or other alternative arrangements should we so choose to enter into such arrangements. In addition, the terms of any collaboration or other arrangements that we may enter into may not be favorable to us or may restrict our ability to enter into further collaboration or other arrangements with third parties. For example, collaboration agreements may contain exclusivity arrangements which limit our ability to work with other pharmaceutical companies to expand the applications for our PRINT technology, as is the case in our collaboration agreement with GSK which restricts our ability to use PRINT for inhaled applications with respect to certain identified compounds. If we are unable to establish licensing and collaboration arrangements or the terms of such agreements we enter into are unfavorable to us or restrict our ability to work with other pharmaceutical companies, we may not be able to expand the applications for our PRINT technology or commercialize our products, if and when approved, and our business and prospects may be materially and adversely affected. Our collaboration and licensing arrangements may not be successful. Our collaboration and licensing arrangements, as well as any future collaboration and licensing arrangements that we may enter into, may not be successful. The success of our collaboration and licensing arrangements will depend heavily ~~on~~ **69on** the efforts and activities of our collaborators, which are not within our control. We may, in the course of our collaboration and licensing arrangements, be subject to numerous risks, including, but not limited to, the following: ● our collaborators may have significant discretion in determining the efforts and resources that they will contribute; ● our collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing. For example, in July 2018, GSK notified us of its decision to discontinue development of the inhaled antiviral for viral exacerbations in COPD after completion of its related Phase 1 clinical trial and we do not believe that GSK is currently advancing any program under our collaboration; ● our collaborators may independently, or in conjunction with others, develop products that compete directly or indirectly with our product candidates; ● we may grant exclusive rights to our collaborators that would restrict us from collaborating with others. For example, we are currently subject to certain restrictions with regard to our ability to enter into collaboration arrangements to use PRINT for the development of inhaled therapeutics using certain identified compounds pursuant to our collaboration with GSK; ● our collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to

potential liability; ● disputes may arise between us and our collaborators, which may cause a delay in or the termination of our research, development or commercialization activities; ● our collaboration and licensing arrangements may be terminated, and if terminated, may result in our need for additional capital to pursue further drug product development or commercialization. For example, our development and licensing agreement with G & W Laboratories, Inc., was mutually terminated in April 2018; ● our collaborators may own or co- own certain intellectual property arising from our collaboration and licensing arrangements with them, which may restrict our ability to develop or commercialize such intellectual property; and ● our collaborators may alter the strategic direction of their business or may undergo a change of control or management, which may affect the success of our collaboration arrangements with them. ~~53Risks~~ -- **Risks** Related to our Intellectual PropertyWe may be subject to claims from third parties that our products infringe their intellectual property rights. The pharmaceutical industry has experienced rapid technological change and obsolescence in the past, and our competitors have strong incentives to stop or delay any introduction of new drug products or related technologies by, among others, establishing intellectual property rights over their drug products or technologies and aggressively enforcing these rights against potential new entrants into the market. We expect that we and other industry participants will be increasingly subject to infringement claims as the number of competitors and drug products grows. Our commercial success depends in large part upon our ability to develop, manufacture, market and sell our drug products or product candidates without infringing on the patents or other proprietary rights of third parties. It is not always clear to industry participants, including us, what the scope of a patent covers. Due to the large number of patents in issue and patent applications filed in our industry, there is a risk that third parties will claim that our products or technologies infringe their intellectual property rights. Claims for infringement of intellectual property which are brought against us, whether with or without merit, and which are generally uninsurable, could result in time- consuming and costly litigation, diverting our management' s attention from our core business and reducing the resources available for our drug product development, manufacturing and marketing activities, and consequently have a material and adverse effect on our business and prospects, regardless of the outcome. Moreover, such proceedings could put our patents at risk of being invalidated or interpreted narrowly and ~~our~~ **70our** patent applications at risk of not being issued. We also may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Uncertainties resulting from the initiation and continuation of litigation or other proceedings could also have a material and adverse effect on our ability to compete in the market. Third parties making claims against us could obtain injunctive or other equitable relief against us, which could prevent us from further developing or commercializing our product candidates. In particular, under the Hatch- Waxman Act, the owner of patents listed on the Orange Book and referenced by an NDA applicant may bring patent infringement suit against the NDA applicant after receipt of the NDA applicant' s notice of paragraph IV certification. For example, in ~~June 2020, United Therapeutics asserted a patent challenge directed to the Orange Book listed patents for Tyvaso by filing a complaint against us in the U. S. District Court for the District of Delaware, thereby triggering an automatic 30- month regulatory stay on final approval of the NDA for YUTREPIA. As a result of United Therapeutics' patent challenge, the FDA was prohibited from approving the NDA for YUTREPIA until the expiration of the 30- month stay. In August 2022, prior to the expiration of the 30- month stay, the Court found that the asserted claims of one of the patents, the ' 793 Patent, were both valid and infringed by the Company and ordered that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the ' 793 Patent. However, in December 2023, the United States Court of Appeals for the Federal Circuit affirmed the earlier decision by the PTAB, which found all claims of the ' 793 Patent to be unpatentable due to the existence of prior art cited by us in inter partes review proceedings. As a result of this decision by the United States Court of Appeals for the Federal Circuit, in December 2023, we filed a motion for Judge Andrews to set aside the injunction he issued. If we are unable to have the injunction set aside, we may be subject to significant delay and incur substantial costs in litigation before we are able to commercialize YUTREPIA, if at all. In addition, in~~ connection with an amendment to our NDA filed in July 2023 to add PH- ILD as an indication for YUTREPIA, a new notice of the paragraph IV certification was provided to United Therapeutics as the owner of the patents that are the subject of the certification to which the NDA for YUTREPIA refers. As a result, United Therapeutics filed the New Hatch- Waxman Litigation, in which it **sought** ~~is seeking~~ a preliminary injunction **. While the motion for a preliminary injunction was denied, United Therapeutics may still seek injunctive relief in the New Hatch- Waxman Litigation** . Although we do not believe United Therapeutics is entitled to a ~~new 30- month stay or~~ preliminary injunction in connection with the New Hatch- Waxman Litigation, it is possible that the Court could ~~rule that a new mandatory 30- month delay has been triggered with respect to the approval of the 505 (b) (2) NDA application or that we are enjoined~~ -- **enjoin us** from commercializing YUTREPIA for the treatment of PH- ILD. In addition, United Therapeutics may seek to assert newly issued patents against us, including U. S. Patent Number 11, 723, 887, and may seek to enjoin the FDA from granting final approval to YUTREPIA or enjoin us from launching YUTREPIA, including through temporary restraining ~~order~~ **orders or injunctions that** they ~~are seeking~~ **may seek** in the **New** FDA Litigation. ~~54In~~ **In** the event of a successful infringement claim against us, including an infringement claim filed in response to a paragraph IV certification, we may be required to pay damages, cease the development or commercialization of our drug products or product candidates **, limit the label of our products to fewer indications than intended** , re- engineer or redevelop our drug products or product candidates or enter into royalty or licensing agreements, any of which could have a material and adverse impact on our business, financial condition and results of operations. Any effort to re- engineer or redevelop our products would require additional monies and time to be expended and may not ultimately be successful. Infringement claims may be brought against us in the future, and we cannot assure you that we will prevail in any ensuing litigation given the complex technical issues and inherent uncertainties involved in intellectual property litigation. Our competitors may have substantially greater resources than we do and may be able to sustain the costs of such litigation more effectively than we can. Our commercial success depends largely on our ability to protect our intellectual property. Our commercial success depends, in large part, on our ability to obtain and maintain patent protection and trade secret protection in the United States and elsewhere in respect of our product candidates and PRINT

technology. If we fail to adequately protect our intellectual property rights, our competitors may be able to erode, negate or preempt any competitive advantage we may have. To protect our competitive position, we have filed and will continue to file for patents in the United States and elsewhere in respect of our product candidates and PRINT technology. The process of identifying patentable subject matter and filing a patent application is expensive and time- consuming. We cannot assure you that we will be able to file the necessary or desirable patent applications at a reasonable cost, in a timely manner, or at all. Further, since certain patent applications are confidential until patents are issued, third parties may have filed patent applications for subject ~~matters~~ **matter** covered by our pending patent applications without us being aware of such applications, and our patent applications may not have priority over patent applications of others. In addition, we cannot assure you that our pending patent applications will result in patents being obtained. Once published, all patent applications and publications throughout the world, including our own, become prior art to our new patent applications and may prevent patents from being obtained or interfere with the scope of patent protection that might be obtained. The standards that patent offices in different jurisdictions use to grant patents are not always applied predictably or uniformly and may change from time to time. Even if we have been or are able to obtain patent protection for our product candidates or PRINT technology, if the scope of such patent protection is not sufficiently broad, we may not be able to rely on such patent protection to prevent ~~third~~ **71third** parties from developing or commercializing product candidates or technology that may copy our product candidates or technology. The enforceability of patents in the pharmaceutical industry involves complex legal and scientific questions and can be uncertain. Accordingly, we cannot assure you that third parties will not successfully challenge the validity, enforceability or scope of our patents. A successful challenge to our patents may lead to generic versions of our drug products being launched before the ~~expiry~~ **expiration** of our patents or otherwise limit our ability to stop others from using or commercializing similar or identical products and technology. A successful challenge to our patents may also reduce the duration of the patent protection of our drug products or technology. In addition, we cannot assure you that we will be able to detect unauthorized use or take appropriate, adequate and timely actions to enforce our intellectual property rights. If we are unable to adequately protect our intellectual property, our business, competitive position and prospects may be materially and adversely affected. Even if our patents or patent applications are unchallenged, they may not adequately protect our intellectual property or prevent third parties from designing around our patents or other intellectual property rights. If the patent applications we file or may file do not lead to patents being granted or if the scope of any of our patent applications is challenged, we may face difficulties in developing our product candidates, companies may be dissuaded from collaborating with us, and our ability to commercialize our product candidates may be materially and adversely affected. We are unable to predict which of our patent applications will lead to patents or assure you that any of our patents will not be found invalid or unenforceable or challenged by third parties. The patents of others may prevent the commercialization of product candidates incorporating our technology. In addition, given the amount of time required for the development, clinical testing and regulatory review of new product candidates, any patents protecting our product candidates may expire before or shortly after such product candidates might become approved for commercialization. ~~55Moreover~~ **Moreover**, the issuance of a patent is not conclusive as to the inventorship of the patented subject matter, or its scope, validity or enforceability. We cannot assure you that all of the potentially relevant prior art, that is, any evidence that an invention is already known, relating to our patents and patent applications, has been found. If such prior art exists, it may be used to invalidate a patent or may prevent a patent from being issued. **Questions may also arise as to the ownership of our patents. For instance, in May 2024, United Therapeutics filed a complaint in the Superior Court in Durham County, North Carolina, in which it is seeking declaratory judgement such that all right, title and interest in and to any patentable or unpatentable inventions, discoveries, and ideas made or conceived by the Former Employee while employed by the Company should be assigned and transferred to United Therapeutics because they involved the use of United Therapeutics' confidential information. If successful, United Therapeutics could obtain an ownership interest in our patents, which may either limit our ability to prevent United Therapeutics from using out patented inventions or even allow United Therapeutics to prevent us from using our own patented inventions.** In addition, we, our collaborators or our licensees may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. As a result, we may miss potential opportunities to seek patent protection or strengthen our patent position **. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. While various extensions may be available, the life of a patent, and 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. We intend to seek extensions of patent terms in the United States and, if available, in other countries where we prosecute patents. In the United States, the Hatch- Waxman Act permits patent owners to request a patent term extension, based on the regulatory review period for a product, of up to five years beyond the normal expiration of the patent, which is limited to one patent claiming the approved drug product or use in an indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO, in the United States, and comparable regulatory authorities in other countries, may not agree with our assessment of whether such 72extensions are available, and may refuse to grant extensions to our patents, or grant more limited extensions than we had requested. In such event, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our preclinical and clinical data in their marketing approval applications with the FDA to launch their drug product earlier than might otherwise be the case**. If we are unable to protect our trade secrets, the value of our PRINT technology and product candidates may be negatively impacted, which would have a material and adverse effect on our competitive position and prospects. In addition to patent protection, we rely on trade secret protection to protect certain aspects of our intellectual property. We also license trade secrets

from Pharmosa with respect to L606. While we require parties who have access to any portion of our trade secrets, such as our employees, consultants, advisers, CROs, CMOs, collaborators and other third parties, to enter into non- disclosure and confidentiality agreements with us, we cannot assure you that these parties will not disclose our proprietary information, including our trade secrets, in breach of their contractual obligations. Enforcing a claim that a party has illegally disclosed or misappropriated a trade secret is difficult, costly and time- consuming, and we may not be successful in doing so. If the steps we have taken to protect our trade secrets are deemed by the adjudicating court to be inadequate, we may not be able to obtain adequate recourse against a party for misappropriating our trade secrets. Trade secrets can be difficult to protect as they may, over time, be independently discovered by our competitors or otherwise become known despite our trade secret protection. If any of our trade secrets were to be lawfully obtained or independently developed by our competitors, we would have no right to prevent such competitors, or those to whom they communicate such technology or information, from using that technology or information to compete with us. Such competitors could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If our trade secrets were to be disclosed to or independently developed by our competitors, our competitors may be able to exploit our PRINT technology to develop competing product candidates, and the value of our PRINT technology and our product candidates may be negatively impacted. This would have a material and adverse effect on our competitive position and prospects. We rely on licenses to intellectual property that are owned by third parties. We have entered and may, in the future, enter into license agreements with third parties to license the rights to use their technologies in our research, development and commercialization activities. License agreements generally impose various diligence, milestone ~~payments~~ **payment** , royalty, insurance and other obligations on us, and if we fail to comply with these obligations, our licensors may have the right to terminate these license agreements. Termination of these license agreements or the reduction or elimination of our licensed rights or the exclusivity of our licensed rights may have an adverse impact on, among others, our ability to develop and commercialize our product candidates. We cannot assure you that we will be able to negotiate new or reinstated licenses on commercially acceptable terms, or at all. In addition, we license certain patent rights for our PRINT technology from UNC under the UNC License. Under the UNC License, UNC has the right to terminate our license if we materially breach the agreement and fail to cure such breach within the stipulated time. In the event that UNC terminates our license and we have a product that relies on that license, including YUTREPIA, it may bring a claim against us, and if they are successful, we may be required to compensate UNC for the unauthorized use of their patent rights through the payment of royalties. Similarly, under our license agreement with Pharmosa, Pharmosa has the right to terminate our license if we materially breach the agreement and fail to cure such breach within the stipulated time. In the event that Pharmosa terminates our license and we have a product that relies on that license, including L606, it may bring a claim against us, and if they are ~~56successful~~ **successful** , we may be required to compensate Pharmosa for the unauthorized use of their patent rights through the payment of royalties. ~~Also~~ **73Also** , the agreements under which we license patent rights may not give us control over patent prosecution or maintenance, so that we may not be able to control which claims or arguments are presented and may not be able to secure, maintain or successfully enforce necessary or desirable patent protection from those patent rights. We do not have primary control over patent prosecution and maintenance for certain of the patents we license, and therefore cannot assure you that these patents and applications will be prosecuted or maintained in a manner consistent with the best interests of our business. We also cannot assure you that patent prosecution and maintenance activities by our licensors, if any, will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. Pursuant to the terms of some of our license agreements with third parties, some of our third- party licensors have the right, but not the obligation, in certain circumstances, to control the enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents. Even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors, and we cannot assure you that we will receive such cooperation on commercially acceptable terms, or at all. We also cannot assure you that our licensors will allocate sufficient resources or prioritize their or our enforcement of these patents or defense of these claims to protect our interests in the licensed patents. If we cannot obtain patent protection, or enforce existing or future patents against third parties, our competitive position, business and prospects may be materially and adversely affected. Further, licenses to intellectual property may not always be available to us on commercially acceptable terms, or at all. In the event that the licenses we rely on are not available to us on commercially acceptable terms, or at all, our ability to commercialize our PRINT technology or product candidates, and our business and prospects, may be materially and adversely affected. We may **become involved in litigation to protect our intellectual property or enforce our intellectual property rights, which could be expensive, time- consuming and may not be successful. Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, we may engage in litigation to, among others, enforce or defend our intellectual property rights, determine the validity or scope of our intellectual property rights and those of third parties, and protect our trade secrets. Such actions may be time- consuming and costly and may divert our management' s attention from our core business and reduce the resources available for our clinical development, manufacturing and marketing activities, and consequently have a material and adverse effect on our business and prospects, regardless of the outcome. In addition, in an infringement proceeding, a court may decide that a patent owned by, or licensed to, us is invalid or unenforceable, or may refuse to stop the other party from using the technology in question on the ground that our patents do not cover such technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that our confidential information may be compromised by disclosure. We may** not be able to enforce our intellectual property rights throughout the world. Filing, prosecuting, enforcing and defending patents on our PRINT technology and our product candidates throughout

the world may be prohibitively expensive and may not be financially or commercially feasible. In countries where we have not obtained patent protection, our competitors may be able to use our proprietary technologies to develop competing product candidates. Also, the legal systems of non- U. S. jurisdictions may not protect intellectual property rights to the same extent or in the same manner as the laws of the United States, and we may face significant difficulty in enforcing our intellectual property rights in these jurisdictions. The legal systems of certain developing countries may not favor the enforcement of patents and other intellectual property rights. We may therefore face difficulty in stopping the infringement or misappropriation of our patents or other intellectual property rights in those countries. ~~We~~ **74We** need to protect our trademark, trade name and service mark rights to prevent competitors from taking advantage of our name recognition. We believe that the protection of our trademark, trade name and service mark rights, such as Liquidia, the Liquidia logo, PRINT, and YUTREPIA, is an important factor in product recognition, protecting our brand, maintaining goodwill and maintaining or increasing market share. We may expend substantial cost and effort in an attempt to register new trademarks, trade names and service marks and maintain and enforce our trademark, trade name and service mark rights. If we do not adequately protect our rights in our trademarks, trade names and service marks from infringement, any name recognition that we have developed in those trademarks could be lost or impaired. Third parties may claim that the sale or promotion of our products, when and if approved, may infringe on the trademark, trade name and service mark rights of others. Trademark, trade name and service mark infringement problems occur frequently in connection with the sale and marketing of pharmaceutical products. If we become involved in any dispute regarding our trademark, trade name and service mark rights, regardless of whether we prevail, we could be required to engage in costly, distracting and time- consuming litigation that could harm our business. If the ~~57trademarks~~ -- **trademarks** , trade names and service marks we use are found to infringe upon the trademarks, trade names or service marks of another company, we could be liable for damages and be forced to stop using those trademarks, trade names or service marks, and as a result, we could lose all the name recognition that has been developed in those trademarks, trade names or service marks. Risks Related to the Manufacturing of our Product Candidates Our product candidates are based on our proprietary, novel technology, which has not been used to manufacture any products that have been previously approved by the FDA, making it difficult to predict the time and cost of development and of subsequently obtaining final regulatory approval. Our future success depends on the successful development of our novel PRINT technology and products based on it, including YUTREPIA, and the development of L606 using Pharmosa' s proprietary liposomal technology. To our knowledge, no regulatory authority has granted final approval to market or commercialize drugs made using our PRINT technology or Pharmosa' s liposomal technology. We may never receive final approval to market and commercialize any product candidate that uses our PRINT technology or Pharmosa' s liposomal technology. Even if we receive final approval to market YUTREPIA and / or L606, we will need to scale up our manufacturing capabilities to effectively commercialize the products. We have never completed a scale up of our PRINT manufacturing process or the manufacturing process for L606, and, if we are unable to do so in an effective and timely manner, our ability to commercialize these products, even if they receive final FDA approval, will be adversely affected. We may experience unexpected challenges as we ramp up our manufacturing capacity to meet demand or during commercial manufacturing, which may result in our inability to supply sufficient quantities of product to meet demand. The manufacturing process for our products is complex, due in part to strict regulatory requirements. A failure of our quality control systems in our facilities or those of our CMOs could cause problems to arise in connection with facility operations for a variety of reasons, including equipment malfunction, viral contamination, failure to follow specific manufacturing instructions, protocols and standard operating procedures, problems with raw materials or environmental factors. Such problems could affect production of a single batch or a series of batches, requiring the destruction of products, or could halt manufacturing operations altogether. For instance, as we scale up the manufacture of YUTREPIA, we are adjusting the speed and ~~temperature~~ **scale** at which our **bulk powder is manufactured and at which** blister packs are sealed ~~to reduce the risk of the product being exposed to moisture~~ . Our failure to meet required quality standards may result in our failure to timely deliver products to our customers in sufficient quantities to meet demand, which in turn could damage our reputation for quality and service. Any such incident could, among other things, lead to increased costs, lost revenue, damage to our reputation and relationships with patients, health care providers and **third- party** ~~payers~~ **payors** , time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches. With respect to our commercial manufacturing, if problems are not discovered before the product is released to the market, we may be subject to regulatory actions, ~~including~~ **75including** product recalls, product seizures, injunctions to halt manufacture and distribution, restrictions on our operations, civil sanctions, including monetary sanctions, and criminal actions. In addition, such issues could subject us to litigation, the cost of which could be significant. Our **facilities are subject to extensive and ongoing regulatory requirements and failure to comply with these regulations may result in significant liability. Our company and our facilities are subject to payment of fees, registration and listing requirements, ongoing review and periodic inspections by the FDA and other regulatory authorities for compliance with quality system regulations, including the FDA' s cGMP requirements. These regulations cover all aspects of the manufacturing, testing, quality control and record- keeping of our drug products. Furthermore, the facilities where our product candidates are manufactured may be subject to additional inspections by the FDA before we can obtain final marketing approval and remain subject to periodic inspection even after our product candidates have received marketing approval. Suppliers of components and materials, such as active pharmaceutical ingredients, used to manufacture our drug products are also required to comply with the applicable regulatory standards. The manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We and any contract manufacturers that we may engage in the future must comply with cGMP requirements. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and contamination controls. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing,**

operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Compliance with these regulatory standards often requires significant expense and effort. If we or our suppliers are unable to comply with the applicable regulatory standards or take satisfactory corrective steps in response to adverse results of an inspection, this could result in enforcement action, including, among others, the issue of a public warning letter, a shutdown of or restrictions on our or our suppliers' manufacturing operations, delays in approving our drug products and refusal to permit the import or export of our drug products. Any adverse regulatory action taken against us could subject us to significant liability and harm our business and prospects. Our operations are concentrated in Morrisville, North Carolina and interruptions affecting us or our suppliers due to natural **or man- made** disasters or other unforeseen events could materially and adversely affect our operations **and result in losses that may not be covered by insurance** . Most of our current operations are concentrated in Morrisville, North Carolina. In addition, our inventory **and certain equipment necessary for the manufacturing of our raw materials and for encapsulating and packaging our products** is ~~warehoused~~ **held** in a limited number of locations. **Our** ~~A fire~~ , **and** ~~flood, hurricane, earthquake or~~ **our suppliers' operations could be subject to the impact of natural or man- made disasters and** other ~~disaster~~ **business disruptions, which include, but are not limited to, hurricanes, flooding, typhoons, tornados, wildfires and fires, drought, extreme heat, earthquakes, water shortages, blizzards and other extreme weather conditions, as well as power outages, telecommunications, transportation or other infrastructure failure, cybersecurity incidents or physical security breaches, public health emergencies, such as pandemics and epidemics, and geopolitical conflicts, including acts of terrorism, war and civil disorder** or unforeseen ~~event~~ **events ,** resulting in significant damage to our facilities **, to** ~~or~~ **our** ~~to~~ inventory ~~held by us~~ **or to equipment which is necessary for our operations, which** could significantly disrupt or curtail or require us to cease our operations. It would be difficult, costly and time- consuming to transfer resources from one facility to another, to repair or replace our facility or to replace inventory **or equipment** in the event that it is significantly damaged. In addition, our insurance may not be sufficient to cover all of our losses and may not continue to be available to us on acceptable terms, or at all. **The cost of insurance has increased significantly, including as a result of the impact of climate change and inflation, and we may not be able to obtain sufficient coverage at a reasonable cost to protect us against losses from such disasters or unforeseen events.** In addition, if one of our suppliers experiences a similar disaster or unforeseen event, we could face significant loss of our inventory and significant delays in obtaining ~~our~~ **76our** supplies or be required to source supplies from an ~~58alternative~~ -- **alternative** supplier and may incur substantial costs as a result. Any significant uninsured loss, prolonged or repeated disruption to operations or inability to operate, experienced by us or by our suppliers, could materially and adversely affect our business, financial condition and results of operations. **We** ~~In addition, for L606, we rely upon single sources of supply for the active pharmaceutical ingredient and manufacture of bulk drug that~~ are **subject** ~~located in Taiwan. Although we are working~~ to **information technology systems failures** ~~establish a secondary supply chain outside of Taiwan~~ , **security breaches** ~~if hostilities were to break out between Taiwan and China~~ , **loss or leakage** ~~we may be unable to secure a supply~~ of ~~L606~~ **data, technological malfunctions or other disruptions** , which could ~~limit~~ **result in, among other things, material disruption of** our **product** ~~ability to continue~~ development **programs, financial losses, the inability to process transactions, the unauthorized release** of ~~L606~~ **confidential information** and ~~materially~~ **reputational risk, restrictions on accessing critical information** and ~~adversely affect~~ **potential exposure to liability, all of which would negatively impact** our business, financial condition ~~and~~ **or** results of operations. ~~Risks Related~~ **Our use of technology, infrastructure and data is critical** to our ~~Employees~~ **continued operations.** We ~~depend~~ **are susceptible to operational, financial and information security risks resulting from security breaches, loss or leakage of data, technological malfunctions or other disruptions. Successful security breaches or technological malfunctions affecting us, our CROs, CMOs, suppliers or other third- party service providers can result in, among other things, material disruption of our product development programs, financial losses, the inability to process transactions, the unauthorized release of confidential information, proprietary or other business information (including personal data), reputational risk, restrictions** on ~~skilled labor~~ **accessing critical information and potential exposure to liability. Cyber- attacks include , but are not limited to, deployment of harmful malware, ransomware, denial- of- service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of our and our service providers' systems and the information on such systems. Cyber- attacks can also include phishing attempts or e- mail fraud to cause unauthorized payments or information to be transmitted to** ~~and~~ **an unintended recipient, or to permit unauthorized access to systems. As cybersecurity threats continue to evolve, we may be required to use additional resources to continue to modify or enhance protective measures or to investigate security vulnerabilities, which could have a material adverse effect on** our business **, financial condition or results of operations. Any security breach or other incident, whether actual or perceived, could impact our reputation** and ~~prospects may be adversely affected if we~~ **/ or operations, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to** lose **existing customers. For example,** the ~~services~~ **loss** of **clinical trial data from clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover** ~~our~~ **or** ~~skilled personnel, including~~ **reproduce the data. To the extent that any disruption or security breach affects our systems (or** those **of** ~~in senior management, or~~ **our third** ~~are unable to attract new skilled personnel. Our ability to continue our operations and manage our potential future growth depends on our ability to hire and retain suitably skilled and qualified employees, including those in senior management, in the long~~ **party service providers)** ~~term. Due to the specialized nature of our~~ **or** ~~work, there is~~ **were to result in** a **loss** ~~limited supply~~ of ~~suitable candidates. We compete with~~ **or accidental, unlawful or unauthorized access, use, release or** other ~~biotechnology and pharmaceutical~~

~~companies~~ **processing of personally identifiable information** , **confidential** ~~educational and research institutions and government entities, among others, for~~ **or proprietary information** ~~research, technical, clinical and sales and marketing personnel. In addition, in order to manage our~~ **or damage** ~~potential future growth effectively, we will need~~ to ~~improve~~ **our data** ~~our~~ **or applications** ~~financial controls and systems and~~ , ~~as necessary, recruit sales, marketing, managerial and finance personnel. The loss of the services of members of~~ our ~~sales team~~ **product development programs** could ~~seriously harm our ability to successfully implement our business strategy. If we are unable to attract and retain skilled personnel, including in particular Roger Jeffs, our Chief Executive Officer, our business and prospects may~~ be materially **disrupted and we could incur liability and become subject to significant fines, penalties or liabilities for any noncompliance to certain privacy and security laws. We have also outsourced elements of our information technology infrastructure, and as a result, a number of third- party vendors have access to our confidential information. If the information technology systems of our third- party vendors become subject to disruptions or security breaches that compromise our confidential, proprietary or other business information (including personal data), we may incur liability and reputational damage but have insufficient recourse against such third parties. We will also have to expend significant resources to mitigate the impact of such** ~~and~~ **an** ~~adversely affected~~ **event and develop and implement protections to prevent future events of this nature from occurring** . **Further, despite the implementation of security measures, our information technology systems and those of our third- party service providers are vulnerable to cybersecurity attacks, breakdowns or other damages or disruptions from service interruptions, system malfunction, unauthorized access or use, natural and man- made disasters, geopolitical conflicts and telecommunications, power outages or other infrastructure failures. Although we currently hold cybersecurity insurance, the costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses.** ~~Risks~~ **77Risks** Related to our Common StockFuture sales of our common stock or securities convertible into our common stock in the public market could cause our stock price to fall. Our stock price could decline as a result of sales of a large number of shares of our common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. As of March ~~11~~ **10** , ~~2024~~ **2025** , ~~76~~ **85** , ~~027~~ **298** , ~~776~~ **537** shares of our common stock were outstanding, of which ~~58~~ **77** , ~~990~~ **091** , ~~106~~ **301** shares of common stock, or ~~77~~ **90** . ~~6~~ **4** % of our outstanding shares as of March ~~11~~ **10** , ~~2024~~ **2025** , are freely tradable without restriction or further registration under the Securities Act ~~of 1933~~ , ~~as amended~~ **provided however** , ~~or~~ **some of these shares are held by persons deemed to be " affiliates " under** the Securities Act, **including** ~~unless held by~~ our ~~" affiliates~~ **officers and directors** , ~~"~~ as ~~that term is defined~~ **well as our principal stockholders, and may not be sold except: (i)** in **compliance with** Rule 144 under the Securities Act **or** (**ii** ~~" Rule 144 "~~) **pursuant to any other applicable exemption under the Securities Act** . The ~~resale of the~~ remaining ~~17~~ **8** , ~~037~~ **207** , ~~670~~ **236** shares held by our stockholders as of March ~~11~~ **10** , ~~2024~~ **2025 have not been registered under the** ~~is currently prohibited or otherwise restricted as a result of securities~~ **Securities** ~~law provisions~~ **Act and may be only be sold (i) pursuant to an effective registration statement under the Securities Act covering the sale of those shares, (ii) in compliance with Rule 144 under the Securities Act or (iii) pursuant to any other applicable exemption under the Securities Act** . Shares issued upon **purchase under the employee stock purchase plan or upon** the exercise of stock options **or vesting of restricted stock units** outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, any applicable market standoff and lock- up agreements, and Rule 144 and Rule 701 under the Securities Act. ~~As of March 11, 2024, the holders of 9, 210. 134 shares, or 12. 1 %, of our outstanding shares as of March 11, 2024, have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.~~ We have ~~also~~ registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans, including the employee stock purchase plan. **We** ~~Once we register the offer and sale of shares for the holders of registration rights, they can be freely sold in the public market upon issuance or resale (as applicable), subject to lock- up agreements, if any. 59We~~ expect that the market price of our common stock may be volatile, and you may lose all or part of your investment. The trading prices of the securities of pharmaceutical and biotechnology companies have been highly volatile. As such, the trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. The market price for our common stock may be influenced by many factors, including: ● results **and timing of commencement or completion** of any clinical trials of any product candidate we may develop, including L606, or those of our competitors; ● the success of Sandoz' s Treprostinil Injection to which we have commercial rights ~~to~~ pursuant to the Promotion Agreement; ● the market acceptance of the RG Cartridge for the subcutaneous administration of Treprostinil Injection; ● whether ~~Mainbridge is~~ **we and Sandoz are** able to complete the development of a new pump for the subcutaneous administration of Treprostinil Injection and obtain FDA clearance on a timely basis or at all; ● our cash resources; ● the approvals or success of competitive products or technologies; ● potential approvals of any product candidate we may develop, including YUTREPIA and L606, for marketing by the FDA or equivalent foreign regulatory authorities **(and, if approved, the scope of the indications for which such product candidates are approved)** or any failure to obtain such approvals; ● our involvement in significant lawsuits, such as stockholder litigation, litigation involving the FDA, including the **New** FDA Litigation, or ~~patent~~ litigation **related to intellectual property** , including inter partes review proceedings and Hatch- Waxman litigation with originator companies or others which may hold patents, including the ongoing litigation in connection with the patents **, trade secrets and confidential information** that United Therapeutics has asserted against us; ● regulatory or legal developments in the United States and other countries; **78** ● the results of our efforts to commercialize any product candidate we may develop, including YUTREPIA and L606, in the event we receive final approval from the FDA; ● developments or disputes concerning 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; ● the results of our efforts to discover, develop, acquire or in- license additional product candidates or products; ● actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; ● variations in our financial results or those of companies that are perceived to be similar to us; ● changes in the structure of healthcare payment systems; ● market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations; ● general economic, industry and market conditions; and ● the other factors described in this " Risk Factors " section. The stock market in general, and market prices for the securities of pharmaceutical companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In several recent situations when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results. ~~60Our~~ -- **Our** principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval. Our executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned ~~38~~ **26** . ~~9~~ **2** % of our ~~capital~~ **common** stock as of March ~~1~~ **10** , ~~2024~~ **2025** . Accordingly, our executive officers, directors and principal stockholders have significant influence in determining the composition of our board of directors (the " Board "), and voting on all matters requiring stockholder approval, including mergers and other business combinations, and continue to have significant influence over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us that you may believe are in your best interests as one of our stockholders. This in turn could have a material adverse effect on our stock price and may prevent attempts by our stockholders to replace or remove the Board or management. As a public company, we are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to do so may adversely affect investor confidence in us and, as a result, the trading price of our shares. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. In addition, any future testing by us conducted in connection with Section 404 of the Sarbanes- Oxley Act of 2002, as amended (the " Sarbanes- Oxley Act ") or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. ~~As~~ **79As** required by the Sarbanes Oxley Act and commencing with the fiscal year ended December 31, 2019, we were required to furnish a report by management on, among other things, the effectiveness of our internal controls over financial reporting. See Item 4. Controls and Procedures for additional information **. Because we are a " smaller reporting company, " we may take advantage of certain scaled disclosures available to us, resulting in holders of our securities receiving less Company information than they would receive from a public company that is not a smaller reporting company. We are a " smaller reporting company " as defined under Rule 12b- 2 of the Exchange Act. As a smaller reporting company, we may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our common stock held by non- affiliates is less than $ 250 million measured on the last business day of our second fiscal quarter, or (ii) our annual revenue is less than $ 100 million during the most recently completed fiscal year and our common stock held by non- affiliates is less than $ 700 million measured on the last business day of our second fiscal quarter. Based on the closing price of our common stock on June 30, 2024 we will remain a smaller reporting company through at least the end of 2025. To the extent we take advantage of any reduced disclosure obligations, it may make it harder for investors to analyze the Company' s results of operations and financial prospectus in comparison with other public companies. As a smaller reporting company, we are permitted to comply with scaled- back disclosure obligations in our SEC filings compared to other issuers, including with respect to disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We have elected to adopt the accommodations available to smaller reporting companies. Until we cease to be a smaller reporting company, the scaled- back disclosure in our SEC filings will result in less information about our company being available than for other public companies. If investors consider our common stock less attractive as a result of our election to use the scaled- back disclosure permitted for smaller reporting companies, there may be a less active trading market for our common stock and our share price may be more volatile** . Anti- takeover provisions in our charter documents and under Delaware law could make an acquisition of us difficult, limit attempts by our stockholders to replace or remove our current management and adversely affect our stock price. Provisions of our certificate of incorporation and bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our stock. Among other things, the certificate of incorporation and bylaws: ● permit the Board to issue up to 10 million shares of preferred stock, with any rights, preferences and privileges as they may designate; ● provide that the authorized number of directors may be changed only by resolution of our Board; ● provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

● require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be taken by written consent; ● create a staggered board of directors such that all members of our Board are not elected at one time; ● allow for the issuance of authorized but unissued shares of our capital stock without any further vote or action by our stockholders; and ● establish advance notice requirements for nominations for election to the Board or for proposing matters that can be acted upon at stockholders' meetings. ~~61In~~ **In** addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (" DGCL ") which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any stockholder owning in excess of 15 % of our outstanding stock for a period of three years following the date on which the stockholder obtained such 15 % equity interest in us. ~~The~~ **80The** terms of our authorized preferred stock selected by our Board at any point could decrease the amount of earnings and assets available for distribution to holders of our common stock or adversely affect the rights and powers, including voting rights, of holders of our common stock without any further vote or action by the stockholders. As a result, the rights of holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued by us in the future, which could have the effect of decreasing the market price of our common stock. Any provision of our certificate of incorporation or bylaws or Delaware corporate law that has the effect of delaying or deterring a change in control could limit opportunities for our stockholders to receive a premium for their shares of common stock, and could also affect the price that investors are willing to pay for our common stock. Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees. Our certificate of incorporation provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws; or (iv) any action asserting a claim against us governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Securities Act or Exchange Act. Furthermore, our bylaws designate the federal district courts of the United States as the 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 is deemed to have received notice of and consented to the foregoing provisions. This choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds more favorable for disputes with us or our directors or officers, which may discourage such lawsuits against us and our directors or officers. Alternatively, if a court were to find this choice of forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition, prospects or results of operations. Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. We have never declared or paid cash dividends on our equity securities. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of our existing ~~RIFA with~~ HCR **Agreement** preclude us, and the terms of any future debt or financing agreement may preclude us, from paying dividends. As a result, capital appreciation, if any, of our equity securities will likely be your sole source of gain for the foreseeable future. An impairment of our long- lived contract acquisition costs and intangible assets, including goodwill, could have a material non- cash adverse impact on our results of operations. In connection with the accounting for our RareGen acquisition, we have recorded significant amounts of contract acquisition costs, intangible assets, and goodwill. Under GAAP, we must assess, at least annually and potentially more frequently, whether the value of goodwill has been impaired. Contract acquisition costs and amortizing intangible assets will be assessed for impairment in the event of an impairment indicator. The valuation of goodwill depends on a variety of factors, the success of **our** ~~the Company' s~~ business, including our ability to obtain regulatory approval for YUTREPIA, ~~62global~~ -- **global** market and economic conditions, earnings growth and expected cash flows. Impairments may be caused by factors outside **our** ~~the Company' s~~ control, such as actions by the FDA, increasing competitive pricing pressures, and various other factors. Significant and unanticipated changes or our inability to obtain or maintain regulatory approvals for our product candidates, including the NDA for YUTREPIA, could require a non- cash charge for impairment in a future period, which may significantly affect our results of operations in the period of such charge. **81** ~~General Risk FactorsGeneral Risks Related to the Commercialization of our Product CandidatesOur business and operations may be adversely affected by the effects of health epidemics, including the COVID- 19 pandemic. Our business and operations could be adversely affected by health epidemics in regions where we have offices, manufacturing facilities, concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of clinical trial sites, contract manufacturers or suppliers and contract research organizations upon whom we rely. For example, starting in December 2019, a novel strain of the coronavirus (" COVID- 19 ") was reported to have surfaced in Wuhan, China and spread to multiple countries, including the U. S. and several European countries. In March 2020, the World Health Organization declared COVID- 19 a global pandemic and the U. S. declared the COVID- 19 pandemic a national emergency. The COVID- 19 pandemic has resulted in travel and other restrictions in order to reduce the spread of the disease, including state and local orders across the United States that, among other things, directed individuals to shelter at their places of residence, directed businesses and governmental agencies to cease non- essential operations at physical locations, prohibited certain non- essential gatherings and events and ordered cessation of non- essential travel. Throughout 2020 and 2021, similar executive orders were issued by state and local governments, and states of emergency had been declared at the state and local level in most jurisdictions throughout the U. S. As recently as April 2022, ports and airports in Shanghai, China have been closed due to another outbreak of COVID- 19, resulting in a lockdown of the~~

city and disruption to export and import activities. In the U. S., many of these executive orders have been rescinded, however, we remain vigilant and continue to monitor the ongoing COVID- 19 pandemic closely to determine if additional actions are required. Remote work policies, quarantines, shelter- in- place and similar government orders, shutdowns or other restrictions on the conduct of business operations related to the COVID- 19 pandemic may negatively impact productivity and our research and development activities, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. In addition, although our employees are accustomed to working remotely, changes in internal controls due to remote work arrangements may result in control deficiencies in the preparation of our financial reports, which could be material. Such orders may also impact the availability or cost of materials, which would disrupt our supply chain and could affect our ability to conduct ongoing and planned clinical trials and preparatory activities. The extent to which the COVID- 19 pandemic impacts our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence at the time of this Annual Report on Form 10- K, such as the severity and duration of future outbreaks (including from the spread of COVID- 19 variants or mutant strains), the duration and effect of business disruptions and the short- term effects, the administration, availability and efficacy of vaccination programs and the ultimate effectiveness of travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease. We expect the impact of COVID- 19 on the FDA' s operations will continue to evolve. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects. In addition, to the extent the COVID- 19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this " Risk Factors " section and the " Risk Factors " sections of the documents incorporated by reference herein. 63We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability. Our business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting geopolitical tensions. U. S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine. In February 2022, a full- scale military invasion of Ukraine by Russian troops began. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine has led to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain interruptions, which has contributed to periods of high inflation globally. We are continuing to monitor inflation, the situation in Ukraine and global capital markets and assessing its potential impact on our business. The global economy has been, and may continue to be, negatively impacted by Russia' s invasion of Ukraine. As a result of Russia' s invasion of Ukraine, the U. S., the European Union, the United Kingdom, and other G7 countries, among other countries, have imposed substantial financial and economic sanctions on certain industry sectors and parties in Russia. Broad restrictions on exports to Russia have also been imposed. These measures include: (i) comprehensive financial sanctions against major Russian banks; (ii) additional designations of Russian individuals with significant business interests and government connections; (iii) designations of individuals and entities involved in Russian military activities; and (iv) enhanced export controls and trade sanctions limiting Russia' s ability to import various goods. Russian military actions and the resulting sanctions could continue to adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds. In addition, on October 7, 2023, Hamas militants and members of other terrorist organizations infiltrated Israel' s southern border from the Gaza Strip and conducted a series of terror attacks on civilian and military targets. Thereafter, Hamas launched extensive rocket attacks on Israeli population and industrial centers located along the Israeli border with the Gaza Strip. Shortly following the attack, Israel' s security cabinet declared war against Hamas and launched an aerial bombardment of various targets within the Gaza Strip. The Israeli government subsequently called for the evacuation of over one million residents of the northern part of the Gaza Strip and initiated ground operations in the Gaza Strip. It is possible that other terrorist and / or regional organizations will join the hostilities as well, including Hezbollah in Lebanon, and Palestinian military organizations in the West Bank, resulting in a widening of the conflict. The intensity and duration of Israel' s current war against Hamas is difficult to predict as are such war' s economic implications on the global economy. Furthermore, because of current geopolitical tensions, the Biden administration has recently signed multiple executive orders regarding China. One particular executive order titled Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy, signed on September 12, 2022, will likely impact the pharmaceutical industry to encourage U. S. domestic manufacturing of pharmaceutical products. Moreover, there have been Congressional legislative proposals, such as the recent bill titled the Biosecure Act, to discourage contracting with Chinese companies on the development or manufacturing of pharmaceutical products. Any additional executive orders or legislative action regarding or potential sanctions on China could materially impact our current manufacturing partners. Although our business has not been materially impacted by these geopolitical tensions to date, such matters may affect our business and it is impossible to predict the extent to which our operations, or those of our suppliers and manufacturers, will be impacted in the short and long term, or the ways in which such matters may impact our business. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict but could be substantial. Any such disruptions may also magnify the impact of other risks described herein. 64If the FDA or comparable regulatory authorities in other countries approve generic versions of our product candidates, or do not grant our product candidates a sufficient period of market exclusivity before approving their generic versions, our ability to generate revenue may be adversely affected. Once an NDA is approved, the drug product covered will be listed as a reference listed drug in the FDA' s Orange Book. In the United States, manufacturers of drug products may seek approval of generic versions of reference listed drugs through the submission of abbreviated new drug applications, or ANDAs. In support of an

ANDA, a generic manufacturer is generally required to show that its product has the same active pharmaceutical ingredient (s), dosage form, strength, route of administration and conditions of use or labeling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug. Generic drug products may be significantly less expensive to bring to market than the reference listed drug, and companies that produce generic drug products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug product, a significant percentage of the sales of any reference listed drug may be lost to the generic drug product. The FDA will not approve an ANDA for a generic drug product until the applicable period of market exclusivity for the reference listed drug has expired. The applicable period of market exclusivity varies depending on the type of exclusivity granted. A grant of market exclusivity is separate from the existence of patent protection and manufacturers may seek to launch generic versions of our drug products following the expiry of their respective marketing exclusivity periods, even if our drug products are still under patent protection at the relevant time. Any competition that our product candidates may face, if and when such product candidates are approved for marketing and commercialized, from generic versions could substantially limit our ability to realize a return on our investment in the development of our product candidates and have a material and adverse effect on our business and prospects. We are subject to risks related to information technology systems, including cyber- security risks; successful cyber- attacks or technological malfunctions can result in, among other things, financial losses, the inability to process transactions, the unauthorized release of confidential information and reputational risk, all of which would negatively impact our business, financial condition or results of operations. Our use of technology is critical to our continued operations. We are susceptible to operational, financial and information security risks resulting from cyber- attacks or technological malfunctions. Successful cyber- attacks or technological malfunctions affecting us, our CMOS or our business partners can result in, among other things, financial losses, the inability to process transactions, the unauthorized release of confidential or proprietary information and reputational risk. As cybersecurity threats continue to evolve, we may be required to use additional resources to continue to modify or enhance protective measures or to investigate security vulnerabilities, which could have a material adverse effect on our business, financial condition or results of operations. General Risks Related to the Development and Regulatory Approval of our Product CandidatesEven if we obtain marketing approval for our product candidates in the United States, we or our collaborators may not obtain marketing approval for the same product candidates elsewhere. We may enter into strategic collaboration arrangements with third parties to commercialize our product candidates outside of the United States. In order to market any product candidate outside of the United States, we or our collaborators will be required to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be recognized or accepted by regulatory authorities in other countries, and obtaining marketing approval in one country does not mean that marketing approval will be obtained in any other country. Approval processes vary among countries and additional product testing and validation, or additional administrative review periods, may be required from one country to the next. Seeking marketing approval in countries other than the United States could be costly and time- consuming, especially if additional preclinical studies or clinical trials are required to be conducted. We currently do not have any product candidates approved for sale in any jurisdiction, including non- U. S. markets, and we do not have experience in obtaining marketing approval in non- U. S. markets. We currently also have not identified any collaborators to market our products 65outside of the United States and cannot assure you that such collaborators, even if identified, will be able to successfully obtain marketing approval for our product candidates outside of the United States. If we or our collaborators fail to obtain marketing approval in non- U. S. markets, or if such approval is delayed, our target market may be reduced, and our ability to realize the full market potential of our products will be adversely affected. General Risks Related to Healthcare RegulationThe pharmaceutical industry is subject to a range of laws and regulations in areas including healthcare program requirements and fraud, waste, and abuse; healthcare and related marketing compliance and transparency; and privacy and data security. Our failure to comply with these laws and regulations as they are, or in the future become, applicable to us may have an adverse effect on our business. Healthcare providers, physicians and third- party payors often play a primary role in the recommendation and prescription of any drug products for which we may obtain marketing approval, or for which we may provide contracted promotional services to third parties. Our current and future arrangements with healthcare providers, physicians, third- party payors and customers, and our sales, marketing and educational activities, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations (at the federal and state level) that may constrain our business or financial arrangements and relationships through which we market, sell, or distribute drug products. In addition, we may be subject to transparency laws and patient privacy regulation by both the federal government and the states in which we conduct our business. We also plan to conduct clinical trials and may in the future conduct business in jurisdictions outside of the United States, which may cause us to become subject to transparency law and privacy regulations in those jurisdictions as well. The laws that may affect our ability to operate include, but are not limited to, the following examples: ● The federal Anti- Kickback Statute, or AKS, prohibits, among other things, persons and entities including pharmaceutical manufacturers from, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, 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, or order of, or the arranging for an item or service for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs. ● The federal civil and criminal false claims laws and civil monetary penalty laws impose a range of prohibitions and compliance considerations. For example, the False Claims Act, or the FCA, prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to, or approval by, the federal government that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. Claims resulting from a violation of the federal AKS constitute a false or fraudulent claim for purposes of the FCA. Promotion that is deemed to be " off label " can be the basis of FCA exposure. ● Federal law includes provisions (established under the Health Insurance

Portability and Accountability Act of 1996) addressing healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Violations of these statutes is a felony and may result in fines, imprisonment or exclusion from governmental programs. ● Privacy and data security laws may apply to our business. Under Section 5 (a) of the Federal Trade Commission Act, the Federal Trade Commission expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of 66its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. States may also impose requirements, for example the California Consumer Privacy Act created data privacy obligations for covered companies and providing privacy rights to California residents, including the right to opt out of certain disclosures of their information. In addition, if we engage in business activities outside of the United States, including clinical trials that we plan to conduct outside of the United States, we may become subject to privacy and data security laws in those additional jurisdictions in which we operate or conduct clinical trials. ● The federal physician payment transparency requirements, sometimes referred to as the " Physician Payments Sunshine Act, " requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under government healthcare programs to annually report to the Centers for Medicare and Medicaid Services, or the CMS, information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Payments and transfers of value made to certain other providers such as nurse practitioners and physician assistants will also need to be reported under the Sunshine Act. ● For both investigational and commercialized products, interactions with or communications directed to healthcare professionals, patients or patient- or disease- advocates or advocacy groups, and payors, are subject to heightened scrutiny by the FDA. Relative to nonpromotional communications, for example, there are specific and limited FDA accommodations for nonpromotional, truthful and non- misleading sharing of information regarding products in development and off- label uses including dissemination of peer- reviewed reprints, support of independent continuing medical education, and healthcare economic discussions with payors. In a competitive environment, a company' s communications about products in development may also be subject to heightened scrutiny. ● Analogous state laws and regulations, such as state anti- kickback and false claims laws, may apply to items or services reimbursed by any third- party payor, including commercial insurers, and in some cases may apply regardless of payor (i. e., even for self- pay scenarios). Some state laws require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report pricing and marketing information, including, among other things, information related to payments to physicians and other healthcare providers or marketing expenditures, state and local laws that require the registration of pharmaceutical sales representatives. Many of these state laws differ from each other in significant ways and may not have the same effect, and may apply more broadly or be stricter than their federal counterparts, thus complicating compliance efforts; and ● Price reporting laws require the calculation and reporting of complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursements or discounts on our drug products. Participation in such programs and compliance with their requirements may subject us to increased infrastructure costs and potentially limit our ability to price our drug products. Ensuring that our business and business arrangements with third parties comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource- consuming and can divert management' s attention from the business, even if the government ultimately finds that no violation has occurred. If our operations are found to be in violation of any of the laws or regulations described above or any other laws or government regulations that apply to us, we may be subject to penalties and potentially, the curtailment or restructuring of our operations as well as additional governmental reporting obligations and oversight, any of which could adversely affect our ability to operate our business and our results of operations. 67Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our products and product candidates and affect the prices we may obtain. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA, is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our product candidates are the following: ● establishment of a new pathway for approval of lower- cost biosimilars to compete with biologic products; ● an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents; ● an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; ● a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point- of- sale discounts off negotiated prices; ● extension of manufacturers' Medicaid rebate liability; ● expansion of eligibility criteria for Medicaid programs; ● expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; ● a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and ● a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA.

On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, enacted in August 2011, required sequestration that included aggregate reductions of Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2032, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will increase in future years of the sequester. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and an increase in the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, in March 2021, the American Rescue Plan Act of 2021 was signed into law, which, among other things, eliminated the statutory cap on drug manufacturers' Medicaid Drug Rebate Program rebate liability, effective January 1, 2024. Under current law enacted as part of the ACA, drug manufacturers' Medicaid Drug Rebate Program rebate liability is capped at 100 % of the average manufacturer price for a covered outpatient drug. We expect that other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price 68that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to price our products at what we consider to be a fair or competitive price, generate revenue, attain profitability, or commercialize our product candidates, if approved. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Individual states in the United States have become increasingly active in implementing regulations designed to contain pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Most significantly, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation; and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. In response to the executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our ability to price our products appropriately, which could negatively impact 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, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects. 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 or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. General Risks Related to Our Dependence on Third PartiesWe rely on third parties to conduct our preclinical studies and clinical trials. We currently rely on, and plan to continue to rely on, third- party contract research organizations, or CROs, to monitor and manage data for our preclinical studies and clinical trials. However, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable regulatory standards and our reliance on CROs does not relieve us of our regulatory responsibilities. The CROs on which we rely are required to comply with FDA regulations (and the regulations of comparable regulatory authorities in other countries) regarding GCP. Regulatory authorities enforce GCP standards through periodic inspections. If any of the CROs on which we rely fail to comply with the applicable GCP standards, the clinical data generated in our clinical trials may be deemed unreliable. While we have contractual agreements with these CROs, we have limited influence over their actual performance and cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical trials. A failure to comply with the applicable regulations in the conduct of the preclinical studies and clinical trials for our product candidates may require us to repeat such studies or trials, 69which would delay the process of obtaining marketing approval for our product candidates and have a material and adverse effect on our business and prospects. Some of our CROs have the ability to terminate their respective

agreements with us if, among others, it can be reasonably demonstrated that the safety of the patients participating in our clinical trials warrants such termination. If any of our agreements with our CROs is terminated, and if we are not able to enter into agreements with alternative CROs on acceptable terms or in a timely manner, or at all, the clinical development of our product candidates may be delayed and our development expenses could be increased. General Risks Related to Legal Compliance MattersEven if we obtain regulatory approval for a product candidate, our products and business will remain subject to ongoing regulatory obligations and review. If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, drug supply chain security surveillance and tracking, advertising, promotion, sampling, record- keeping, conduct of post- marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and comparable requirements outside of the United States. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Any regulatory approvals that we may receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our product candidates, 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 minimization tools. We will also be required to report certain adverse reactions and production problems, if any, to the FDA or other regulatory agencies and to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product' s approved label. As such, we may not promote our products for indications or uses for which they do not have FDA or other regulatory agency approval. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post- marketing clinical studies to verify the safety and efficacy of our product candidates in general or in specific patient subsets. An unsuccessful post- marketing study or failure to complete such a clinical study could result in the withdrawal of marketing approval. Furthermore, any new legislation addressing drug safety issues could result in delays in product development or commercialization or increased costs to assure compliance. Foreign regulatory authorities impose similar requirements. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things: ● issue warning letters asserting that we are in violation of the law; ● seek an injunction or impose civil or criminal penalties or monetary fines; ● suspend or withdraw regulatory approval; ● suspend any of our ongoing clinical trials; ● refuse to approve pending applications or supplements to approved applications submitted by us or our strategic partners; ● restrict the marketing or manufacturing of our products; ● seize or detain products, or require a product recall; ● refuse to permit the import or export of our product candidates; or ● refuse to allow us to enter into government contracts. 70Any 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 revenue from our product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. 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. 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 and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. Environmental, social and governance matters may impact our business and reputation. Governmental authorities, non- governmental organizations, customers, investors, external stakeholders and employees are increasingly sensitive to environmental, social and governance, or ESG, concerns, such as diversity and inclusion, climate change, water use, recyclability or recoverability of packaging, and plastic waste. This focus on ESG concerns may lead to new requirements that could result in increased costs associated with developing, manufacturing and distributing our products. Our ability to compete could also be affected by changing customer preferences and requirements, such as growing demand for more environmentally friendly products, packaging or supplier practices, or by failure to meet such customer expectations or demand. While we strive to improve our ESG performance, we risk negative stockholder reaction, including from proxy advisory services, as well as damage to our brand and reputation, if we do not act responsibly, or if we are perceived to not be acting responsibly in key ESG areas, including equitable access to medicines and vaccines, product quality and safety, diversity and inclusion, environmental stewardship, support for local communities, corporate governance and transparency, and addressing human capital factors in our operations. If we do not meet the ESG expectations of our investors, customers and other stakeholders, we could experience reduced demand for our products, loss of customers, and other negative impacts on our business and results of operations. Climate change or legal, regulatory or market measures to address climate change may negatively affect our business, results of operations, cash flows and prospects. We believe that climate change has the potential to negatively affect our business and results of operations, cash flows and prospects. We are exposed to physical risks (such as extreme weather conditions or rising sea levels), risks in transitioning to a low- carbon economy (such as additional legal or regulatory requirements, changes in technology, market risk and reputational risk) and social and human effects (such as population dislocations and harm to health and well- being) associated with climate change. These risks can be either acute (short- term) or chronic (long- term). The adverse impacts of climate change include

increased frequency and severity of natural disasters and extreme weather events such as hurricanes, tornados, wildfires (exacerbated by drought), flooding, and extreme heat. Extreme weather and sea- level rise pose physical risks to our facilities as well as those of our suppliers. Such risks include losses incurred as a result of physical damage to facilities, loss or spoilage of inventory, and business interruption caused by such natural disasters and extreme weather events. Other potential physical impacts due to climate change include reduced access to high- quality water in certain regions and the loss of biodiversity, which could impact future product development. These risks could disrupt our operations and its supply chain, which may result in increased costs. New legal or regulatory requirements may be enacted to prevent, mitigate, or adapt to the implications of a changing climate and its effects on the environment. These regulations, which may differ across jurisdictions, could result in us being subject to new or expanded carbon pricing or taxes, increased compliance costs, restrictions on greenhouse gas emissions, investment in new technologies, increased carbon disclosure and transparency, upgrade of facilities to meet new building codes, and the redesign of utility systems, which could increase our operating costs, including the cost of electricity and energy used by us. Our supply chain would likely be subject to these same transitional risks and would likely pass along any increased costs to us. 71General Risks Related to our Intellectual PropertyWe may become involved in litigation to protect our intellectual property or enforce our intellectual property rights, which could be expensive, time- consuming and may not be successful. Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, we may engage in litigation to, among others, enforce or defend our intellectual property rights, determine the validity or scope of our intellectual property rights and those of third parties, and protect our trade secrets. Such actions may be time- consuming and costly and may divert our management' s attention from our core business and reduce the resources available for our clinical development, manufacturing and marketing activities, and consequently have a material and adverse effect on our business and prospects, regardless of the outcome. In addition, in an infringement proceeding, a court may decide that a patent owned by, or licensed to, us is invalid or unenforceable, or may refuse to stop the other party from using the technology in question on the ground that our patents do not cover such technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that our confidential information may be compromised by disclosure. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. While various extensions may be available, the life of a patent, and 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. We intend to seek extensions of patent terms in the United States and, if available, in other countries where we prosecute patents. In the United States, the Hatch- Waxman Act permits patent owners to request a patent term extension, based on the regulatory review period for a product, of up to five years beyond the normal expiration of the patent, which is limited to one patent claiming the approved drug product or use in an indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO, in the United States, and comparable regulatory authorities 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 grant more limited extensions than we had requested. In such event, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our preclinical and clinical data in their marketing approval applications with the FDA to launch their drug product earlier than might otherwise be the case. General Risks Related to the Manufacturing of our Product CandidatesOur facilities are subject to extensive and ongoing regulatory requirements and failure to comply with these regulations may result in significant liability. Our company and our facilities are subject to payment of fees, registration and listing requirements, ongoing review and periodic inspections by the FDA and other regulatory authorities for compliance with quality system regulations, including the FDA' s cGMP requirements. These regulations cover all aspects of the manufacturing, testing, quality control and record- keeping of our drug products. Furthermore, the facilities where our product candidates are manufactured may be subject to additional inspections by the FDA before we can obtain final marketing approval and remain subject to periodic inspection even after our product candidates have received marketing approval. Suppliers of components and materials, such as active pharmaceutical ingredients, used to manufacture our drug products are also required to comply with the applicable regulatory standards. The manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We and any contract 72