Risk Factors Comparison 2025-03-05 to 2024-03-05 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

Investing in our common stock involves significant risk and investors should carefully consider the risks described below, together with all other information included or referenced in this Annual Report on Form 10- K. There are numerous and varied risks, known and unknown, that may prevent us from achieving our goals. The risks described below are not the only ones we will face. In addition to the other information in this Annual Report on Form 10- K, any of the factors set forth below could significantly and negatively affect our business, financial condition, results of operations or prospects and the trading price of our stock. This section contains forward- looking statements. You should refer to the explanation of the qualifications and limitations on forward- looking statements at the beginning of this Annual Report on Form 10- K ~~. The dollar amounts presented in this section are depicted in thousands~~ . Summary of Risk Factors Material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, those relating to: • we may need to raise substantial funds in the future to fund our operations. These funds may not be available on acceptable terms or at all and our ability to fund the execution of our business objectives cannot be assured. A failure to obtain this necessary capital when needed could force us to delay, limit, scale back or cease some or all operations. • we have incurred significant operating losses since inception and cannot assure you that we will ever achieve or sustain profitability; • we may fail to obtain regulatory approvals to market our products in the United States or in other countries; • ~~the failure to overcome a present stay on~~ Libervant ~~entering~~ **for ARS patients aged between two and five years being blocked from remaining in** the U. S. market due to a competitor' s orphan drug market exclusivity status; • the development of pharmaceutical products involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product; • if our competitors are better able to develop products for the diagnosis and treatment of diseases of the central nervous system and the treatment for anaphylaxis that are safer, more effective, less costly, easier to use or otherwise more attractive than our PharmFilm technology, our business will be adversely impacted; • even if our product candidates are approved for commercial sale, if we are unable to develop a sales and marketing infrastructure, we may not be successful in commercializing our products in the United States; • our ability to commercialize our product candidates will depend in part on the extent to which reimbursement will be available from government and health administration authorities, private health maintenance organizations and health insurers, and other healthcare payors; • any delays or changes to the timing, cost and success of clinical trials for Anaphylm and our other product candidates; • failure to generate sufficient data in our PK and PD comparability submission for FDA approval of Anaphylm; ~~• data in our PK and PD comparability as submitted to the FDA for approval of Libervant two to five years is insufficient;~~ • we have entered into, and may enter into collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships with third- parties that may not result in the development of commercially viable products or the generation of significant future revenues; • we are and will be dependent on third- party CROs to conduct all of our clinical trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated and we may not be able to obtain regulatory approval for any of our product candidates; • our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel; • our ability to protect our intellectual property and proprietary technology is uncertain; • we may be subject to damages resulting from claims that we, or our colleagues, have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non- competition or non- solicitation agreements with our competitors; • our products and operations are subject to extensive governmental regulation, and failure to comply with applicable requirements could cause our business to suffer; • if we issue more shares of our Common Stock to raise capital, our current stockholders will incur substantial dilution; • we may be subject to damages resulting from litigation matters currently pending against Aquestive; • cybersecurity continues to affect businesses and could cause business interruption; ~~• our business and operations may be adversely affected by the COVID- 19 pandemic;~~ and • adverse developments affecting the financial services industry which could adversely affect our current and projected business operations and our financial condition and results of operations. Risks Related to Our Financial Condition and Need for Additional Capital We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability. Some of our product candidates will require substantial additional development time and resources before we are able to receive regulatory approvals, implement commercialization infrastructure and strategies, or license product out to begin generating revenue from product sales or royalty streams. Our current product candidates are still in their early stages, and we may not generate substantial revenue from sales or royalties of our product candidates in the near term, if ever. We have devoted most of our financial resources to product development. To date, we have financed our operations primarily through the sale of equity and debt securities, proceeds from our debt facilities, and from revenues from certain product licenses and collaborations. The extent of future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenue. The development, regulatory approval process, and commercialization of drug candidates involve significant risk and significant uncertainty, including matters over which we have no control. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to fully predict the timing or amount of our expenses. We expect to incur substantial expenses going forward, which we expect will increase as we expand our development activities and product portfolio. Some of the

expenses we expect to incur going forward include: • conducting clinical trials of our product candidates; • seeking regulatory approval for any of our product candidates that successfully complete clinical development; • maintaining, expanding and protecting our intellectual property portfolio; • acquiring or in- licensing new technologies or development- stage or approved products; • activities related to pre- commercialization **and commercialization** of products; • adding clinical, scientific, operational, financial, and management information systems personnel, including personnel to support our product development and to support our operations as a public company; and • experiencing incremental costs due to delays or encountering any issues with any of the above, including, but not limited to, failed or not fully successful trials, complex results, safety issues or other regulatory challenges. We expect to continue to incur net losses for at least the next few years as we pursue the development efforts and commercialization of our product candidates. Our net losses may fluctuate significantly from period to period, depending on regulatory approval developments concerning our product candidates, the timing of our planned clinical trials and expenditures on our other research and development. We expect our expenses will continue to be substantial in ~~2024~~ **2025** and future periods as we continue to: • ~~continue to~~ clinically develop Anaphylm and provide supporting data needed for market approval from the FDA **, anticipated NDA submission, pre- commercialization preparations including manufacturing and regulatory inspections and commercialization activities** ; • ~~continue to~~ seek licensing and other transactions of our product candidates; ~~and~~ • ~~continue to~~ engage with the FDA to overcome the present stay on Libervant entering the U. S. market due to a competitor' s orphan drug market exclusivity status **: • commercialize Libervant for ARS patients between two and five years of age; and • clinical development of our product candidate AQST- 108** . We expect to continue to manage the timing and level of expenses in light of the declining Suboxone revenues, while focusing on the development and commercialization of Anaphylm . Until we become profitable, if..... milestones may harm our future capital position . We will need substantial additional capital to fund our operations, which may not be available on acceptable terms, if at all. Our cash requirements for ~~2024~~ **2025** and beyond include expenses related to continuing development and clinical evaluation of our products, manufacture and supply costs, costs of regulatory filings, patent prosecution expenses and litigation expenses, expenses related to commercialization of our products, as well as costs to comply with the requirements of being a public company operating in a highly regulated industry. As of December 31, ~~2023~~ **2024** , we had $ ~~23~~ **71** . ~~9~~ **5** million of cash and cash equivalents. Capital may be available under our ATM facility, which we initially established in 2019, **and** under which, from time to time, we may offer and sell shares of our Common Stock **pursuant to the Amended Equity Distribution Agreement with Piper Sandler & Co** . ~~The~~ **. On April 3, 2024, we filed a new shelf registration statement on Form S- 3 (the" 2024 Registration Statement"), which was declared effective by the SEC on April 23, 2024. Included in the 2024 Registration Statement are: (i) a base prospectus registering the offer, issuance and sale of up to $ 250, 000 worth of Common Stock, preferred stock, debt securities, warrants, rights and units and (ii) the $ 100, 000** ATM facility ~~has approximately~~ **prospectus. The remaining authorized balance of the ATM facility was** $ **100, 000 as** ~~24. 0 million worth~~ of ~~shares of Common Stock available at~~ December 31, ~~2023~~ **2024 . For additional information regarding shares sold under the ATM facility subsequent to December 31, 2024, see Management' s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources and Part II Item 8. Financial Statements and Supplementary Data, Note 24, Subsequent Events** . In April 2022, we entered into a Purchase Agreement with Lincoln Park, under which, from time to time, we may cause Lincoln Park to purchase shares of our Common Stock. The Purchase Agreement with Lincoln Park has approximately an equivalent to 6, 486, 623 shares ~~to~~ **available for** purchase at December 31, **2024. For the years ended December 31, 2024 and** 2023 **, we did not sell shares in connection with the Lincoln Park Purchase Agreement. We have no current intent to use the Lincoln Park facility and the Lincoln Park Purchase agreement will expire on April 12, 2025** . On November 1, 2023, we reduced our debt payment obligations when we issued (the " Offering ") $ 45, 000 aggregate principal amount of our 13. 5 % Notes. A portion of the net proceeds from the Offering was used to redeem all of the outstanding 12. 5 % Notes and to pay expenses relating to the Offering, with the balance of the proceeds to be used for general corporate purposes. Interest on the 13. 5 % Notes accrues at a rate of 13. 5 % per annum and is payable quarterly in arrears on March 30, June 30, September 30 and December 30 of each year (each, a " Payment Date "). The 13. 5 % Notes are interest only until June 30, 2026, whereupon on such date and each Payment Date thereafter, we will also pay an installment of principal of the 13. 5 % Notes pursuant to a fixed amortization schedule, along with a portion of an Exit Fee determined as of the applicable date of prepayment, payment, acceleration, repurchase or redemption, as the case may be. **.** Until we become profitable,if ever,we expect to need to raise significant additional capital in the future through equity or debt issuances,or both,to continue to manage our expenses to extend our capital runway,in order to further the development,and regulatory approval of our products and product candidates,and to conduct our business.We have no committed sources of additional capital,and there can be no assurance that such needed capital or debt financing will be ~~available or~~ available on favorable terms,or at all.We may seek to obtain additional capital in the future through the issuance of our Common Stock,through other public or private equity or debt financings,through potential non- dilutive capital raising events that may result from royalty streams that may be realizable from our licensed products or licensed intellectual property,through collaborations or licensing arrangements with other companies,and through the sale of assets,including product,product candidates,plants or other tangible assets,or by other means,if available.We may not be able to raise additional capital or other funding on terms acceptable to us,or at all,and any failure to raise capital as and when needed could compromise our ability to execute on our business plan and cause us to delay or curtail our operations until such funding is received.To the extent that we raise additional funds by issuance of equity securities,our stockholders would experience dilution,and debt financings,if available (and subject to all of the existing restrictions and conditions under our debt instruments) may involve increased restrictive covenants and increased fixed payments or may otherwise further constrain our financial flexibility. **To the extent** ~~We also may seek outlicensing opportunities for our proprietary products and product candidate programs~~ that we **raise additional funds through collaborative** ~~currently plan to self- commercialize,including for~~ **or licensing arrangements** ~~Libervant and Anaphylm~~ , **it**

may be necessary to relinquish some rights to ~~or~~ **our** ~~explore other~~ **intellectual property or grant licenses on terms that are not favorable to us.In addition,payments made by** potential **collaborators** ~~liquidity options or strategic opportunities.Such strategic opportunities could include asset sales,outlicensing or other monetization opportunities of our~~ **or** ~~proprietary products~~ **licensees generally will depend upon our achievement of negotiated development** and ~~product candidates,including Libervant and Anaphylm,although we cannot assure that any~~ **regulatory milestones.Failure to achieve these milestones may harm our future capital position** If adequate funds are not available for our liquidity needs and cash requirements, as and when needed, from the sources referred to above or otherwise, or at all, we would be required to engage in expense management activities such as reducing staff, delaying, significantly scaling back, or even discontinuing some or all of our current or planned research and development programs and clinical and other product development activities, or reducing our future commercialization efforts and otherwise significantly reducing our other spending and adjusting our operating plan, and we would need to seek to take other steps intended to improve our liquidity. We also may be required to evaluate additional licensing opportunities, if any become available, of our proprietary product candidate programs that we currently plan to self-commercialize or explore other potential liquidity opportunities or other alternatives or options or strategic alternatives, including asset sales, although we cannot assure that any of these actions would be available or available on reasonable terms. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that would likely result in our stockholders losing most, if not all, of their investment in Aquestive. We may sell additional equity, incur debt or raise funds through licensing arrangements to fund our operations, which may result in dilution to our stockholders, impose restrictions on our business or require us to relinquish proprietary rights. Aquestive has experienced a history of net losses and our accumulated deficits totaled $ ~~319~~ **363** . ~~1~~ **2** million as of December 31, ~~2023~~ **2024** . The net losses and accumulated deficits were partially offset by gross margins from sales of commercialized licensed and proprietary products, license fees, milestone and royalty payments from commercial licensees and co- development parties. In November 2020, we began utilizing the ATM facility. For the year ended December 31, ~~2023~~ **2024** , we sold 4, ~~958~~ **557** , ~~341~~ **220** shares which provided net proceeds of approximately $ ~~9~~ **11** . ~~0~~ **8** million, after deducting commissions and other transaction costs of $ 0. ~~5~~ **6** million. ~~This~~ **On April 3, 2024, we filed the" 2024 Registration Statement", which was declared effective by the SEC on April 23, 2024. Included as part of the 2024 Registration Statement are: (i) a base prospectus registering the offer, issuance and sale of up to $ 250, 000 worth of Common Stock, preferred stock, debt securities, warrants, rights and units and (ii) the $ 100, 000** ATM facility ~~has approximately~~ **prospectus. The remaining authorized balance of the ATM facility was** $ **100, 000 as of** ~~24. 0 million available at~~ December 31, ~~2023~~ **2024 . For additional information regarding shares sold under the ATM facility subsequent to December 31, 2024, see Management' s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources and Part II Item 8. Financial Statements and Supplementary Data, Note 24, Subsequent Events** . Until such time, if ever, that we can generate sufficient revenue to fully fund our operations, we would need to seek additional capital and cash resources through public or private equity or debt financings, third- party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the stockholders' existing ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financings may be coupled with an equity component, such as warrants to purchase shares of our common stock, which could also result in dilution of existing stockholders' ownership. The incurrence of additional indebtedness would result in increased fixed payment obligations and could also result in certain increased restrictive covenants (most, if not all, of which currently exist under our existing debt facilities), such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights or sell assets, and other operating restrictions that could adversely impact our ability to conduct our business and continue to result in liens being placed on all of our assets and intellectual property. If we were to default on such indebtedness, we could lose all such assets and intellectual property and our ability to operate our business. If we raise additional funds through collaborations, or strategic alliance, marketing, distribution or licensing arrangements with third parties, we may need to relinquish valuable rights to our technologies, product candidates or future revenue streams or grant licenses on terms that are not favorable to us. Even if we can generate revenues from our operations in the future, our revenues and operating income ~~is~~ **are** likely to fluctuate significantly from year- to- year or quarter- to- quarter and create volatility in our stock price. Even if we are able to generate future revenues, our results of operations would likely continue to vary significantly from year- to- year and quarter- to- quarter. Variations may result from, among other factors: • the timing of FDA or any other regulatory approval, delay in any FDA or other regulatory approvals, or failure to obtain any such FDA or other regulatory approvals; • competitor' s product candidates obtaining FDA or other regulatory approval, which may include orphan drug market exclusivity for seven years in the U. S., before our product has received any such regulatory approval and / or orphan drug exclusivity, or obtaining other FDA marketing exclusivity that blocks U. S. market access for our product candidates; • the timing of process validation for particular product candidates; • the timing of addressing any additional data required to obtain FDA approval of Anaphylm and delays as a result thereof; • changes in the timing of and the amount we spend to research, develop, acquire, license or promote new product candidates; • the timing, amount we spend on, and outcome of our research, development, preclinical studies and clinical trial programs; • serious or unexpected health or safety concerns related to our products or product candidates; • the introduction of new branded and generic products by others that render our product candidates obsolete, subject to greater competition or noncompetitive; • our ability to maintain selling prices and gross margins on our products; • changes in coverage and reimbursement policies of health plans and other health insurers, including changes to Medicare, Medicaid and similar government healthcare programs; • our ability to comply with complex governmental regulations applicable to many aspects of our business; • increases in the cost of raw materials used to manufacture our products and product candidates; • manufacturing and supply interruptions, including product rejections or recalls due to failure to comply with manufacturing

specifications or current Good Manufacturing Practices; • timing of revenue recognition related to our collaboration agreements; • our ability **to fund the commercialization of, commence a commercial operation, and actually commercialize our proprietary products and product candidates, if approved by the FDA; • our ability** and the significant cost to protect our intellectual property and avoid infringing the intellectual property of others and any adverse developments in any related legal proceeding or in other legal proceedings of any nature; and • the outcome and cost of existing or possible future litigation with third parties. Our level of indebtedness and significant debt service obligations could constrain our ability to invest in our business and make it more difficult for us to fund our operations. We have substantial debt and substantial debt service obligations. At December 31, ~~2023~~ **2024** , we had an aggregate principal amount of $ 45. 0 million of outstanding indebtedness, represented by the 13. 5 % Notes. In the future, we will need to raise additional funds. Because of our indebtedness: • we may have difficulty satisfying our obligations with respect to our existing indebtedness including the repayment of such indebtedness; • we may have difficulty obtaining financing in the future (and we have substantial restrictions on incurring any additional indebtedness under our current debt instruments) for working capital, capital expenditures, acquisitions or other purposes; • we will need to use a substantial portion of our available cash flow to pay interest and principal on our debt, which will reduce the amount of money available to finance our operations and other business activities; • we may be more vulnerable to general economic downturns and adverse industry conditions; • if cash flow from revenues from licensed product or collaborative arrangements are insufficient to satisfy our obligations with respect to our existing indebtedness, we may be forced to seek to sell assets (subject to obtaining consent under the Indenture) or seek additional capital, which we may not be able to accomplish on favorable terms, if at all; • we could be limited in our flexibility in planning for, or reacting to, changes in our business and in our industry in general; • we could be placed at a competitive disadvantage compared to our competitors that have less debt, less debt restriction or less restrictive debt covenants; • our failure to comply with the financial and other restrictive covenants in our debt instruments which, among other things, limits our ability to incur additional debt and sell or dispose of assets, could result in an event of default that, if not cured or waived, would have a material adverse effect on our business or prospects; and • our tangible and intangible assets, including our intellectual property, are subject to first priority liens and may be used to satisfy our outstanding debt. We intend to satisfy our current and future debt service obligations with our existing cash and cash equivalents and potential access to other funding. However, we may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under the Indenture and 13. 5 % Notes or any other debt instruments we may enter into. Failure to make required debt service payments or comply with other covenants under our existing debt facilities or such other debt instruments would result in an event of default and acceleration of amounts due, which would have a material adverse effect on our business, financial condition and results of operations. We are dependent upon the commercial success of our licensed **and proprietary** products and other licensing activities to generate revenue for the near future. Although we are in the process of testing and developing proprietary product candidates and may seek to acquire rights in other approved drugs, we anticipate that our ability to generate revenue and to become profitable in the near future will depend upon the continued commercial success of Sympazan, Suboxone ~~, Exservan,~~ and Azstarys in the U. S., the continued commercial success of Ondif in Brazil **and Emylif in the EU** , and our ability to commercialize our product ~~candidate~~ Libervant ~~subject~~ **for pediatric patients between** ~~to~~ **two** ~~FDA approval for U. S. market access, including our ability to overcome the current orphan drug market exclusivity of another approved drug, which is difficult to establish~~ and **five years of** ~~with limited precedent. There can be no assurance that the FDA will agree~~ -- **age** ~~with our position seeking to overcome such market exclusivity and approve Libervant for U. S. market access~~ . Further, there is no assurance that we will become commercially successful to the extent necessary to become profitable. If our current products are not commercially successful, our ability to generate manufacturing and sale margins and licensing or royalty revenues will be impaired. Without those revenues, our ability to continue planned development initiatives and commercialization efforts would be limited. Due to our dependence on the commercial success of our products, delays or setbacks in the commercial success of any of these products would likely materially adversely affect our business, prospects, results and operations and financial consideration. A substantial portion of our revenues is derived from a single customer and license and any loss or material reduction in revenues from such significant customer would adversely affect our business. Historically, a substantial portion of our revenues in each quarter and year has been derived from a single customer and this trend is expected to continue while we continue to develop, seek regulatory approval of and seek to commercialize our proprietary products and product candidates. If revenues from such key customer were to decline significantly, it would materially adversely affect our business, financial condition and results of operations. Indivior accounted for approximately **62 % and** 80 % ~~and 76 %~~ of our revenues for **2024 and** 2023 ~~and 2022~~ , respectively, and we believe in the future will continue to account for a substantial part of our revenues. Further, the Indivior License Agreement under which we manufacture and supply Suboxone to Indivior on an exclusive basis, may be terminated should certain causes or events occur. For example, either party to the Indivior License Agreement may terminate the relationship in connection with a material breach by the other party of its contractual obligations. Indivior may also terminate the Indivior License Agreement if the FDA or other applicable regulatory authority declares our manufacturing site to no longer be suitable for the manufacture of Suboxone or Suboxone is no longer suitable to be manufactured due to health or safety reasons. In addition, the Indivior Licensing Agreement currently has a one-year term, subject to automatic one- year renewals unless either party provides the other party with twelve months' prior notice of non- renewal. As a result, there can be no assurance that either party will not terminate the Indivior License Agreement either due to any future breach of obligation, other termination cause or event, or notice of non- renewal. Any such termination would have a material adverse impact on our business, results of operations, capital position and prospects. Although Suboxone has continued to retain meaningful market share, we expect erosion of this sunsetting branded product over time, which will further affect our total revenues and our results from operations. Indivior is a party to a number of lawsuits alleging Indivior engaged in deceptive and misleading marketing and distribution practices in its distribution and sale of Suboxone and seeking a monetary relief. We cannot assess whether this settlement and disposition will have a material adverse financial impact on our business,

prospects, liquidity, financial condition and operating results. ~~We have been involved in antitrust litigation in connection with the launch of Suboxone and any adverse decisions in such litigation could impair our ability to raise addition capital and significantly harm our business. We were named as a defendant in antitrust litigation brought against us and Indivior. The litigation involves allegations that we have engaged in conduct intended to interfere with the introduction of generic drug products that would compete with Suboxone in the marketplace. On October 19, 2022, the court in that lawsuit entered an order dismissing all claims against Aquestive in the lawsuit. The order dismissing all claims against Aquestive could be appealed by the plaintiffs in the case. We are not able to determine or predict whether the plaintiffs will appeal the order or the ultimate outcome of this proceeding or provide a reasonable estimate or range of estimates of the possible outcome or loss, if any, in this matter. For more information, please see Part II Item 8. Financial Statements and Supplementary Data, Note 22, Contingencies.~~ Risks Related to Development and Commercialization of Our Products and Product Candidates Our business ~~was significantly~~ **could be** adversely affected **if** ~~by the determination by FDA that~~ Libervant ~~is approvable, but not approved for U. S.~~ market access ~~. On September 25, 2020, we received a CRL from the FDA~~ for **ARS patients between** ~~Libervant. The FDA issues a CRL to~~ **two** ~~indicate that the review cycle for an~~ **and** ~~application~~ **five years of age** is **blocked** ~~complete, but the application cannot be approved in its current form. In the CRL, the FDA cited that, in a study submitted by Aquestive with the NDA, certain weight groups showed a lower drug exposure level than desired. In a Type A meeting with the FDA in November 2021, the FDA confirmed that these issues may be addressed by utilizing modeling and simulations for an updated dosing regimen. We resubmitted a revised weight- based dosing regimen with modeling and simulations in December 2020. In February 2021, the FDA provided feedback on the December 2020 submission which provided clarity regarding the information that the FDA expected to see in our population pharmacokinetic (PK) model and safety data as it relates specifically to the patient population included in the studies. In June 2021, we resubmitted our NDA to the FDA. In July 2021, the FDA accepted our resubmission filing of the NDA and assigned a PDUFA target goal date of December 23, 2021. In addition to responding to a number of information requests, the FDA concluded an audit of our post marketing adverse event reporting capabilities, requested and received additional information about the patent coverage for the product, approved for use the trade name for Libervant, and made recommendations for changes in language related to our packaging. Concurrently, we spoke with the FDA Office of Orphan Products Development and provided additional information supplementing our original correspondence to the group. On December 20, 2021, we received notification from the FDA that it was not ready to act by the PDUFA target goal date of December 23, 2021 for our NDA for Libervant Buccal Film and was unable to provide an estimate of the timing of an expected action. On February 15, 2022, the FDA notified us that it was continuing to consider whether the orphan- drug exclusivity granted for another approved product affects the approvability of Libervant and could not provide a specific update regarding timeliness or an anticipated action date for approval of Libervant~~ . On August 30, 2022, the FDA provided an approvable letter for Libervant that stated that Libervant was not cleared for U. S. market access until the orphan drug market exclusivity for Valtoco, a competing **nasal spray** product, ends in January 2027. ~~A company~~ **On April 29, 2024, we announced** that ~~obtains~~ **the** FDA **approved U. S. market access for Libervant in ARS patients between two to five years of age. In May 2024, Neurelis, Inc., the maker of Valtoco, filed a complaint in the U. S. District Court for the District of Columbia against the FDA, HHS, and certain government officials. The complaint in this matter alleges that the defendants violated the Administrative Procedure Act by approving Aquestive' s NDA for Libervant ® for ARS patients aged between two and five years, and asked the court to vacate that** approval **and enjoin the defendants from approving Libervant** for ~~a designated orphan drug receives market exclusivity~~ **this pediatric patient population until January 10, 2027, the scheduled date** for **the expiration of the ODE granted for Valtoco by the FDA. Aquestive intervened in the litigation to defend the approval of Libervant for this pediatric patient population. The Company' s motion for a stay of the District Court' s order granting Neurelis' motion for summary Judgment is pending. The Company also filed an appeal of the District Court' s order with the U. S. District Court of Appeals for the District of Columbia. The Company has also submitted a request to the FDA** that ~~drug for~~ the ~~designated indication~~ **FDA determines that Libervant** for ~~a period~~ **ARS patients between the ages** of ~~seven~~ **two and five** years ~~from the grant date in the United States. This orphan drug exclusivity approval may prevent a subsequent product seeking FDA approval from being marketed in the United States during the exclusivity period for the same active moiety for the same orphan drug indication except in the case where the drug candidate sponsor~~ is ~~able to demonstrate, and the FDA concludes, that the later drug is "~~ clinically superior ~~"~~ to the **existing FDA** approved products ~~(e~~ **. g., safer, more effective, or For** ~~providing a major contribution~~ **greater detail, see Part II Item 8. Financial Statements and Supplementary Data, Note 23, Contingencies** to ~~patient care) within~~ **our financial statements and in Part I Item 1. Business, If Neurelis prevails on** the ~~meaning of~~ **appeal or the** FDA **does** ~~regulations and guidance. In assessing whether a drug candidate sponsor has demonstrated that its drug candidate provides a " major contribution to patient care " over and above the currently approved drugs, which is evaluated by the FDA on a case by case basis, there is no~~ **not** ~~one objective standard and the FDA has determined that~~ **make a determination of clinical superiority in favor of** Libervant **, we may be required** ~~is not" clinically superior"~~ to **withdraw Libervant from the U. S. market until such time as the ODE expires for** Valtoco **in** ~~. There is no assurance that the FDA will determine that Libervant is" clinically superior" to Valtoco prior to~~ January 2027 **. This** ~~, and therefore we~~ would ~~not earn any~~ **result in significant changes to our business and delay in future** revenues **to** ~~, if any, until then~~ **the Company from Libervant** ~~in the United States~~ . We cannot be certain that we will be able to successfully develop our product candidates or obtain regulatory approval for our product candidates. Prior to receiving approval to commercialize any of our drug products, we must demonstrate with substantial evidence from well- controlled clinical trials, and to the satisfaction of the FDA and / or other regulatory authorities in the U. S. and other countries, that our particular product candidates are both safe and effective. For each drug product, we must demonstrate its efficacy and monitor its safety throughout the process. If development within these parameters is unsuccessful, our business could be harmed, and our stock price could be adversely affected. We currently have product candidates in preclinical and clinical development. Our business depends

primarily on the successful clinical development, regulatory approval and commercialization of our product candidates. Before our product candidates can be marketed, the FDA and other comparable foreign regulatory agencies must approve our applicable NDA or comparable regulatory submissions. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is very uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Further, positive results from earlier stage clinical trials may not be predictive of later clinical trials or other regulatory developments. In addition, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical trials after achieving positive results in early stage development, and we cannot be certain that we will not face similar setbacks. Also, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval. Even after successful completion of clinical testing, there is a risk that the FDA may request further information from us, disagree with our findings or otherwise undertake a lengthy review of our submission. We **may be asked to provide further justification and evidence to support the application for approval at an FDA Advisory Committee meeting, which requires significant time and resources to prepare. FDA staff, and the public, may also present their own analyses of the clinical trial data, and discuss other issues at an Advisory Committee meeting. FDA Advisory Committees are typically asked to comment on whether they believe there is adequate safety and effectiveness data to support approval. Advisory Committees may also recommend that FDA request additional studies before approval or suggest changes to a product' s proposed labeling. Advisory Committees make nonbinding recommendations to FDA. FDA generally follows the recommendations, but is not legally bound to do so. We** also face hurdles and setbacks by reason of competitors' drug candidates obtaining FDA or other regulatory approvals, including orphan drug market exclusivity, prior to our obtaining FDA or other regulatory approval of our similar drug candidate. Even if the FDA approves our NDA, we may be unable to successfully commercialize our products and product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to the numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen, and other clinical trial protocols, and the rate of dropout among clinical participants. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates and, correspondingly, our business and financial prospects, would be materially adversely affected. It is also possible that the FDA will not approve an application that we may submit, or our product candidates may not obtain appropriate regulatory approvals necessary for us to commence clinical trials for our product candidates. Any delay or failure in obtaining required approvals could have a material adverse effect on our business. This process from development to commercialization can take many years and will likely require the expenditure of substantial resources beyond the proceeds we currently have on hand, without any guarantee or assurance that we will be successful with regulatory approval, or commercial success, of such product candidate. Even if we obtain approval from the FDA and comparable foreign regulatory authorities for our current and future product candidates, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post- approval study or risk management requirements. If we are unable to obtain regulatory approval, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of that product candidate or any other product candidate that we may in- license, develop or acquire in the future. If we do not obtain market exclusivity for ~~our~~ certain of our products, including orphan drug exclusivity, our business may be harmed. We have ~~sought~~ **received** orphan drug market exclusivity for our drug candidate Libervant **for ARS patients aged between two and five years,** and may in the future seek market exclusivity for other product candidates, including orphan drug market exclusivity. Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals in the United States. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of market exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same disease for seven years. Orphan drug exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation must be requested before submitting an application for marketing approval. A company that first obtains FDA approval for a designated orphan drug for the designated rare disease or condition receives orphan drug market exclusivity for that drug for the designated disease for a period of seven years in the United States. This orphan drug exclusivity prevents the FDA from approving another application to market a drug containing the same active moiety for the same orphan indication, except in very limited circumstances, including when the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care within the meaning of FDA regulations and guidance. In addition, a designated orphan drug may not receive orphan drug **market** exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Even if we receive orphan drug designation for one or more of our drug candidates, we may not be the first to obtain marketing approval for the orphan- designated indication due to the uncertainties associated with developing product candidates. If any of these other pharmaceutical companies obtains approval of an NDA before we are able to receive approval for one or more of our drug candidates with the same active moiety for the same indication, we would be barred from marketing that product in the United States during the seven- year orphan drug exclusivity period, unless we could demonstrate that such drug candidate is clinically superior to the approved products or satisfies one of the other limited exceptions to such orphan drug exclusivity. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition

because different drugs with different active moieties can be approved for the same condition or a drug with the same active moiety can be approved for a different indication **as currently permitted pursuant to FDA regulations in the United States** . Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, even if we intend to seek orphan drug designation for any of our product candidates or indications, we may never receive such designations or obtain orphan drug exclusivity. **See Part II, Item 8. Financial Statements and Supplementary Data, Note 23, Contingencies.** Also, overcoming ~~the~~ **a grant of** orphan drug **market** exclusivity is difficult to establish, with limited precedent **. In April 2024 the FDA approved Libervant ® (diazepam) Buccal Film, 5 mg, 7. 5 mg, 10 mg, 12. 5 mg, and 15 mg, for ARS patients between the ages of two and five years. This FDA approval was recently determined to be granted in error by the U. S. District Court for the District of Columbia in a lawsuit brought by Neurelis, Inc.** , and there can be no assurance that the **Company will be successful in its appeal of this court ruling or that the** FDA will **grant** ~~agree with~~ our ~~position~~ **current request** seeking **an FDA determination that Libervant for this young patient population is clinically superior** to ~~overcome such~~ **other FDA approved ARS drugs in order to maintain the exclusive approval of Libervant in this age and indication. Even if we maintain our market access approval of Libervant for this age group in this indication, if we fail to receive U. S. orphan drug** market exclusivity **for** ~~and approve~~ Libervant for **this age group in this indication** ~~U. S. market access with orphan drug exclusivity. If we fail to receive such exclusive rights~~ , our ability to prevent competitors from manufacturing, marketing and selling competing products will be materially impaired, and our results of operations and financial condition may be significantly adversely affected. Clinical trials may be delayed, suspended or terminated for many reasons, which will increase our expenses and delay the time it takes to develop our product candidates. We may experience delays in our ongoing or future preclinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule. The commencement and completion of clinical trials for our clinical product candidates may be delayed suspended or terminated as a result of many factors, including: • the FDA disagreeing as to the design, protocol or implementation of our clinical studies; • the delay or refusal of regulators or IRBs, to authorize us to commence a clinical trial at a prospective trial site; • changes in regulatory requirements, policies and guidelines; • delays or failure to reach an agreement on acceptable terms with prospective CROs, and clinical trial sites; • the inability to enroll or delays in enrolling a sufficient number of patients in trials, particularly in orphan indications, to observe statistically significant treatment effects in the trial; • having clinical sites deviate from the trial protocol; • negative or inconclusive results from ongoing preclinical studies or clinical trials, which may require us to conduct additional preclinical studies or clinical trials or to abandon projects that we had expected to be promising; • reports from preclinical testing of other similar therapies that raise safety or efficacy concerns; • regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others; • lower than anticipated retention rates of patients and volunteers in clinical trials; • our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a trial; • delays in establishing the appropriate dosage levels; and • exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials. If we experience delays in the commencement or completion of any clinical trial of our product candidates, or if any clinical trials suspended or terminated, our costs may substantially increase and the commercial prospects of our product candidates may be harmed and our ability to generate revenue from sales of any product candidate will be delayed or not realized at all. Significant preclinical study or clinical trial delays also could shorten the period during which we have exclusive rights to commercialize a product candidate or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize a product candidate. We have ~~directly marketed just a single product, Sympazan. With this~~ limited **commercialization** experience **and** ~~, we~~ may lack the necessary expertise, personnel and resources to successfully commercialize our other product candidates that must first receive regulatory approval, either on our own or together with collaborators. We rely on our third- party licensees to commercialize our multiple licensed products and to date have only marketed, through our own efforts and with the services of third- party outsourcing vendors, including contract sales personnel, our first self- developed product, Sympazan, launched in December 2018. With the license of Sympazan to Assertio in October ~~,~~ 2022, we scaled back many of our commercial operations, including elimination of our sales and marketing force **. However, in April 2024, we launched Libervant for ARS patients between two and five years of age** . Given our limited history of direct experience in commercializing product candidates, and current limited commercial operations, we have no long- term experience upon which to measure our ability or success in commercializing future product candidates, if approved, or our ability to make predictions about financial results or prospects of any future launches of product candidates, if approved. Our ongoing commercial strategy for our product candidates involves the development of a commercial infrastructure that spans multiple jurisdictions and is dependent upon our ability to build an infrastructure that is capable of implementing our commercial product launch strategy. The establishment and development of our commercial infrastructure will be expensive and time consuming, and we may not be able to develop our commercial infrastructure successfully or in a timely manner, or at all. Doing so will require a high degree of coordination and compliance with laws and regulations in numerous territories, including in the United States, each state, and other countries in which we do business, including restrictions on advertising practices, enforcement of intellectual property rights, restrictions on pricing or discounts, transparency laws and regulations, and unexpected changes in regulatory requirements and tariffs. If we are unable to effectively coordinate such activities or comply with such laws and regulations, our ability to commercialize our product candidates in the United States and other jurisdictions in which they are or may be available will be materially adversely affected. We also intend to enter into strategic licenses with third parties to commercialize our product candidates ~~outside of the United States~~ . We may have difficulty establishing relationships with third parties on terms that are acceptable to us, or in all of the regions where we wish to commercialize our products, or at all. If we are unable to build our own distribution and marketing

capabilities or to find suitable licensees for the commercialization of our products and product candidates, if approved, we may have difficulties generating revenue from them and our business, results of operations, financial condition and prospects and the trading price of our stock may be materially adversely affected. Our success depends upon attaining significant market acceptance of our licensed **products and proprietary** products and product candidates, if approved, among patients, physicians, pharmacists and the medical community. It is possible that we may not complete development of our product candidates or obtain regulatory approval for those product candidates. Even if we do complete development and obtain regulatory approval for our product candidates, our product candidates may not gain market acceptance among patients, physicians, nurses, pharmacists, the medical community or third- party payors, which is critical to commercial success. Market acceptance of our products and any product candidate for which we receive approval depends on a number of factors, including: • the timing of market introduction of the product candidate as well as competitive products; • the clinical indications for which the product candidate is approved; • the potential and perceived advantages of such product candidate over alternative treatments; • favorable pricing and the availability of coverage and adequate reimbursement by third- party payors and government authorities; • relative convenience and ease of administration; • any negative publicity related to our or our competitors' products that include the same active ingredient; • the prevalence and severity of adverse side effects, including limitations or warnings contained in a product' s FDA- approved labeling; and • the effectiveness of sales and marketing efforts. Even if a potential product displays a favorable efficacy and safety profile in clinical trials, market acceptance of the product will not be known until a period of time after it is launched. If our products or product candidates, if approved, fail to achieve an adequate level of acceptance by patients, physicians, nurses, pharmacists, the medical community or third- party payors, we will be unable to generate significant revenues, and we may not become or remain profitable. In addition, the potential market opportunities for our product candidates are difficult to estimate. Our estimates of the potential market opportunities are predicated on several key assumptions such as industry knowledge and publications, third- party research reports or analyses and other analytical information. While we believe that our internal assumptions are reasonable, these assumptions may be inaccurate. If any of the assumptions proves to be inaccurate, then the actual market for our product candidates could be smaller than our estimates of the potential market opportunity. If the actual market for our product candidates is smaller than we expect, or if the products fail to achieve an adequate level of acceptance by physicians, health care payors and patients, our revenue from product sales may be limited and we may be unable to achieve or maintain profitability. Further, we may not be able to hire or contract for a sales force that is sufficient in size or has adequate expertise in the medical markets that we intend to target for our product candidates in the future. Any failure or delay in the development of our sales, marketing and distribution capabilities would adversely impact the commercialization of our product candidates, if approved. Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and any allegations of our failure to comply with such approved indications could limit our sales efforts and have a material adverse effect on our business. The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct- to- consumer advertising, industry- sponsored scientific and educational activities, promotional activities involving the internet and off- label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products and product candidates, our ability to effectively market and sell our products may be reduced and our business may be materially adversely affected. While physicians in the U. S. may choose and are generally permitted to prescribe drugs for uses that are not described in the product' s labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote our products is narrowly limited to those indications that are specifically approved by the FDA. These " off- label " uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U. S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off- label use. Promotional activities that fail to comply with the FDA' s regulations or guidelines may be subject to warnings from, or enforcement action by, these authorities and may cause the FDA to issue warning letters or untitled letters, bring an enforcement actions, suspend or withdraw an approved product from the market, require a recall or institute fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could materially harm our reputation and our business significantly. We could incur substantial costs and disruption to our business and delays in the launch of our product candidates if our competitors and / or collaborators bring legal actions against us, which could harm our business and operating results. We cannot predict whether our competitors or potential competitors, some of whom we collaborate with, may bring legal action against us based on our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, claiming, among other things, infringement of their intellectual property rights, breach of contract, false or disparaging statements about another company' s products or product candidates, or other legal theories. To date we have been subject to a number of claims of this nature. In defending such lawsuits, whether or not they are with or without merit or are ultimately determined in our favor, we would continue to face costly litigation and diversion of technical and management personnel. These lawsuits could hinder our ability to enter the market early with our product candidates and thereby hinder our ability to influence usage patterns when fewer, if any, of our potential competitors have entered the market, which could adversely impact our potential revenue from such product candidates. Some of our competitors have substantially greater resources than we do and could be able to sustain the cost of litigation to a greater extent and for longer periods of time than we can. Furthermore, an adverse outcome of a dispute may require us: to pay damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed a party' s patent or other intellectual property rights; to cease making, licensing or using products that are alleged to incorporate

or make use of the intellectual property of others; to expend additional development resources to reformulate our products or prevent us from marketing a product; and to enter into potentially unfavorable royalty or license agreements in order to obtain the rights to use necessary technologies. Guidelines and recommendations published by government agencies can reduce the use of our products or product candidates. Government agencies promulgate regulations and guidelines applicable to certain drug classes which may include our products and product candidates. Regulations and guidelines of government agencies may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Regulations or guidelines suggesting the reduced use of certain drug classes which may include our products and product candidates or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our products or product candidates or negatively impact our ability to gain market acceptance and market share. For example, Suboxone, which treats opioid addiction, has as one of its active ingredients an opioid, buprenorphine. Revisions to regulations or guidelines suggesting the reduced use of opioid drugs such as buprenorphine could result in decreased use of Suboxone. We face significant competition from other pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. The pharmaceutical industry is intensely competitive and subject to rapid and significant technological change. We expect to have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug administration technologies that are more effective than our products or product candidates. In addition, our competitors may file citizen petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505 (b) (2) or other filing pathways. We believe that our ability to successfully compete will depend on, among other things: • the efficacy and safety of our products and product candidates; • the time it takes for our product candidates to complete preclinical and clinical development and receive marketing approval; • our ability to maintain a good relationship with regulatory authorities; • our ability to commercialize and market any of our product candidates after receiving regulatory approval; • the price of our products relative to pricing of branded or generic competitors; • whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare and Medicaid; • our ability to protect intellectual property rights related to our products and product candidates; • our ability to manufacture on a cost- effective basis for our products and product candidates that receive regulatory approval; and • acceptance by physicians and other healthcare providers of any of our products and product candidates that receive regulatory approval. If our competitors' market products that are more effective, safer or less expensive than our product candidates, or that reach the market sooner than our product candidates, our products may enter the market too late in the cycle and may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because we have limited research and development capabilities, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to achieve and maintain coverage and adequate reimbursement from third- party payors for our licensed products or product candidates, if approved, their commercial success may be severely hindered. Successful commercialization of our licensed products and product candidates, if approved, will depend in part on the extent to which coverage and adequate reimbursement are available from third- party payors, including governmental healthcare programs such as Medicare and Medicaid, commercial health insurers and managed care organizations, and how quickly such coverage and reimbursement can be obtained, if obtained at all. Third- party payors determine which medications they will cover and establish reimbursement levels. Reimbursement decisions by third- party payors depend upon a number of factors, including, among other things, each third- party payor' s determination that use of a product is: • a covered benefit under its health plan; • appropriate and medically necessary for the specific condition or disease; • cost effective; and • neither experimental nor investigational. Obtaining coverage and reimbursement approval from third- party payors may be a time consuming and costly process that could require us to provide supporting scientific, clinical and cost- effectiveness data, including results from expensive pharmacoeconomic studies, beyond the data required to obtain marketing approval, to each third- party payor. There is no guarantee that we will be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. Cost containment is a primary concern of the U. S. healthcare industry and elsewhere as well as for governmental authorities. Third- party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for medical products and services. Third-party payors may deny reimbursement for covered products if they determine that a medical product was not used in accordance with third- party payor coverage policies, such as required procedures for cost- effective diagnosis methods and other conditions that must be met before the third- party payor will provide coverage for use of a product. For example, insurers may establish a " step- edit " system that requires a patient to first use a lower price alternative product prior to becoming eligible for reimbursement of a higher price product. Third- party payors also may refuse to reimburse for drugs, procedures and devices deemed to be experimental, or that are prescribed for an unapproved indication. It is also possible that a third- party payor may consider our products or product candidates as substitutable by less expensive therapies and only offer to reimburse patients for

the less expensive product. Even if we show improved efficacy or improved convenience of administration with our products or product candidates, pricing of existing drugs may limit the amount that can be charged for our licensed products or product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on investment in product development. Further, third- party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA- approved products for a particular indication. Further, some third- party payors challenge the prices charged for medical products and may impose price controls or require that drug companies provide them with predetermined discounts from list prices. Obtaining and maintaining reimbursement status is time- consuming and costly. No uniform policy for coverage reimbursement for products exists among third- party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is generally a time- consuming and costly process that requires us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Levels of reimbursement may also decrease in the future, and future legislation, regulation or reimbursement policies of third- party payors may adversely affect the reimbursement available for and the pricing of our product candidates, once approved, which in turn, could negatively impact the demand for our product candidates. If payors are not adequately reimbursed for our licensed products or product candidates, they may reduce or discontinue purchases of them, which would result in a significant shortfall in achieving revenue expectations and negatively impact our business, prospects and financial condition. Our relationships with customers, physicians, and third- party payors will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Healthcare providers, physicians and third- party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any licensed products currently marketed and any product candidates for which we obtain marketing approval in the future. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third- party payors may subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti- Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations promulgated thereunder. These laws will impact, among other things, our clinical research programs and our proposed sales, marketing and educational programs for our product candidates, if approved. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to: • the federal Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, 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. **Under** ~~The Patient Protection and Affordable Care Act, as amended, or~~ the PPACA ~~, amended the~~ **a person or entity no longer needs to have actual knowledge of this statute or specific** intent ~~requirement of~~ **to violate it and action that may be customary in** ~~the~~ **other** ~~federal~~ **industries ma unintentionally violate the** Anti- Kickback Statute ~~. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it~~ ; • federal civil and criminal false claims laws, including, without limitation, the False Claims Act, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. The PPACA provides, and recent government cases against pharmaceutical and medical device manufacturers support, the view that federal Anti- Kickback Statute violations and certain marketing practices, including off- label promotion, may implicate the False Claims Act; • HIPAA created federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e. g., public or private); • HIPAA, as amended by ~~the Health Information Technology for Economic and Clinical Health Act, or~~ HITECH, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization on entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, and their respective business associates who provide services involving the creation, use or disclosure of HIPAA protected health information; • federal transparency laws, including the federal Physician Payments Sunshine Act, which is part of the PPACA, that require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program, with specific exceptions, to report annually to ~~the Centers for Medicare & Medicaid Services, or~~ CMS ~~,~~ information related to: (i) payments or other " transfers of value " made to physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse- midwives and teaching hospitals; and (ii) **certain** ownership and investment interests held by physicians and their immediate family members, with such information being made publicly available through a searchable website; • state and foreign law equivalents of each of the above federal laws; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or pricing information; state laws that require pharmaceutical companies to comply with the

pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; and state and local laws that require the registration of pharmaceutical sales representatives; and • state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. 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. 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 civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and the provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and / or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. Recently enacted and future healthcare reform legislation or regulation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and may adversely affect the prices we, or they, may obtain and may have a negative impact on our business and results of operations. 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, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability, or the ability of any future collaborators, to profitably sell any products for which we, or they, obtain marketing approval. Among policymakers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and / or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for any approved products. In March 2010, President Obama signed into law the PPACA. Among the provisions of the PPACA of importance to our business, including our ability to commercialize and the prices we may obtain for any of our products and product candidates that are approved for sale, are the following: • an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee does not apply to sales of certain products approved exclusively for orphan indications; • expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133 % of the federal poverty level, thereby potentially increasing a manufacturer' s Medicaid rebate liability; • expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of " average manufacturer price, " or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans; • addition of more entity types eligible for participation in the Public Health Service 340B drug pricing program, or the 340B program; • ~~establishment of the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50 % point- of- sale- discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; • the BBA, that among other things, increased the manufacturer' s subsidy under this program from 50 % to 70 % of the negotiated price, beginning in 2019; •~~ a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and • establishment of the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2 % under the sequestration (i. e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation, including the BBA, extended the 2 % reduction, on average, to ~~2027~~ **2032**, subject to additional Congressional action. Sequestration may result in additional reductions in Medicare and other healthcare funding and, if we obtain regulatory approvals, may otherwise affect the prices we may obtain for our product candidates or the frequency with which our product candidates may be prescribed or used if approved. Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015 **(** ~~, or~~ MACRA **)** ~~, which was fully implemented in 2022~~. **The** ~~At this time, it is unclear how the~~ introduction of the Medicare quality payment program ~~will impact overall~~ **has shifted the focus of** physician reimbursement **from volume** ~~and their choice of medications~~ to ~~use~~ **value, encouraging higher quality and more cost-**

effective care . Further, legislative changes to or regulatory changes under the PPACA remain possible in the U. S. Congress and under the ~~Biden~~ **second- term Trump** administration. The nature and extent of any legislative or regulatory changes to the PPACA, including repeal and replacement initiatives, are uncertain at this time. It is possible that the PPACA repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits, including limited coverage for drugs. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 **(“** ~~, or the~~ TCJA **”)** , which was signed into law by President Trump **during his first administration** , ~~includes a provision repealing, effective~~ **effectively eliminated** ~~January 1, 2019,~~ the ~~tax- based shared responsibility payment~~ **federal “ individual mandate ” penalty** imposed by the PPACA on ~~certain~~ individuals who ~~fail~~ **failed** to maintain qualifying health coverage for all or part of a year ~~that is commonly referred to as the “ individual mandate~~ . **Shortly thereafter** ~~” In addition~~ , the BBA ~~,~~ amended the PPACA to close the coverage gap in most Medicare drug plans, commonly referred to as the “ donut hole. ” The ~~scope~~ **Inflation Reduction Act** of **2022, which was signed into law by President Biden, has since eliminated the coverage gap and replaced it with a $ 2, 000 annual cap on out- of- pocket spending for covered drugs. As the second Trump presidency has commenced, we will continue to evaluate the impact of the PPACA on our business, and the** potential ~~future legislation to modify or~~ **for its further** repeal ~~and replace the PPACA provisions is highly uncertain in many respects. We continue to evaluate the potential impact of the PPACA and its possible repeal~~ or replacement ~~on our business~~ . The costs of prescription pharmaceuticals in the United States have also been the subject of considerable discussion in the United States, and members of Congress and the administration have stated that they will address such costs through new legislative and administrative measures. This focus has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. ~~The~~ **In 2022, the** Biden administration ~~has begun taking executive actions to address drug pricing and other healthcare policy changes. On July 9, 2021, President Biden~~ signed **into law** an Executive Order to promote competition in..... additional pricing pressures. Most recently, the Inflation Reduction Act ~~of 2022~~ , **which** ~~or IRA,~~ included a number of significant drug pricing reforms, ~~which include~~ **including** the establishment of a drug price negotiation program within the ~~U. S. Department of Health and Human Services, or~~ HHS ~~(beginning~~ **that, starting** in 2026 ~~) that~~ **, will** ~~requires~~ . **require** manufacturers to charge a negotiated “ maximum fair price ” for certain selected drugs or pay an excise tax for noncompliance ~~,~~ **;** the establishment **, beginning in 2023,** of rebate payment requirements on manufacturers under Medicare Parts B and D to penalize price increases that outpace inflation **;** ~~(first due in 2023),~~ and a redesign of the Part D benefit, as part of which manufacturers are required to provide discounts on Part D drugs ~~(~~ **,** beginning in 2025 ~~) ,reduce prices for prescription drugs,including prices paid by the federal government for such drugs~~ . ~~In response to the~~ **Additionally,President Biden issued a subsequent** Executive Order **directing the Secretary of the HHS consider whether new payment and delivery models would lower drug costs,though** ,on ~~September 9,2021,HHS issued a Comprehensive Plan for Addressing High Drug Prices that identified potential legislative policies and administrative tools that Congress and~~ the ~~agency can pursue in~~ **first day of his second term,President Trump repealed that Executive** ~~order~~ **Order** ~~to make drug prices more affordable and equitable,improve and promote competition throughout the prescription drug industry,and foster scientific innovation~~ .At the state level,legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing,including price or patient reimbursement constraints,discounts,restrictions on certain product access and marketing cost disclosure and transparency measures,and,in some cases,designed to encourage importation from other countries and bulk purchasing.We expect that we may experience more rigorous coverage criteria and additional downward pricing pressure as the result of these and other healthcare reform measures that may be adopted in the future.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 generate revenue,attain profitability,or commercialize our drugs.We expect that additional state and federal healthcare reform measures will be adopted in the future,any of which could limit the amounts that federal and state governments will pay for healthcare products and services,which could result in reduced demand for our **product candidates or additional pricing pressures.Additionally,policy changes resulting from the new presidential administration may create sudden and unexpected shifts in the operations of HHS that might impact both existing and planned operations** . The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates to other available product candidates. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired. Risks Related to Our Reliance on Third Parties We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed. We have relied upon and plan to continue to rely upon third- party CROs to monitor and manage data for our preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with FDA laws and regulations regarding current good clinical practice, or GCP, which are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization, or ICH, guidelines for all of our products in clinical development. Regulatory authorities enforce GCP through

periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under the current cGMP regulations. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. In addition, portions of the clinical trials for our product candidates are expected to be conducted outside of the United States, which will make it more difficult for us to monitor CROs and visit clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCP. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process. Some of our CROs have an ability to terminate their respective agreements with us if, among other reasons, it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third- party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we strive to manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. We rely on limited sources of supply for our thin film foil, and any disruption in the chain of supply may impact production and sales and cause delay in developing and commercializing our proprietary PharmFilm Technology product candidates. We currently have relationships with two third parties for the manufacture of our thin film foil. Because of the unique equipment and process for manufacturing our thin film foil, transferring manufacturing activities for our foil to an alternate supplier would be a time- consuming and costly endeavor, and there are only a limited number of manufacturers that we believe are capable of performing this function for us. Switching thin film foil suppliers may involve substantial cost and could result in a delay in our desired clinical and commercial timelines. If any of our thin film foil manufacturers breach or terminate their agreements with us, we would need to identify an alternative source for the thin film foil manufacture and supply of foil to us for the development and commercialization of the applicable products. Identifying an appropriately qualified source of alternative thin film foil supply for any one or more of these product candidates could be time consuming, and we may not be able to do so without incurring material delays in the development and commercialization of our product candidates, or in satisfying our manufacturing and supply commitments and obligations for our licensed products, which could harm our financial position, the commercial potential for our licensed products and product candidates, and our results of operations, as well as to result in a default in our supply commitments and obligations. Any alternative thin film foil vendor would also need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if we appoint a new manufacturer for supply of our licensed products that differs from the manufacturer used for clinical development of such products. For our product candidates, we expect that only one supplier will initially be qualified as a vendor with the FDA. If supply from the approved vendor is interrupted, there could be a significant disruption in our development and supply activities. These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our approved products and product candidates, cause us to incur higher costs and prevent successful commercialization of our licensed products and product candidates, if approved. Furthermore, if our suppliers fail to deliver the required commercial quantities of components and active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, we would likely be in default in our supply obligations, which could result in the termination of our supply agreements, our incurring potential default damages and our loss of significant revenues. We rely on third parties to manufacture ~~active pharmaceutical ingredients, or~~ API ~~,~~ for our licensed products and product candidates, and we intend to rely on third parties to manufacture the API for other approved products. The commercialization of any of our licensed products and product candidates, if approved, could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of API or fail to do so at acceptable quality levels or prices or fail to maintain or achieve satisfactory regulatory compliance. We currently rely, and expect to continue to rely, on third parties to manufacture API for our licensed products and our product candidates, and control only certain aspects of their activities. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it could delay our supply of licensed products, proprietary product candidate programs and commercialization activities. Our reliance on these third parties reduces our control over these activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards and any applicable trial protocols or our obligations under our product supply commitments and obligations. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we will

not be able to complete, or may be delayed in completing, clinical trials required to support future regulatory submissions and approval of our product candidates and we would likely be in default in our supply commitments and obligations for our licensed products, which could result in the termination of our supply agreements, our incurring potential default damages and our loss of significant revenues. The facilities used by us, and by our third- party API manufacturers, to manufacture our licensed products and product candidates must maintain a compliance status acceptable to the FDA or other applicable regulatory authorities pursuant to inspections that will be conducted after we submit our NDA to the FDA. If we or any of our third- party API manufacturers cannot successfully manufacture material that conforms to our specifications and the applicable regulatory authorities' strict regulatory requirements, or pass regulatory inspection, we or they will not be able to secure or maintain regulatory approval for the manufacturing facilities. In addition, we have no control over the ability of third- party API manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Further, as we scale up manufacturing of our product candidates and conduct required stability testing, product, packaging, equipment and process-related issues may require refinement or resolution in order for us to proceed with our planned clinical trials and obtain regulatory approval for commercialization of our product candidates. In the future, for example, we may identify impurities in the product manufactured by us or for us for commercial supply, which could result in increased scrutiny by the regulatory agencies, delays in our clinical program and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for our licensed products and product candidates. If the FDA or any other applicable regulatory authority does not approve these facilities for the manufacture of our products or if they withdraw any such approval in the future, or if our suppliers or third- party manufacturers decide they no longer want to manufacture our products, we would need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates and which could also result in default in our supply commitments and obligations for our licensed products, our incurring potential default damages and our loss of significant revenues. More generally, we and our API manufacturers of pharmaceutical products, may often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Additionally, we and our API manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments, such as recent events in Ukraine and Russia, or other geopolitical uncertainty. If we or our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to manufacture our products, or to make our product candidates available for clinical trials and development purposes or to further commercialize any of our licensed products and product candidates in the United States, would be jeopardized. Any delay or interruption in our ability to meet commercial demand may result in the loss of significant potential revenues and could adversely affect our ability to gain market acceptance for approved products as well as a potential default of our supply commitments or obligations. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Additionally, if supply from one approved API manufacturer is interrupted, there could be a significant disruption in commercial supply. Regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and would likely result in a delay in our desired clinical and commercial timelines and disrupt our supply commitment and obligations. The occurrence of any of these factors could have a material adverse effect on our business, results of operations, financial condition and prospects. The design, development, manufacture, supply, and distribution of our licensed products and our product candidates is highly regulated and technically complex. All entities involved in the preparation of therapeutics for clinical trials or commercial sale are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP and equivalent foreign standards. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. The development, manufacture, supply, and distribution of our products and our product candidates is highly regulated and technically complex. We, along with our third-party providers, must comply with all applicable regulatory requirements of the FDA and foreign authorities. We, or our API and component manufacturers, must supply all necessary documentation in support of our regulatory filings for our product candidates on a timely basis and must adhere to the FDA' s GLP and cGMP regulations enforced by the FDA through its facilities inspection program, and the equivalent standards of the regulatory authorities in other countries. Any failure by us or by our third- party API or component manufacturers to comply with cGMP or failure to scale- up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. Our facilities and quality systems and the facilities and quality systems of some or all of our third- party API and component manufacturers must also pass a pre- approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities in any country may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities and quality systems do not pass a pre- approval plant inspection, FDA approval of our product candidates, or the equivalent approvals in other jurisdictions, will not be granted. Regulatory authorities also may, at any time following approval of a product for sale, inspect our manufacturing facilities or those of our third- party suppliers or contractors. If any such inspection identifies a failure to comply

with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and / or time-consuming for us or a third- party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales of our approved products or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. If we or any of our third- party API or component manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending NDA for a new drug product or revocation of a pre- existing approval. As a result, our business, financial condition and results of operations may be materially harmed resulting in a significant loss of revenues and results and resulting in a potential default in our supply commitments or obligations, which could lead to termination of our supply agreements, our incurrence of default damages and our loss of significant revenues. We may not be successful in establishing development and commercialization collaborations, which could adversely affect, and potentially prohibit, our ability to develop our product candidates. Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approvals, establishing manufacturing capabilities and marketing approved products are expensive, we continue to explore collaborations or licensing arrangements with third parties that have available resources and experience both in the United States and in territories outside of the United States. We continue to explore selective collaborations with third parties for development and commercialization of our products and candidates both in and outside of the United States. We may, however, be unable to advance the development and / or commercialization of our products and product candidates in territories outside of the United States, which may limit the market potential for certain products and product candidates outside the U. S. In situations where we enter into a development and commercial collaborative arrangement for a product or product candidate, we may also seek to establish additional collaborations for development and commercialization in territories outside of those addressed by the first collaborative arrangement for such product or product candidate. There are a limited number of potential licensees, and we expect to face competition in seeking appropriate licensees. If we are unable to enter into any development and commercial collaborations and / or sales and marketing arrangements on acceptable terms, if at all, we may be unable to successfully develop and seek regulatory approval for our product or product candidates and / or effectively market and sell approved products, if any, in all of the territories outside of the United States where it may otherwise be valuable to do so. Whether we reach an agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include the likelihood of approval by the FDA or foreign regulatory authorities, the potential market for the product or product candidate, the costs and complexities of delivering such product or product candidate to patients, competing products, and industry and market conditions generally. Collaborations are complex and time- consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain significant additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue. We may not be successful in maintaining development and commercialization collaborations, and any collaborators may not devote sufficient resources to the development or commercialization of our products or product candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop and successfully commercialize certain of our products and product candidates and our financial condition and operating results. When we establish collaborative arrangements, such collaboration may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and prospects. If we collaborate with a third- party for development and commercialization of a product or product candidate, we can expect to relinquish some or all of the control over the future success of that product or product candidate to the third- party. It is possible that a third- party collaborator may not devote sufficient resources to the development or commercialization of our product or product candidate or may otherwise fail in development or commercialization efforts, in which event the development and commercialization of such product or product candidate could be delayed or terminated and our business could be substantially harmed. In addition, the terms of any collaboration or other arrangement that we establish may not prove to be favorable to us or may not be perceived as favorable, which may negatively impact the trading price of our Common Stock. In some cases, we may be responsible for continuing development of a product or product candidate or research program under a collaboration, and the payment we receive from our licensee may be insufficient to cover the cost of this development. Moreover, collaborations and sales and marketing arrangements are complex and time consuming to negotiate, document and implement, and they may require substantial resources to maintain. We are subject to a number of additional risks associated with our dependence on collaborations with third parties, the occurrence of which could cause our collaborative arrangements to fail, including that: • we may be required to undertake the expenditure of substantial operational, financial and management resources; • we may be required to issue equity securities that would dilute our stockholders' percentage of ownership; • we may be required to assume substantial actual or contingent liabilities; • strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and commercialization and may substantially increase the cost of developing and commercializing our products and product candidates; • business combinations of a strategic collaborator or significant changes in a strategic collaborator' s business strategy may affect a strategic collaborator' s willingness or ability to complete its obligations under any arrangement; • strategic collaborators could decide to move forward with a competing product or product candidate developed either independently or in collaboration with others, including our competitors; • collaborators may not perform their obligations as expected; • clinical trials conducted as part of any of these collaborations may not be successful; • collaborators may not actively or aggressively pursue development and commercialization of any product candidates that seek to achieve, or that achieves, regulatory approval; • we may not have access to or may be restricted from disclosing certain information regarding product candidates being developed or

commercialized under a collaboration; • a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate; and • collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. If any such collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, the development or commercialization of our products or product candidates could be delayed and our business and prospects harmed. All of the risks relating to product development, regulatory approval and commercialization apply to the activities of our existing and future collaborators. Additionally, conflicts may arise between us and our third- party collaborators, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. For example, our existing revenue streams are largely dependent on Indivior, which holds the global commercialization rights to our approved product, Suboxone. During the years ended December 31, **2024 and** 2023 ~~and 2022~~ , Indivior represented **62 % and** 80 ~~% and 76~~ % of our total revenue, respectively. If any such conflicts were to arise with Indivior or any other third party collaborators, one or more of the following events could result, each of which could delay or prevent the development or commercialization of our product or product candidates and harm our business: • reductions in the payment of royalties or other payments we believe are due pursuant to the applicable collaborative arrangement; • actions taken by a third- party collaborator inside or outside our collaboration which could negatively impact our rights or benefits under our collaboration; • unwillingness on the part of a third- party collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; and • decision by our third- party collaborator to terminate or significantly reduce the relationship. Risks Related to Our Business Operations and Industry We may experience difficulties in managing growth if our business expands to meet future needs, which could disrupt our operations. Although it is not expected to be imminent, if we need to expand **our business** to meet demands in growth of our manufacturing operations ~~,~~ **in connection with the continued** commercialization of Libervant **for ARS patients aged between two and five years, and** , if granted **full** U. S. market access, ~~or~~ **for commercialization of Libervant for older patients, and to accommodate the potential commercialization of Anaphylm in the first quarter 2026, if approved by the FDA, or other** additions to our product pipeline in the future, we would expect to expand our employee base to increase our managerial **, regulatory, compliance** , scientific and engineering, operational, sales, marketing, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants, contractors and contract employees. Also, our management may need to divert a disproportionate amount of its attention away from our day- to- day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and / or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our products and product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth. In addition, any growth in our management team could add increased expense which we must absorb, without necessarily having commensurate growth in our revenues. Also, to date, we have only directly marketed ~~one~~ **two** ~~product~~ **products** in the market. If we commercialize and directly market ~~Libervant~~ **Anaphylm** , if approved for U. S. market access, this could require a significant upfront expense and create a rapid growth in our workforce. This increase in expense may negatively impact our results of operations and may add to our need for additional funds. Our licensed products and, if approved, product candidates, may give rise to potential product liability claims or false marketing claims, and, if successful claims are brought against us, we may incur substantial liability. As a pharmaceutical company, we operate in a market that is subject to significant risk of liability. The sales of any of our licensed products and product candidates for which we may obtain marketing approval and the use of our product candidates in clinical trials, if any, exposes us to the risk of product liability claims alleging adverse effects from such products or product candidates and false marketing claims relating to the commercialization of such products or product candidates. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies, others selling or otherwise coming into contact with our products or product candidates, or governmental agencies. Suboxone, which treats opioid addiction, has as one of its active ingredients an opioid, buprenorphine. There can be no assurance that we will not become the target of claims relating to opioid addiction as have companies that market opioids. **We have been named as a defendant with Indivior in product liability claims related to dental injuries for use of Suboxone. For more detailed information regarding these claims, see Part II Item 8. Financial Statements and Supplementary Data, Note 23, Contingencies to our financial statements.** Any product liability claims, or false marketing claims, could have a material adverse effect on our business, financial position, results of operations and future growth prospects. If we cannot successfully defend against product liability claims or false marketing claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims or false marketing claims may result in: • impairment of our business reputation; • withdrawal of clinical study participants; • substantial costs due to litigation; • distraction of management' s attention from our primary business; • substantial monetary awards to patients or other claimants; • the inability to commercialize our licensed products and product candidates; and • decreased demand for our licensed products or product candidates, if approved for commercial sale. We may not be able to maintain insurance coverage, and our existing or any future insurance policies or our own resources may not sufficiently cover claims for damages that we may receive in the future. Our business exposes us to potential product liability and other liability risks that are inherent in

clinical development, manufacturing, marketing, sale and use of human therapeutic products. It is generally necessary for us to secure certain levels of insurance as a condition for the conduct of clinical trials and any sale or use of our products. We have procured product liability insurance with respect to the sale of our licensed products and all clinical trials performed to date for which we were responsible (i. e., in respect of our internal product pipeline). Further, we may seek to expand our insurance coverage for our licensed products and our marketing and commercialization of any future approved product candidates as well as other risks related to our business. Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at an acceptable cost to us or in sufficient amounts to protect us against losses due to liability **. The product liability claim against us with respect to Suboxone may make obtaining product liability insurance coverage at an acceptable cost more problematic** . On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could materially adversely affect our results of operations and business. We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively. Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber- attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. We have previously been the target of a phishing attack that resulted in unauthorized access to our email system. While our systems have been secured and strengthened, there can be no assurance that we will not experience cyber- attacks in the future, suffer indirect consequences from a cyber- attack on a third-party, or fail to anticipate, identify or offset threats of potential cyber- attacks or security breaches in a timely manner. This is especially so considering the nature of cyber- attack techniques, which change frequently, can be difficult to detect for extended periods of time and often are not recognized until they succeed. System failures, accidents or security breaches could cause interruptions in our operations and could result in a material disruption of our product development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of product development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed. Business interruptions at our manufacturing facilities could delay us in the process of developing our product candidates. Our headquarters are located in Warren, New Jersey and we have manufacturing facilities in Portage, Indiana. If we encounter any disruptions to our operations at these sites or one were to shut down for any reason, including by fire, natural disaster, such as a hurricane, tornado or severe storm, power outage, systems failure, labor dispute or other unforeseen disruption, then we may be prevented from effectively operating our business. Our coverage for natural disasters may be somewhat limited for floods or earthquakes and we may not carry sufficient business interruption insurance for any unexpected events to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations. Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing. Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive. Our operations involve hazardous materials and we and third parties with whom we contract must comply with environmental laws and regulations, which can be expensive and restrict how we do business. As a pharmaceutical company, we are subject to environmental and safety laws and regulations, including those governing the use of hazardous materials. The cost of compliance with health and safety regulations is substantial. Our business activities involve the controlled use of hazardous materials. Our research and development activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and manufacturers and suppliers with whom we may contract are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of accidental contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean- up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. We cannot guarantee ~~that~~ that the safety procedures utilized by third-party manufacturers and suppliers with whom we may contract will comply with the standards prescribed by laws and regulations or will eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and U. S. federal and state or other applicable authorities may curtail our use of certain materials and / or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do maintain environmental liability insurance coverage to mitigate our exposure in the event of an accident or environmental discharge. In the event that we may be held liable for any consequential damage and any resulting claims for damages, which may exceed our insured limits and financial resources, we may incur costs that may materially adversely affect our business, results of operations and prospects, and the value of our shares. Risks Related to Government Regulation If the FDA does not conclude that our product candidates

satisfy the requirements for the 505 (b) (2) regulatory approval pathway, or if the requirements for approval of any of our product candidates under Section 505 (b) (2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful. We intend to seek FDA approval through the 505 (b) (2) regulatory pathway for each of our product candidates described in this report. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch- Waxman Act, added Section 505 (b) (2) to the Federal Food, Drug, and Cosmetic Act, or FDCA. Section 505 (b) (2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant. If the FDA does not allow us to pursue the 505 (b) (2) regulatory pathway for our product candidates as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. Moreover, the inability to pursue the 505 (b) (2) regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are permitted to pursue the 505 (b) (2) regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate. In addition, notwithstanding the approval of a number of products by the FDA under Section 505 (b) (2) over the last few years, certain competitors and others have objected to the FDA' s interpretation of Section 505 (b) (2). We expect that our competitors could file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical studies that support their approval, contain deficiencies. If the FDA' s interpretation of Section 505 (b) (2) is successfully challenged, the FDA may be required to change its Section 505 (b) (2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505 (b) (2). Our products or product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance, cause us to suspend or discontinue clinical trials, abandon product candidates, or result in significant negative consequences following marketing approval, if any. As with many pharmaceutical and biological products, treatment with our products or product candidates may produce undesirable side effects or adverse reactions or events. Although the nature of our products or product candidates as containing active ingredients that have already been approved means that the side effects arising from the use of the active ingredient or class of drug in our products or product candidates is generally known, our products or product candidates may still cause undesirable side effects. These could be attributed to the active ingredient or class of drug or to our unique formulation of such products or product candidates, or other potentially harmful characteristics. Such characteristics could cause us, our IRBs, clinical trial sites, the FDA or other regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay, denial or withdrawal of regulatory approval, which may harm our business, financial condition and prospects significantly. Further, if any of our products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution; • the FDA may require implementation of a ~~Risk Evaluation and Mitigation Strategy, or~~ REMS; • regulatory authorities may require the addition of labeling statements, such as warnings or contraindications; • we may be required to change the way the product is administered or conduct additional clinical studies; • we could be sued and held liable for substantial damages for harm caused to patients; and • our reputation may suffer. Any of the above described events could prevent us from achieving or maintaining market acceptance of the affected product or product candidate, significantly affect our revenues and profitability from such products, and could substantially increase the costs of commercializing our products and product candidates. Our business is subject to extensive regulatory requirements and our approved products and product candidates that obtain regulatory approval will be subject to ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize such products. Even after a product is approved, we will remain subject to ongoing FDA and other regulatory requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, import, export, record- keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report adverse events, or AEs, and any failure of a product to meet the specifications in the NDA. 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. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. In addition, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. For example, a product' s approval may contain requirements for potentially costly post- approval studies and surveillance to monitor the safety and efficacy of the product, or the imposition of a REMS program. The holder of an NDA is subject to payment of user fees and adherence to commitments made in the NDA. A manufacturer is also subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs. If we or a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing. If we or our products or product candidates or our manufacturing facilities fail to comply with applicable regulatory requirements, a regulatory agency may: • issue warning letters or untitled letters asserting that we are in violation of the law; • impose restrictions on the marketing or manufacturing of the product; • seek an injunction or impose civil, criminal and / or administrative penalties, damages, assess monetary fines, require disgorgement, consider exclusion from participation in Medicare, Medicaid and other federal healthcare programs and require curtailment or restructuring of our operations; • suspend or withdraw regulatory approval; • suspend any ongoing clinical trials; • refuse to approve a pending NDA or supplements to an NDA submitted by us; • seize product; or •

refuse to allow us to enter into government contracts. Similar post- market requirements may apply in foreign jurisdictions in which we may seek approval of our products. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to market our products or commercialize our product candidates and generate revenues. In addition, the FDA' s regulations, policies or guidance may change and new or additional statutes or government regulations in the United States and other jurisdictions may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post- approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market or license our products and / or product candidates, which would materially adversely affect our ability to generate revenue and achieve or maintain profitability. Regulatory approval is required for each of our products in each jurisdiction in which we intend to market or license such products, and the inability to obtain such approvals would limit our ability to realize their full market potential. In order to market products outside of the United States, we or our licensees must comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. However, the failure to obtain regulatory approval in one jurisdiction may adversely impact the ability to obtain regulatory approval in another jurisdiction. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs and require additional non- clinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. If we or our licensees fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed. If we fail to develop, acquire or in- license other product candidates or products, our business and prospects will be limited. Our long- term growth strategy is to develop and commercialize a portfolio of product candidates in addition to our existing products and product candidates. We may also acquire or in- license early to mid- stage new chemical entities, or NCEs. Although we have internal research and development capacity that we believe will enable us to make improvements to existing compounds, we do not have internal drug discovery capabilities to identify and develop entirely new chemical entities or compounds. As a result, our primary means of expanding our pipeline of product candidates is to develop improved formulations and administration methods for existing FDA- approved products and / or select and acquire or in- license product candidates for the treatment of therapeutic indications that complement or augment our current targets, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Developing new formulations of existing products or identifying, selecting and acquiring or in- licensing promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual development, acquisition or in- license of a particular product candidate, potentially resulting in a diversion of our management' s time and the expenditure of significant resources with no resulting benefit. If we are unable to add additional product candidates to our pipeline, our long- term business and prospects will be limited. Public concern regarding the safety of any of our drug products could result in the inclusion of unfavorable information in our labeling or require us to undertake other activities that may entail additional costs. Considering widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the establishment of risk management programs that may, for example, restrict distribution of drug products after approval. The FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the FDAAA authorizes the FDA to, among other things, require post- approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. The FDAAA also significantly expands the federal government' s clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of this law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials. If the FDA requires us to provide additional clinical or preclinical data for any of our approved drug products, the indications for which that product candidate was approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize any approved product may be otherwise adversely impacted.

Uncertainty about presidential administration initiatives could negatively impact our business, financial condition and results of operations. There is significant uncertainty with respect to legislation, regulation and government policy at the federal level, as well as the state and local levels. Recent events, including the 2024 U. S. presidential election, have created a climate of heightened uncertainty and introduced new and difficult- to- quantify macroeconomic and political risks with potentially far- reaching implications. The presidential administration' s changes to U. S. policy may impact, among other things, the U. S. and global economy, international trade and relations, unemployment, immigration, taxes, healthcare, the U. S. regulatory environment, inflation and other areas. Although we cannot predict the impact, if any, of these changes to our business, they could adversely affect our business, financial condition, operating results and cash flows. Until we know what policy changes are made and how those changes impact our business and the business of our

competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them. Risks Related to Our Intellectual Property If we are unable to obtain or protect intellectual property rights of any of our products and product candidates, we may not be able to compete effectively in our market. We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and our product candidates. The issuance, scope, validity, enforceability, strength and commercial value of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own, or in- license, may fail to result in issued patents with claims that cover the products or product candidates, if approved, in the United States or in foreign countries or territories. If this were to occur, early generic competition could be expected against our products and product candidates, if approved. There may be relevant prior art relating to our patents and patent applications which could invalidate a patent or prevent a patent from issuing based on a pending patent application. In particular, because the active pharmaceutical ingredients in many of our product candidates have been on the market as separate products for many years, it is possible that these products have previously been used off- label in such a manner that such prior usage would affect the validity of our patents or our ability to obtain patents based on our patent applications. The patent prosecution process is expensive and time- consuming. We or our licensors may not be able to prepare, file and prosecute all necessary or desirable patent applications for a commercially reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we or our licensors 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. Moreover, depending on the terms of any future in- licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology in- licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable, processes for which patents are difficult to enforce or which we choose not to seek to patent, and any other elements of our drug development and reformulation processes that involve proprietary know- how, information or technology that is not covered by patents. Although we generally require all of our colleagues to assign their inventions to us, and we generally seek to have all of our colleagues, consultants, advisors and any third parties who have access to our proprietary know- how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors or other third parties. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA is considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA' s disclosure policies may change in the future, if at all. If we are unable to prevent material disclosure of the non- patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition. We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world. Filing and prosecuting patent applications and defending patents covering our products or product candidates, if approved, in all countries throughout the world would be prohibitively expensive. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement rights are not as strong as those in the United States or Europe. These products may compete with our products or product candidates, and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, we may decide to abandon national and regional patent applications before grant. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology. The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or

license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions. Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection **and could increase** ~~. For example, on September 16, 2011,~~ the ~~Leahy- Smith America Invents Act,~~ **uncertainties and costs surrounding the prosecution of** ~~or~~ **our** ~~the Leahy- Smith Act, was signed into law. The Leahy- Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way~~ patent applications ~~will be prosecuted~~ and ~~may also affect patent litigation. The United States Patent and Trademark Office, or USPTO, has developed new and untested regulations and procedures to govern~~ the **enforcement** ~~full implementation of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy- Smith Act has also introduced procedures making it easier for~~ - **or defense of our** ~~third parties to challenge~~ issued patents, **all** ~~as well as to intervene in the prosecution~~ of **which could have a material adverse effect on our business** ~~patent applications. Finally, the Leahy- Smith Act contains new statutory provisions that still require the USPTO to issue new regulations for their implementation~~ and **financial condition** ~~it may take the courts years to interpret the provisions of the new statute~~ . The U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce existing patents or patents that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce existing patents or patents that we may obtain in the future. ~~Accordingly, it is too early to tell what, if any, impact the Leahy- Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.~~ Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. We **have in the past and** are **likely** ~~currently, and~~ in the future ~~will likely continue~~ to be, involved in lawsuits to protect or enforce our patents. These lawsuits are expensive and require us to expend substantial financial resources, are time consuming, may continue for many years for one or more claims and may be unsuccessful. Competitors may infringe our patents or the patents of any potential licensors. To counter infringement or unauthorized use, we have been, and in the future may be, required to file infringement claims, which are expensive and time- consuming ~~. For example, beginning in August 2013, we filed patent infringement lawsuits against six generic companies in the U. S. District Court for the District of Delaware for the approval by the FDA of generic versions of Suboxone in the United States. Of these, cases against all but one of the six generic companies have been resolved. We are also seeking to enforce our patent rights as further described in Part II Item 8. Financial Statements and Supplementary Data, Note 22, Contingencies~~ . In an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. Interference proceedings invoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease

using the related technology or to attempt to license rights to it from the prevailing party. Our business could be significantly harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our bringing or defending litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees from our core business. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. **A** ~~As described in Part II Item 8. Financial Statements and Supplementary Data, Note 22, Contingencies to our consolidated financial statements, a~~ number of our issued patents ~~are involved in litigation. In addition to the challenges we face in those litigation matters, a number of our issued patents are or~~ have been involved in administrative proceedings, such as reexamination and inter partes review at the USPTO and opposition at the EPO. **The matters are resolved, but in possible future proceedings,** ~~There~~ **there** can be no assurance that all claims of the challenged patents will be upheld or that the patents challenged by us will be found infringed. We may lose any of the challenged patents entirely, or we may have to amend the scope of claims to an extent which may be considered insufficient to cover our products or product candidates. If any of those scenarios were to occur, we might lose our competitive advantage in our market, and our business could be materially affected. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock ~~. For more information, please see Part II Item 8. Financial Statements and Supplementary Data, Note 22, Contingencies to our consolidated financial statements~~ . Third parties may commence legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business. Our commercial success depends, in part, upon our ability, and the ability of our existing and future collaborators, to develop, manufacture, market and sell our products and product candidates, if approved, and use our proprietary technologies without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. We may have been and in the future may become party to or be threatened with adversarial proceedings or litigation regarding intellectual property rights with respect to our products, product candidates and technology, which may include interference or derivation proceedings, post grant review and inter partes review before the USPTO or similar adversarial proceedings or litigation in any jurisdiction. Similarly, we or our licensors or collaborators have initiated, and in the future may initiate, such proceedings or litigation against third parties, which may include challenging the validity or scope of intellectual property rights controlled by third parties. Third parties have asserted and, in the future, may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that additional third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe any of those claims are without merit, a court of competent jurisdiction could hold that these third- party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize such product or product candidates unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third- party patents were held by a court of competent jurisdiction to cover aspects of our technology, holders of any such patents may be able to block our ability to develop and commercialize the applicable product or product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid, unenforceable or not infringed by our product or technology. In either case, such a license may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In such event, we may be unable to further practice our technologies or develop and commercialize any of our product candidates at issue, which could significantly harm our business. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates, if approved. Defense of these claims, regardless of their merit, could involve substantial litigation expense and a substantial diversion of employee resources from our business. Third parties making such claims may have the ability to dedicate substantially greater resources to these legal actions than we or our licensors or collaborators can. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. The patents and patent applications that we have covering our products and product candidates are limited to specific formulations and manufacturing processes, and our market opportunity for our products and product candidates may be limited by the lack of patent protection for the active ingredients and by competition from other formulations and manufacturing processes, as well as administration methods that may be developed by competitors. We have obtained and continue to seek to obtain patent protection for our manufacturing technology, drug administering technology and our products and product candidates, including specific formulations and manufacturing processes, which may not be as effective as composition of matter coverage in preventing work- arounds by competitors. As a result, generic products that do not infringe the claims of our issued patents covering formulations and processes are, or may be, available while we are marketing our products. Competitors who obtain the requisite regulatory approval will be able to commercialize products with the same active ingredients as our

products or product candidates so long as the competitors do not infringe any process, use or formulation patents that we have developed for our products or product candidates, subject to any regulatory exclusivity we may be able to obtain for our products. The number of patents and patent applications covering products containing the same active ingredient as our products or product candidates indicates that competitors have sought to develop and may seek to commercialize competing formulations that may not be covered by our patents and patent applications. The commercial opportunity for our products or product candidates could be significantly harmed if competitors are able to develop and commercialize alternative formulations of our products or product candidates that are different from ours and do not infringe our issued patents covering our products or use of our products. Suboxone, Zuplenz, Sympazan **, Libervant** and ~~Exservan~~ **Emylif** have been approved by the FDA, and other product candidates may be approved by the FDA in the future. As additional products of ours are on the market, one or more third parties may also challenge the patents that we control covering our products, which could result in the invalidation or unenforceability of some or all of the relevant patent claims of our issued patents covering our products. If we or one of our licensees initiated legal proceedings against a third- party to enforce a patent covering one of our products or product candidates, the defendant could counterclaim, and have in certain existing proceedings counterclaimed, that the patent covering our product or product candidate is invalid and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are common, and there are numerous grounds upon which a third- party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, post- grant review, and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our products or product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or product candidates. Such a loss of patent protection could have a material adverse impact on our business ~~. For more information, please see Part IV, Note 22, Contingencies to our consolidated financial statements~~ . Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and / or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and licensed patents and / or applications and any patent rights we may own or license in the future. We rely on our outside counsel or our licensees to monitor the status of these fees so that we may make required payments of these fees when due to non- U. S. patent agencies. The USPTO and various non- U. S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non- compliance can result in abandonment or lapse of the patents or patent applications, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market which could harm our business. Our drug development strategy relies heavily upon the 505 (b) (2) regulatory pathway, which requires us to certify that we do not infringe upon third- party patents covering approved drugs. Such certifications typically result in third- party claims of intellectual property infringement, the defense of which will be costly and time- consuming, and an unfavorable outcome in any litigation may prevent or delay our development and commercialization efforts which would harm our business. Litigation or other proceedings to enforce or defend intellectual property rights are often complex in nature, may be very expensive and time- consuming, may divert our management' s attention from other aspects of our business and may result in unfavorable outcomes that could adversely impact our ability to launch and market our product candidates, or to prevent third parties from competing with our products and product candidates. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the USPTO. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Our commercial success depends in large part on our avoiding infringement of the patents and proprietary rights of third parties for existing approved drug products. Because we utilize the 505 (b) (2) regulatory pathway for the approval of our products and product candidates, we rely in whole or in part on studies conducted by third parties related to those approved drug products. As a result, upon filing with the FDA for approval of our product candidates, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA' s Orange Book with respect to our NDA; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our proposed drug product. When we submit a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to the patent owner once our 505 (b) (2) NDA is accepted for filing by the FDA. The third- party may then initiate a lawsuit against us to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our NDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in our favor. If the

third- party does not file a patent infringement lawsuit within the required 45- day period, our NDA will not be subject to the 30-month stay. In addition to paragraph IV litigation noted above, third- party owners of patents may generally assert that we are employing their proprietary technology without authorization. There may be third- party patents or patent applications with claims to materials, formulations or methods of manufacture related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending or subsequently filed patent applications which may later result in issued patents that may be infringed by our products or product candidates. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our product candidates, including the formulation, any method or process involved in the manufacture of any of our product candidates, any molecules or intermediates formed during such manufacturing process or any other attribute of the final product itself, the holders of any such patents may be able to block our ability to commercialize our product candidates unless we obtain a license under the applicable patents, or until such patents expire. In either case, such a license may not be available on commercially reasonable terms or at all. Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. We cannot assure you that our business, products, product candidates and methods do not or will not infringe the patents or other intellectual property rights of third parties. Parties making claims against us may request and / or obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates on a temporary or permanent basis. Defense of these claims, regardless of their merit, involves substantial litigation expense and could be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products or manufacturing processes, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research, manufacture clinical trial supplies or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our products or product candidates, which could harm our business significantly. We cannot provide any assurances that third- party patents do not exist which might be enforced against our products or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties. We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates ~~and companion diagnostic~~ . Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation generally involves substantial costs and can be a distraction to management and other employees. If we are not able to obtain adequate trademark protection or regulatory approval for our brand names, we may be required to re- brand affected products, which could cause delays in getting such product to market, substantively impact successful commercialization of any such product and substantially increasing our costs. To protect our rights in any trademark we use or intend to use for our products or our product candidates, we may seek to register such trademarks. Trademark registration is territory- specific and we must apply for trademark registration in the United States as well as any other country where we intend to commercialize our product or product candidates. Failure to obtain trademark registrations may place our use of the trademarks at risk or make them subject to legal challenges, which could force us to choose alternative names for our product or product candidates. In addition, the FDA and other regulatory authorities outside the United States conduct independent reviews of proposed product names for pharmaceuticals, including an evaluation of the potential for confusion with other pharmaceutical product names for medications. These regulatory authorities may also object to a proposed product name if they believe the name inappropriately makes or implies a therapeutic claim. If the FDA or other regulatory authorities outside the United States object to any of our proposed product names, we may be required to adopt alternative names for our product or product candidates. If we adopt alternative names, either because of our inability to obtain a trademark registration or because of objections from regulatory authorities, we would lose the benefit of our existing trademark applications. As a result, we may be required to expend significant additional resources in an effort to adopt a new product name that would be registrable under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA and other regulatory authorities, which could adversely impact our product brand identity and successful commercialization of any product and increase our costs. Furthermore, we may not be able to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product or our product candidates. Intellectual property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative: • others may be able to make products that are similar to our products or product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed; • we or any potential future licensors might not have been the first to file patent applications covering certain of our inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • it is possible that our pending patent applications will not lead to issued patents; • issued patents that we own or have exclusively licensed may be held invalid or unenforceable as a result of

legal challenges by our competitors; • issued patents that we own or have exclusively licensed may not provide coverage for all aspects of our products or product candidates in all countries; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; and • the patents of others may have an adverse effect on our business. Should any of these events occur, they could significantly harm our business, results of operations and prospects. Risks Related to Ownership of Our Common Stock Our quarterly operating results may fluctuate significantly, and these fluctuations could cause our stock price to decline. We expect our operating results to continue to be subject to significant quarterly and annual fluctuations. These fluctuations could cause our stock price to decline. Our net loss and other operating results will be affected by numerous factors, including: • whether the FDA requires us to complete additional, unanticipated studies, trials or other activities prior to approving any of our current and future product candidates, which would likely delay any such approval; • our execution of other collaborative, licensing or similar arrangements and the timing of payments we may make or receive under these arrangements; • our limited cash resources and substantial indebtedness; • variations in the level of expenses related to our future development programs; • any product liability or intellectual property infringement lawsuit in which we may become involved; • delays in obtaining, failure to obtain, or adverse developments in obtaining FDA and other regulatory approval of our product candidates; • other regulatory developments affecting any of our other current and future product candidates, or the product candidates of our competitors; **• the costs of pre- commercialization and commercialization of any of our approved products that we market ourselves;** and • if any of our current or future product candidates receive regulatory approval, the level of underlying demand for such product candidate and wholesaler buying patterns. If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our Common Stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. Our largest stockholder and management own a significant percentage of our stock and may have the ability to effectively influence matters subject to stockholder approval. As of December 31, ~~2023~~ **2024** , our executive officers and directors beneficially owned approximately ~~9~~ **6** . ~~5~~ **6** % of our outstanding common stock. In addition, Bratton Capital Management L. P. and its affiliates beneficially owned, directly, approximately ~~14~~ **10** . 8 % of our outstanding common stock as of December 31, ~~2023~~ **2024** . Therefore, these stockholders may have, through their respective ownership positions, the ability to influence matters requiring stockholder approval, including elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our Common Stock that you may believe are in your best interest as one of our stockholders ~~. We may incur substantial costs relating to " excess parachute payments " under Sections 280G and 4999 of the Internal Revenue Code of 1986, as amended. We entered into an employment agreement with A. Mark Schobel, our Chief Innovation and Technology Officer, pursuant to which he is entitled to receive an additional tax indemnification payment, or a " gross- up " payment, if the payments and benefits under his employment agreement or any other benefits plans and programs trigger excise tax liability under Section 4999 of the Internal Revenue Code of 1986, as amended, or the Code, for " excess parachute payments. " Under Sections 280G and 4999 of the Code, the excise tax is triggered by change in control- related payments that, in general, equal or exceed three times Mr. Schobel' s average annual taxable compensation over the five calendar years preceding the change in control. The excise tax equals 20 % of the amount of the payment in excess of Mr. Schobel' s average taxable compensation over the preceding five calendar year period (i. e., the excess parachute payments). In addition to providing Mr. Schobel with a tax- gross- up payment, we may not take a federal tax deduction for Mr. Schobel' s excess parachute payments. If an " excess parachute payment " is made to Mr. Schobel, we may incur substantial costs related to a change in control of Aquestive due to the gross- up payment and the lost federal tax deduction for Mr. Schobel' s excess parachute payments~~ . Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. We have incurred substantial losses since the inception of our company and do not expect to become profitable in the near future, if ever. Under currently enacted federal income tax law, to the extent that we continue to generate taxable losses in future years, such unused losses will carry forward to offset future taxable income, if any, but our deductibility of such losses in a future year is generally limited to 80 % of taxable income. Furthermore, under Section 382 of the Code, if a corporation undergoes an " ownership change, " generally defined as a greater than 50 % 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 further limited. We believe that, with our initial public offering, we may have triggered an " ownership change " limitation. In addition, we have experienced and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, including an ownership change as a result of the combined effect of our initial public offering and future equity offerings. As a result, if we earn net taxable income, our ability to use our pre- change net operating loss carryforwards to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. We do not intend to pay dividends on our Common Stock so any returns will be limited to the value of our stock. We have never declared or paid any cash dividend on our Common Stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock. Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third- party to acquire us, or may increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. Some provisions of our charter documents and Delaware law may have anti- takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include: • authorizing the issuance of " blank check " preferred stock, the terms of which may be established

and shares of which may be issued without stockholder approval; • limiting the removal of directors by the stockholders; • creating a classified board of directors; • establishing a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and of our amended and restated bylaws; • prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; • eliminating the ability of stockholders to call a special meeting of stockholders; and • establishing advance notice and other requirements, including compliance with the SEC Universal Proxy Rules, for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings. These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us. Our amended and restated 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 employees. Our amended and restated certificate of incorporation provides that, subject to limited exceptions, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our amended and restated bylaws or any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. This choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation 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 and financial condition.

General Risk Factors

Public health threats such ~~Our business may be adversely affected by the ongoing coronavirus pandemic. Beginning in late 2019, the outbreak of COVID- 19 has~~ **as** ~~evolved into~~ a global pandemic ~~. Depending upon the length and severity of the pandemic or any resurgence~~ , ~~which cannot be predicted, we may experience disruptions that could materially and adversely impact our~~ **or widespread outbreak** ~~business including: • Various aspects~~ of **infectious disease** ~~our clinical trials~~ , **similar** ~~including delays or difficulties in enrolling patients in our clinical trials, in clinical trial site initiation, and in recruiting clinical site investigators and clinical site staff; increased rates of patients withdrawing from clinical trials; diversion of healthcare resources away from the conduct of clinical trials; interruption of key clinical trial activities such as clinical trials site data monitoring due to limitations on travel imposed or recommended by federal or state governments; impact on employees and others or interruption of clinical trial visits or study procedures which may impact the integrity of subject data and clinical study endpoints; and interruption or delays in the operations of the FDA, and comparable foreign regulatory agencies, which may impact regulatory review and approval timelines. • If any third- party in our supply chain for any materials, including active pharmaceutical ingredients and other raw materials supply, which we need for our product candidates for our clinical trials and for the approved products we manufacture and distribute, are adversely impacted by restrictions resulting from the coronavirus pandemic, including staffing shortages, production slowdowns, or disruptions in freight and other transportation services and delivery distribution systems, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our clinical trials, conduct our research, development and clinical operations, and manufacture, distribute and sell our approved products. • Although we have reopened our business office after several months of closure during the coronavirus pandemic, if there is a resurgence of COVID- 19 exposures, we may be forced to close our business office again. However, we would expect that our colleagues in our research and development laboratory and manufacturing facilities would continue to work on site, with appropriate safety and health measures reimplemented in order to reduce risk of transmission, as they did throughout the pandemic. Should such a resurgence occur, our increased reliance on colleagues and other third parties on whom we rely on working from home or having health issues may negatively impact productivity and could limit commercial launch activities for any new approved product, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations. Our colleagues conducting research and development activities might not be able to access our laboratory or manufacturing facilities for an extended period of time as a result of any further closure of our facilities as well as the possibility of further governmental restrictions. As a result, this could delay timely completion of preclinical activities, including completing Investigational New Drug (IND) / Clinical Trial Application (CTA) enabling studies or our ability to select future development candidates, and initiation of clinical or other of our development programs and production and delivery of our products. • The FDA and comparable foreign regulatory agencies may experience disruptions, have slower response times or be under- resourced to continue to monitor our clinical trials or to conduct required activities and review of our product candidates seeking regulatory review and such disruptions could**

~~materially affect the development, timing and approval of our product candidates. • The coronavirus pandemic may impact the requirements of our customers and growth of our approved products. For example, Indivior, our significant customer for Suboxone, had announced that it anticipated coronavirus impact on its product sales. Although we currently do not anticipate any significant interruption in supply, we continue to monitor this situation closely and there is no assurance that disruptions or delay will not occur as a result of a resurgence of COVID- 19 and we cannot accurately predict the adverse impact the coronavirus pandemic will have on orders of our approved product, including Suboxone. We also have experienced in one instance, and could in the future experience, extended customer payment cycles. • As a result of concerns caused by the continuing effects of the coronavirus, we may face issues and investor concerns in raising capital through sales of our Common Stock or other securities, or in seeking to monetize any of our licensed royalty and milestone rights. In addition, a recession, depression or other sustained adverse market event could materially and adversely affect the financial markets, our business, the value of our Common Stock and our ability to obtain on favorable terms, or at all, equity or debt financing or any potential monetization of our royalty streams. The coronavirus pandemic continues to evolve. The ultimate impact of the coronavirus pandemic on us is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, the manufacturing, marketing, distribution and sale of our approved products, the healthcare system or the global economy. Given the uncertainties, we are unable to provide assurance that operations can be maintained as planned prior~~ to the COVID- 19 pandemic **, may create uncertainties about our future operating results and financial conditions. Public health threats, such as the COVID- 19 or any other pandemic, may have an impact on our business, financial condition, results of operations and cash flows. Prolonged volatility or significant disruption of global financial markets due in part to a public health threat could have a negative impact on our business and overall financial position. Other factors and uncertainties include, but are not limited to, increased operational costs associated with operating during and after a pandemic; evolving macroeconomic factors, including general economic uncertainty, increased labor costs, and recessionary pressures; capital and other resources needed to respond to a pandemic; along with the severity and duration of a pandemic. These risks and their impacts are difficult to predict and could continue to otherwise disrupt and adversely affect our operations and our financial performance. In addition, to the extent a global health crisis, epidemic or pandemic, such as theCOVID- 19 pandemic, adversely affects our business, financial condition and results of operations, it may also have the effect of heightening many of the other risks described in this " Risk Factors " section** . Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel **.** We are highly dependent on the principal members of our executive team and other key executives, the loss of whose services may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit key executives or the loss of the services of any executive or key employee might impede the progress of our development and commercialization objectives. Under applicable employment laws, we may not be able to enforce covenants not to compete. Certain of our executive officers' employment agreements include covenants not to compete. These agreements prohibit our executive officers, if they cease working for us, from competing directly with us or working for our competitors for a limited period. We may be unable to enforce these agreements or may not be able to enforce these agreements to their full extent under applicable law. If we cannot demonstrate that our interests would be harmed by such competitive behavior, we may be unable to prevent our competitors from benefiting from the expertise of our former executives and our competitiveness may be diminished. ~~Any~~ **Compliance with ever evolving federal, state, and foreign laws relating to handling of information about individuals involves significant expenditure and resources, and any** failure **by us or our vendors** to comply ~~with applicable~~ **may result in significant liability, negative publicity, and / or an erosion of trust, and could materially adversely affect our business, results of operations, and financial condition. We receive, store, handle, transmit, use and otherwise process information related to individuals. We also depend on a number of third-party vendors in relation to the operation of our business, a number of which process** data ~~protection~~ **on our behalf. We** and **our vendors are subject to a variety of federal, state and foreign data** privacy laws ~~and~~ **, rules,** regulations ~~could lead to significant penalties against us~~ **, industry standards** and ~~adversely impact our operating results. We~~ **other requirements, including those that apply generally to the handling of information about individuals, and those that** are ~~subject~~ **specific** to **certain industries** ~~U. S. data protection laws and regulations~~ **, sectors, contexts, or locations** ~~including laws and regulations that address privacy and data security~~ . **These requirements, and their application, interpretation and amendment are constantly evolving and developing. In the United States,** ~~Numerous~~ **numerous** federal and state laws, including state data breach notification laws and state health information privacy laws, govern the collection, use, and disclosure and protection of health- related and other personal information. **The Federal Trade Commission and state regulators enforce a variety of data privacy issues, such as promises made in privacy policies or** ~~Failure~~ **failures** to ~~comply~~ **appropriately protect information about individuals, as unfair or deceptive acts or practices in or affecting commerce in violation of the Federal Trade Commission Act or similar state laws. We are subject to HIPAA. HIPAA imposes privacy, security and breach notification obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information (" protected health information, " or " PHP ") for or on behalf of such covered entities, and their covered subcontractors. HIPAA requires covered entities and business associates to develop and maintain policies** with ~~data~~ **respect to the** protection ~~laws~~ **of, use** and ~~regulations could~~

disclosure of PHI, including the adoption of administrative, physical and technical safeguards to protect such information, and certain notification requirements in the event of a breach of unsecured PHI. Additionally, under HIPAA, covered entities must report breaches of unsecured PHI to affected individuals without unreasonable delay, not to exceed 60 days following discovery of the breach by a covered entity or its agents. Notification also must be made to the U. S. Department of Health and Human Services Office for Civil Rights, or OCR, and, in certain circumstances involving large breaches, to the media. Business associates must report breaches of unsecured PHI to covered entities within 60 days of discovery of the breach by the business associate or its agents. A non- permitted use or disclosure of PHI is presumed to be a breach under HIPAA unless the covered entity or business associate establishes that there is a low probability the information has been compromised consistent with requirements enumerated in HIPAA. Entities that are found to be in violation of HIPAA as the result ~~in government enforcement~~ **of a breach of unsecured PHI, a complaint about privacy practices or an audit by HHS may be subject to significant civil, criminal and administrative fines and penalties and / or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective** ~~actions~~ **action plan with HHS to settle allegations of HIPAA non- compliance. HIPAA also authorizes state Attorneys General to file suit on behalf of their residents. Courts may award damages, costs** and **attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not** create ~~liability for~~ **a private right of action allowing individuals to sue** us **in** ~~, which could include~~ civil **court** ~~and / or~~ **for** ~~criminal penalties~~ **violations of HIPAA** , ~~private litigation and /~~ **its standards have been used as the basis** ~~or~~ **for** ~~adverse publicity that could negatively affect~~ **duty of care in state civil suits such as those for negligence** ~~our~~ **or** ~~operating results and business~~ **recklessness in the misuse or breach of PHI** . Member states in the European Union and other countries have also adopted data protection laws and regulations which impose significant compliance obligations. ~~In~~ **For example, in** the European Union, **on May 25, 2018** ~~the collection and use of personal health data has been governed by the provisions of~~ the EU ~~Data Protection Directive. The EU General~~ **general** Data Protection Regulation (GDPR) ~~replaced~~ **became applicable throughout** the **EU** ~~Data Protection Directive (with an~~ **and** ~~enforcement date of May 25~~ , ~~2018) and is~~ **as a regulation, has direct effect in all member states. The GDR was** designed to harmonize data privacy laws across **the** ~~Europe and to protect all~~ EU ~~citizens'~~ **and change the way organizations approach** data privacy **. The GDPR introduced new obligations and expanded the extraterritorial reach of the EU data protection regime. It applies to (i) organizations that process personal data in the context of** ~~and~~ **an** ~~will~~ **establishment in the EU (regardless of whether the processing takes place in the EU) and (ii) organizations outside the EY that offer goods or services to data subjects in the EU, or that monitor the behavior of EU data subjects. Compliance with the GDPR involves significant obligations, including requirements around accountability and transparency, contracting with service providers that process personal data, responding to data subjects' rights requests within prescribed timelines, reporting of data breaches to data subjects and. or data protection or supervisory authorities, taking account of data protection as any new services are developed, and limiting the amount of personal data collected, stores or otherwise processed. These obligations and restrictions** have a significant impact on ~~how certain data is processed and handled. The European Union data protection laws and regulations impose strict obligations and restrictions on~~ the ability to collect, analyze and transfer personal data, including **in the context of** health data **from** clinical trials. **Even though we believe we and our vendors are generally in compliance with applicable laws, rules and regulations relating to privacy and data security, these laws are in some cases relatively new and the interpretation and application of these laws are uncertain.** Any failure **or perceived failure by us** to comply with ~~these~~ **data privacy and security** laws ~~and~~ **, rules,** regulations ~~or~~ **, industry standards and** ~~the~~ **other requirements** ~~manner in which they are interpreted or implemented~~ could ~~lead to government enforcement~~ **result in proceedings or** actions ~~and significant penalties~~ against us **by individuals** , **consumer rights groups, government agencies, or others. We could incur significant costs in investigating and defending such claims and, if found liable, pay significant damages or fines or be required to make changes to our business. Further, these proceedings and any subsequent adverse outcomes may subject us to significant negative publicity and** ~~and~~ **an erosion of trust. If any of these events were to occur, our business, results of operations, and financial condition could be materially** adversely **affected** ~~impact our operating results~~ . Our colleagues, principal investigators, consultants and agents may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements and insider trading. We are exposed to the risk of fraud or other misconduct by our colleagues, principal investigators **, contract sales force** , consultants and agents. Misconduct by these parties could include failure to: • comply with FDA regulations or the regulations applicable in other jurisdictions; • provide accurate information to the FDA and other regulatory authorities; • comply with healthcare fraud and abuse laws and regulations in the United States and abroad; • report financial information or data accurately; or • disclose unauthorized activities to us. We may be subject to claims that our colleagues, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our colleagues, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our colleagues' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other colleagues from our core business. The market price of our Common Stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our Common Stock. The market price of our Common Stock since our IPO has been and is likely to be volatile. The stock market in general and the market for biopharmaceutical or pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your Common Stock at or above your purchase price. The market price for our Common Stock may be influenced by many factors, including: •

results of clinical trials of our current and any future product candidates or those of our competitors; • the success or regulatory approval of competitive drugs or therapies; • regulatory or legal developments in the United States and other countries, as to both our products and product candidates and those of our competitors; • developments or disputes concerning patent applications, issued patents or other proprietary rights; • the recruitment or departure of key personnel; • the level of expenses related to our current and any future product candidates or clinical development programs; • the results of our efforts to discover, develop, acquire or in- license additional product candidates; • actual or anticipated changes in estimates as to financial results, development, clinical trials or regulatory approval timelines or recommendations by securities analysts; • our inability to obtain or delays in obtaining adequate drug supply for any approved drug or inability to do so at acceptable prices; • disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; • significant lawsuits, including patent or stockholder litigation; • variations in our financial results or those of companies that are perceived to be similar to us, or our failure to achieve anticipated financial results or funding; • market conditions in the pharmaceutical and biotechnology sectors; • inflation and rising interest rates; • general economic, industry and market conditions; and • the other factors described in this " Risk Factors " section. If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our Company, the price of our Common Stock could decline. The trading market for our Common Stock relies, in part, on the research and reports that industry and financial analysts publish about us or our business. We currently have limited research coverage by industry and financial analysts. Should any analysts then covering our business downgrade their evaluations of our stock, the price of our stock could decline. If any analysts then covering our business cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline. **We** ~~As of December 31, 2023, we~~ are ~~no longer an " emerging growth company, " but still remain~~ a " smaller reporting company ", and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our Common Stock less attractive to investors. **We** ~~As of December 31, 2023, we were no longer an " emerging growth company, " as defined in the JOBS Act. While we were an emerging growth company, we were able to take advantage of exemptions from various reporting requirements that~~ are ~~applicable to other public companies that are not " emerging growth companies, " including exemption from compliance with the auditor attestation requirements of Section 404 (b) of the Sarbanes- Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non- binding advisory vote on executive compensation. Even though we are no longer an emerging growth company, we remain exempt from the auditor attestation requirements of Section 404 (b) of the Sarbanes- Oxley Act pursuant to rules of the SEC. We remain~~ a " smaller reporting company ", as defined in Rule 405 under the Securities Act which ~~means that we are not an investment company, an asset- backed issuer, or a majority- owned subsidiary of a parent company that is not a " smaller reporting company " which~~ allows us to take advantage of many of the ~~same~~ exemptions from disclosure requirements **available to " emerging growth companies, " as defined in the JOBS Act,** including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and certain reduced financial disclosures in our periodic reports, including this Annual Report on Form 10- K. **We** ~~In addition, we~~ are eligible to remain a smaller reporting company ~~,~~ for so long as we have a public float (based on our Common Stock equity) of less than $ 250 million measured as of the last business day of our most recently completed second fiscal quarter or a public float (based on our Common Stock equity) of less than $ 700 million as of such date and annual revenues of less than $ 100 million during the most recently completed fiscal year. We cannot predict if investors will find our Common Stock less attractive because we may rely on these exemptions. If some investors find our Common Stock less attractive as a result of these disclosure exemptions, there may be a less active trading market for our Common Stock and our stock price may be more volatile. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our Common Stock. 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 new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of 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. 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. Sales of a substantial number of shares of our Common Stock in the public market by our existing stockholders would cause our stock price to fall. Sales of a substantial number of shares of our Common Stock by our existing stockholders, including shares issued to colleagues and directors in respect of the termination of our Performance Unit Plans, or PUP Plans, in the public market or the perception that these sales might occur, could depress the market price of our Common Stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our Common Stock. Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act ~~have~~ **has** resulted in a substantial amount of these shares becoming freely tradable without restriction under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our Common Stock. Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial conditions and results of operation. Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to bank failures and market- wide liquidity problems. ~~For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and~~

~~Innovation, which appointed the FDIC as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each sent into receivership.~~ Although the Department of the Treasury, the Federal Reserve and the FDIC **may take** ~~in that situation took~~ action to mitigate the risk of potential losses ~~on the sale of such instruments~~ , widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediate liquidity may exceed the capacity of such program ~~;~~ ~~there is no guarantee, however, that the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion~~ . Although we assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalization our current projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships, and in turn, us. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and / or delays in accessing or actual loss of funds subject to cash management arrangements. In addition, widespread investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and / or projected business operations and financial condition and results of operations. In addition, a critical vendor or business partner could be adversely affected by any of the liquidity or other risks that are described above as factors, which in turn, could have a material adverse effect on our current and / or projected business operations and results of operations and financial condition. Any business partner or supplier bankruptcy or insolvency, or any breach or default by a business partner or supplier, or the loss of any significant business partner or supplier relationships, could result in material adverse impacts on our current and / or projected business operations and financial condition.