Risk Factors Comparison 2024-03-18 to 2023-03-31 Form: 10-K

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Our business, ~~results of operations and~~ financial condition **, results of operations,** and the industry in which we operate are subject to various risks. You should carefully consider the risks described below, in addition to the other information contained in this Form 10- K, before making an investment decision. The risks and uncertainties described below are not the only ones we face **and you should not interpret the disclosure of a risk to imply that the risk has not already materialized** . Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations. Risks Pertaining to Our Business and Industry We currently have no drug products for sale, but we are developing three drug product candidates, **AJ201,** IV ~~Tramadol~~ **tramadol** ~~,~~ **and** BAER- 101 ~~and AJ201~~ . We are dependent on the success of our product candidates, and cannot guarantee that these product candidates will receive regulatory approval or be successfully commercialized. Our business success depends on our ability to obtain regulatory approval to successfully commercialize, market and sell our product candidates, and any significant delays in obtaining approval to commercialize, market and sell our product candidates will have a substantial adverse impact on our business and financial condition. If the applications for any of our product candidates are approved, our ability to generate revenues from such product candidates will depend on our ability to: ● establish and maintain agreements with our contract manufacturers, wholesalers, distributors **,** and group purchasing organizations on commercially reasonable terms; ● obtain sufficient quantities of ~~the~~ our product candidates from qualified third- party manufacturers that manufacture in accordance with ~~Current Good Manufacturing Practices (~~ CGMP ~~)~~ requirements, as required to meet commercial demand at launch and thereafter; ● hire, train, deploy **,** and support our sales force; ● create market demand ~~for our products~~ through our own marketing and sales activities, and **through** any other arrangements ~~to promote this product candidates~~ we may later establish; ● conduct such marketing and sales activities in a manner that is compliant with federal and state laws, **and any applicable foreign regulations,** including restrictions on off- label promotion and anti- kickback requirements; ● obtain and maintain government and private payer reimbursement for our **approved** ~~product~~ **products** ; and ● maintain patent protection and regulatory exclusivity for our product candidates. We may not receive regulatory approval for our product candidates, or their approvals may be delayed, which would have a material adverse effect on our business and financial condition. Our product candidates and other future product candidates and the activities associated with their development and **with their** commercialization **, if approved** , including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale **,** and distribution, are subject to premarket approval and comprehensive regulation by the FDA, DEA **,** and other regulatory agencies in the United States **and potentially foreign governmental authorities** . Failure to obtain marketing approval for our product candidates will prevent us from commercializing our product candidates. We have not received approval to market **any of** our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in conducting preclinical and clinical studies and filing and supporting the applications necessary to gain marketing approvals and expect **to continue** to rely on third party contract research organizations as well as consultants and vendors to assist us in the process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate' s safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates must meet FDA' s standards for safety and efficacy, but may be determined not to be effective, to be only moderately effective, to not be safe for use in its intended population, or may prove to have undesirable or unintended side effects, toxicities **,** or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if approval is granted at all, and can vary substantially based upon a variety of factors, including the type, complexity **,** and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in the regulatory review process for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical studies or clinical trials. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit **,** or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of any of our product candidates or any future product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be materially impaired, thereby negatively impacting our business, financial condition **,** and results of operations. ~~26In~~ **In** addition, even if we were to obtain approval, the approval of the indication for any of our product candidates by such regulatory authorities may, among other things, be more limited than we request. Such regulatory authorities may not approve the price we intend to charge for our product, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. These regulatory authorities may also require the label to contain warnings, contraindications, or precautions that limit the commercialization of that product. Our third- party suppliers may be subject to inspections by the FDA that identifies deficiencies in their manufacturing facilities and concludes they are not operating in compliance with CGMP requirements, which in turn, may force us to identify, qualify **,** and

rely upon additional suppliers. Any of these scenarios could compromise the commercial prospects for our product candidates, or any future product candidates. If serious adverse or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates. If our product candidates or future product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe **,** or more acceptable from a risk- benefit perspective. In our industry, many compounds that initially showed promise in early- stage testing have later been found to cause undesirable side effects that prevented further development of the compound. In the event that our preclinical or clinical trials reveal a high and unacceptable severity and prevalence of side effects, our trials could be delayed, suspended **,** or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of our product candidates or future product candidates for any or all targeted indications. The FDA could also issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve a product candidate. The number of requests for additional data or information issued by the FDA in recent years has increased ~~,~~ and resulted in substantial delays in the approval of several new drugs. Undesirable side effects caused by our product candidates or future product candidates could also result in the inclusion of serious risk information in our product labeling, application of burdensome post- market requirements, or the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn **,** prevent us from commercializing and generating revenues from the sale of our product candidates. Drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial and could result in potential product liability claims. For example, some of the **most common** adverse events observed in the IV ~~Tramadol~~ **tramadol** clinical trials completed to date include nausea, dizziness, drowsiness, tiredness, sweating, vomiting, dry mouth, somnolence **,** and hypotension. With respect to BAER- 101, some of the **most common** adverse events observed in clinical trials completed to- date include dizziness, somnolence, headache, and euphoric mood. With respect to AJ201, some of the **most common** adverse events observed in clinical trials completed to- date include nausea, diarrhea, headache, and abdominal distension. Additionally, if one or more of our current or future product candidates receives marketing approval, and we or others later identify undesirable ~~side effects~~ **adverse events** caused by this product, a number of potentially significant negative consequences could result, including: ● regulatory authorities may require the addition of serious risk- related labeling statements, specific warnings, precautions, ~~or contraindication~~ **contraindications , or limitations of use** ; ● regulatory authorities may suspend or withdraw their approval of the product, or require the suspension of manufacturing ~~,~~ or the recall of the product from the market; ● regulatory authorities may require implementation of burdensome post- market risk mitigation strategies and practices; ● we may be required to change the way the product is administered, conduct additional clinical trials **,** or change the labeling of the product; or ● our reputation may suffer. Any of these events could prevent us from achieving or maintaining marketing approval and market acceptance of our product candidates or future product candidates or could substantially increase our **development and** commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from its sale. ~~27There is no assurance that we will be able to successfully integrate Baergic or develop BAER- 101 or AJ201. There can be no assurance that we will have sufficient capital resources to adequately integrate Baergic or develop BAER- 101 or AJ201. In addition, as with any of our product candidates, we are subject to many external third party risks including regulatory and manufacturing. We could experience financial or other setbacks if our integration of BAER- 101 or AJ201 encounters unanticipated problems, including problems related to execution, integration or underperformance relative to prior expectations. Our management may not be able to successfully integrate any acquired business into our operations or maintain our standards, controls and policies, which could have a material adverse effect on our business, results of operations and financial condition. Consequently, any acquisition we complete may not result in long- term benefits to us or we may not be able to further develop the acquired business in the manner we anticipated. We may need to rely on Fortress to provide administrative and other support, including financial reporting and internal controls, and other transition services to Baergic following our acquisition for a period of time. The failure of the Company to receive such support in a manner that is acceptable to us, could result in a material adverse effect on our business, results of operations and financial condition.~~ We may not be able to manage our business effectively if we are unable to attract and retain key personnel. We may not be able to attract or retain qualified management and commercial, scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital **,** and our ability to implement our business strategy, any of which may have a material adverse effect on our business, financial condition **,** and results of operations. Our employees, consultants, or third- party partners may engage in misconduct or other improper activities, including those that result in noncompliance with certain regulatory standards and requirements, which could have a material adverse effect on our business. We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, consultants **,** or third- party partners could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations **or comparable applicable foreign laws and regulations** , report financial information or data accurately **,** or disclose unauthorized activities to us. In particular, sales, marketing **,** and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing **,** and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs **,** and other business arrangements. Employee, consultant **,** or third- party misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation, as well as civil and criminal liability. The

precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business **, financial condition,** and results of operations, including the imposition of significant fines or other civil and / or criminal sanctions. If we fail to comply with environmental, health **,** and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business. We are subject to numerous environmental, health **,** and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment **,** and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. Although we believe that the safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. ~~28We~~ **We** do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous **,** or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health **,** and safety laws and regulations. These current or future laws and regulations may impair our research, development **,** or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties **,** or other sanctions. We are a " smaller reporting company ~~,~~" and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors. We are a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non- voting common equity held by non- affiliates is more than $ 250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $ 100 million during the most recently completed fiscal year and our voting and non- voting common equity held by non- affiliates is more than $ 700 million measured on the last business day of our second fiscal quarter. Smaller reporting companies are ~~able~~ **allowed** to provide simplified executive compensation disclosure, are exempt from the auditor attestation requirements of the Sarbanes- Oxley Act, and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information **,** or risk factors. We have elected to take advantage of certain of the reduced reporting obligations. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. We are a " controlled company " within the meaning of Nasdaq listing standards and, as a result, qualify for, and rely on, exemptions from certain corporate governance requirements. You will not have the same protections afforded to stockholders of companies that are subject to such requirements. We are a " controlled company " within the meaning of Nasdaq listing standards. Under these rules, a company of which more than 50 % of the voting power is held by an individual, a group **,** or another company is a " controlled company " and may elect not to comply with certain corporate governance requirements of Nasdaq, including (i) the requirement that a majority of the Board of Directors consist of independent directors, (ii) the requirement that we have a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee' s purpose and responsibilities **,** and (iii) the requirement that we have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee' s purpose and responsibilities. We have in the past relied on, and intend to continue to rely on, some or all of these exemptions. Accordingly, you will not have the same protections afforded to stockholders of companies subject to all of the corporate governance requirements of Nasdaq. Certain of our directors currently serve, and in the past, certain officers and directors have served **,** in similar roles with our parent company, affiliates, related parties **,** and other parties with whom we transact business; ongoing and future relationships and transactions between these parties could result in conflicts of interest. We sometimes share directors and / or officers with certain of our parent company, affiliates, related parties **,** or other companies with which we transact business, and such arrangements could create conflicts of interest in the future, including with respect to the allocation of corporate opportunities. While we believe that we have put in place policies and procedures to identify such conflicts **,** and that any existing agreements that may give rise to such conflicts and any such policies or procedures **,** were negotiated at arm' s length in conformity with fiduciary duties, such conflicts of interest may nonetheless arise. The existence and consequences of such potential conflicts could expose us to lost profits, claims by our investors and creditors, violations of Nasdaq' s director and audit committee independence rules **,** and harm to our **business, financial condition, and** results of operations. ~~29Risks~~ -- **Risks** Pertaining to Our ~~FinancesWe~~ -- **Finances We** have incurred significant losses since our inception. We expect to incur losses for the foreseeable future, and may never achieve or maintain profitability. We have a limited operating history. We have focused primarily on in- licensing and developing IV ~~Tramadol~~ **tramadol** , with the goal of supporting regulatory approval for this product candidate. We also recently acquired two new product candidates, BAER- 101 and AJ201, which we are developing. We have incurred losses since our inception in February 2015. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect to continue to incur significant operating losses for the foreseeable future. We also do not anticipate that we will achieve profitability for a period of time after generating material revenues, if ever. If we are unable to generate revenues, we will not

become profitable and may be unable to continue operations without continued funding. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the timing or amount of increased expenses or when or if, we will be able to achieve profitability. In addition, the Company cannot be certain that additional funding will be available on acceptable terms, or at all. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if: ● our product candidates or other future product candidates are approved for commercial sale, due to the necessity in establishing adequate commercial infrastructure to launch such candidate or candidates without substantial delays, including hiring ~~,~~ sales and marketing personnel, and contracting with third parties for warehousing, distribution, cash collection and related commercial activities; ● we are required by the FDA, **and / or other** foreign regulatory authorities, to perform studies in addition to those currently expected; ● there are any delays in completing our clinical trials or the development of any of our product candidates; ● we execute other collaborative, licensing **,** or similar arrangements and the timing of payments we may make or receive under these arrangements; ● there are variations in the level of expenses related to our future development programs; ● there are any product liability or intellectual property infringement lawsuits in which we may become involved; and ● there are any regulatory developments affecting our product candidates or the product candidates of our competitors. Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our development stage ~~product~~ **products** , and we do not know when, or if, we will generate any revenue. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to: ● obtain regulatory approval for our product candidates or any other product candidates that we may license or acquire; ● manufacture commercial quantities of our product candidates or other product candidates, if approved, at acceptable cost levels; and ● develop a commercial organization and the supporting infrastructure required to successfully market and sell our product candidates, if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress our value and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations **, which would have a material adverse effect on our business, financial condition, cash flows, and results of operations and could cause the market value of our securities to decline** . A decline in our value could also cause you to lose all or part of your investment. ~~30Our~~ -- **Our** short operating history makes it difficult to evaluate our business and prospects. We were incorporated on February 9, 2015, and until our acquisition of Baergic had only been conducting operations with respect to IV ~~Tramadol~~ **tramadol** since February 17, 2015. We have not yet demonstrated an ability to successfully obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays **,** and other known and unknown factors. We will need to expand our capabilities to support commercial activities and the recent acquisitions of AJ201 and BAER- 101. We may not be successful in adding such capabilities. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any past quarterly period as an indication of future operating performance. There is substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing. Our audited consolidated financial statements as of December 31, ~~2022~~ **2023** have been prepared under the assumption that we will continue as a going concern for the next twelve months. As of December 31, ~~2022~~ **2023** , we had cash and cash equivalents of $ ~~6~~ **1** . ~~7~~ **8** million and an accumulated deficit of $ ~~80~~ **90** . ~~6~~ **9** million. We do not believe that our cash and cash equivalents are sufficient for the next twelve months. As a result of our financial condition and other factors described herein, there is substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern will depend on our ability to obtain additional funding, as to which no assurances can be given. We continue to analyze various alternatives, including potentially obtaining lines of credit, debt or equity financings **,** or other arrangements. Our future success depends on our ability to raise capital and / or implement the various strategic alternatives discussed above. We cannot be certain that these initiatives or raising additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities after the closing of this offering to raise funds, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current shareholders may experience dilution. If we are unable to obtain funds when needed or on acceptable terms, we may be required to curtail our current development programs, cut operating costs, forego future development and other opportunities **,** or even terminate our operations. We do not have any products that are approved for commercial sale and therefore do not expect to generate any revenues from product sales in the foreseeable future, if ever. We have not generated any product related revenues to date. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing **,** and marketing products with commercial potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability. We will require substantial additional funding, which may not be available to us on acceptable terms, or at all. If we fail to raise the necessary additional capital, we may **have** ~~be unable to raise capital when needed, which would force us~~ to delay, reduce **,** or eliminate our product development programs or commercialization efforts. Our operations have consumed substantial amounts of cash since inception. We expect to significantly increase our spending to advance the clinical development and potential regulatory approval of our product candidates and launch and commercialize any additional product candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets. Even after the completion of future offerings, we may require additional capital for the further development and potential commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures,

and cannot provide any assurance that we will be able to raise funds to complete the development of our products. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back , or discontinue the development or commercialization of one or more of our product candidates. We may also seek collaborators for product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition , and prospects. ~~31Our~~ -- **Our** future funding requirements will depend on many factors, including, but not limited to: ● the potential for delays in our efforts to seek regulatory approval for our product candidates, and any costs associated with such delays; ● the costs of establishing a commercial organization to sell, market , and distribute our product candidates; ● the rate of progress and costs of our efforts to prepare for the submission of an NDA for any product candidates that we may in- license or acquire in the future, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval; ● the costs of filing, prosecuting, defending , and enforcing any patent claims and other intellectual property rights associated with our product candidates, including any such costs we may be required to expend if our licensors are unwilling or unable to do so; ● the cost and timing of securing sufficient supplies of our product candidates from our contract manufacturers in preparation for commercialization; ● the effect of competing technological and market developments; ● the terms and timing of any collaborative, licensing, co- promotion , or other arrangements that we may establish; ● if one or more of our product candidates are approved, the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of one or more of our product candidates; and ● the success of the commercialization of one or more of our product candidates. In order to carry out our business plan and implement our strategy, we may need to obtain additional financing and may choose to raise additional funds through strategic collaborations, licensing arrangements, public or private equity or debt financing, bank lines of credit, asset sales, government grants, or other arrangements. We cannot be sure that any additional funding, if needed, will be available on terms favorable to us or at all. Furthermore, any additional equity or equity- related financing may be dilutive to our stockholders, and debt or equity financing, if available, may subject us to restrictive covenants and significant interest costs. If we obtain funding through a strategic collaboration or licensing arrangement, we may be required to relinquish our rights to our product candidates or marketing territories. Our inability to raise capital when needed would harm our business, financial condition , and results of operations, and could cause our stock value to decline or require that we wind down our operations altogether. Raising additional capital may cause dilution to our existing stockholders, restrict our operations , or require us to relinquish proprietary rights. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, grants , and license and development agreements in connection with any collaborations. To the extent that we raise additional capital through the sale of equity **, instruments exercisable for equity,** or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures , or declaring dividends. If we raise additional funds through collaborations, strategic alliances , or marketing, distribution , or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce , or terminate our product development or future commercialization efforts or grant rights to develop and market any potential product candidates that we would otherwise prefer to develop and market ourselves. **We are currently not compliant with certain** ~~32We have in the past failed to satisfy~~ applicable listing standards of ~~the~~ **The** Nasdaq Capital Market ~~and could fail to satisfy those requirements again in the future~~ , which could result in our common stock being delisted from ~~the~~ **The** Nasdaq Capital Market. Currently our common stock trades on ~~the~~ **The** Nasdaq Capital Market. ~~During~~ **On May 19,** ~~2021~~ **2023** and **September 27,** ~~2022~~ **2023** , we received ~~notification~~ **notifications** from the Listing Qualifications Department of the Nasdaq Stock Market (" Nasdaq ") informing us of certain listing deficiencies related to the minimum ~~required market value of listed securities, minimum~~ stockholders' equity and minimum bid price listing requirements, which led to the issuance of delisting notices. **The Company was afforded a 180- calendar day grace period,** ~~Although~~ -- **through** ~~we have since cured~~ **March 25, 2024, to regain compliance with the minimum bid price requirement. In July 2023, the Company submitted its plan to regain compliance with the minimum stockholders' equity requirement and, on July 17, 2023, Nasdaq granted the Company' s request for an extension of the deadline to November 15, 2023 to regain compliance. On November 20, 2023, Nasdaq formally notified the Company that it had determined to delist the Company' s securities from Nasdaq based on its continued non- compliance with the minimum stockholders' equity requirement. The Company requested a hearing before the Nasdaq Hearings Panel (the " Panel "), which stayed further action by Nasdaq pending completion of the hearing. The hearing before the Panel was held on February 15, 2024 and on March 11, 2024, Nasdaq granted the Company' s request for an extension until May 20, 2024 to regain compliance. The Company intends to closely monitor the closing bid price of the common stock and consider all available options to remedy** these deficiencies ~~and~~ **. While** our common stock **will** ~~continues~~ **continue** to trade on ~~the~~ **The** Nasdaq Capital Market **during this time** , ~~it is possible~~ **there can be no assurance** that ~~we could fall out of compliance again in~~ the ~~future~~ **Company will be successful in its efforts to maintain its Nasdaq listing** . If we fail to maintain compliance with any Nasdaq listing requirements, our common stock could be delisted from ~~the~~ **The** Nasdaq Capital Market. This could severely limit the liquidity of our common stock and your ability to sell our securities on the secondary market. Delisting from the Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities , and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative

results, including the potential loss of confidence by employees, the loss of institutional investor interest , and fewer business development opportunities. If our common stock is delisted by ~~the~~ Nasdaq , the price of our common stock may decline and our common stock may be eligible to trade on the OTC Bulletin Board, another over- the- counter quotation system, or on the pink sheets , where an investor may find it more difficult to dispose of their common stock or obtain accurate quotations as to the market value of our common stock. Further, if we are delisted, we would incur additional costs under requirements of state " blue sky " laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and the ability of our stockholders to sell our common stock in the secondary market. Risks Pertaining to Reliance on Third ~~ParticsIf~~ -- **Parties If** any of our product candidates are approved and our contract ~~manufacturer~~ **manufacturers** ~~fails~~ -- **fail** to produce the ~~product~~ **products** in the volumes that we require on a timely basis, to produce the ~~product~~ **products** according to the applicable quality standards and requirements, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the commercialization of that product candidate, **if approved,** lose potential revenues , or be unable to meet market demand. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. We have entered into a development and supply agreement for the completion of pre- commercialization manufacturing development activities and the manufacture of commercial supplies of IV ~~Tramadol~~ **tramadol** . Any termination or disruption of this relationship may materially harm our business and financial condition, and impact any commercialization efforts for this product candidate. In order to meet anticipated demand for IV ~~Tramadol~~ **tramadol** , if this product candidate is approved, we currently have one manufacturer to provide us clinical and commercial supply of IV ~~Tramadol~~ **tramadol** in accordance with the CGMP requirements. We also may plan to qualify a backup manufacturer, in order to ensure an alternative source and to mitigate any potential supply issues. We have sufficient drug substance for BAER- 101 on hand to execute our planned near- term studies ~~,~~ and are in process of identifying future manufacturers. AnnJi, from whom we license the intellectual property underlying AJ201, has committed to provide us with limited supplies of this product candidate, but we will need to secure longer- term manufacturing sources to complete development and **, if approved,** commercialization of this product **candidate** . Failure to secure such sources could have a material adverse effect on our ability to pursue these product candidates. All of our contract manufacturers must comply with strictly enforced federal, state and, where applicable, foreign regulations, including CGMP requirements enforced by the FDA through its inspectional authority over facilities under the FDCA, as well **as** requirements for controlled substance handling and security requirements enforced by DEA, and while we exercise oversight of our suppliers, we have limited direct control over their compliance with these regulations, as reflected in day- to- day operations. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval, and would limit the availability of our product **candidates, if approved** . Any quality or compliance issue, manufacturing defect , or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re- stocking costs, damage to our reputation , and potential for product liability claims. If the commercial manufacturers upon whom we rely to manufacture our product candidates we may in- license ~~,~~ fail to deliver sufficient commercial quantities on a timely basis , at commercially reasonable prices, we would likely be unable to meet demand for ~~our~~ **any** ~~products~~ -- **product candidates for which we obtain regulatory approval,** and we would lose potential revenues, which could have a material adverse effect on our business, financial condition , and results of operations. ~~33We~~ **We** rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or complying with applicable regulatory requirements. We have relied on third party contract research organizations and clinical research organizations to conduct some of our preclinical studies and all of our clinical trials for IV ~~Tramadol~~ **tramadol , ~~and may do so for~~** BAER- 101, AJ201 , and any other future product candidates. We ~~may~~ **expect to** continue to rely on third parties, such as contract research organizations, clinical research organizations, clinical data management organizations, medical institutions , and clinical investigators, to conduct preclinical studies and clinical trials. The agreements with these third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that could delay our product development activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our legal and regulatory product development responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical studies are conducted in accordance with good laboratory practice **(~~, or~~** " GLP " **)** , as appropriate. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices **(~~, or~~** " GCPs " **)** , for conducting, recording , and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity , and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators , and trial sites. If we or any of our clinical research organizations fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable or unacceptable, and the FDA , or comparable foreign regulatory authorities , may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted using products manufactured and produced in accordance with CGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We **are** also ~~are~~ required to register **certain** ongoing clinical trials and post the results of completed clinical trials on a government- sponsored database, ClinicalTrials. gov, within specified timeframes. Failure to do so can result in fines, adverse publicity , and civil and criminal sanctions. The third parties with whom we have contracted to help perform

our preclinical studies or clinical trials may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines **,** or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, potentially successfully commercialize our product candidates **, if approved** . If any of our relationships with these third-party contract research organizations or clinical research organizations terminates, we may not be able to enter into arrangements with alternative contract research organizations or clinical research organizations or ~~to~~ do so on commercially reasonable terms. Switching or adding additional contract research organizations or clinical research organizations involves additional cost and requires extensive training and management time and focus. In addition, there is a natural transition period when a new contract research organization or clinical research organization commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we carefully manage our relationships with our contract research organizations or clinical research organizations, there can be no assurance that we will not encounter challenges or delays in the future. We contract with third parties for the manufacture of our product candidates for preclinical and clinical testing and expect to continue to do so for potential commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our ~~potential~~ product candidates or products **for which we obtain regulatory approval** or such quantities at an acceptable cost, which could delay, prevent **,** or impair our development or commercialization efforts. We do not own any manufacturing facilities or employ any manufacturing personnel. We rely, and expect to continue to rely, on third- party manufacturers to manufacture our product candidates for preclinical and clinical testing, as well as for commercial manufacture, once any of our product candidates receives marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products **for which we obtain regulatory approval** or such quantities at an acceptable cost or quality, which could delay, prevent **,** or impair our development or potential commercialization efforts. ~~34We~~ **We** may be unable to establish any agreements with such third- party manufacturers or ~~to~~ do so on acceptable terms. Even if we are able to establish agreements with third party manufacturers, reliance on third- party manufacturers entails additional risks, including, but not necessarily limited to: ● reliance on the third party for regulatory compliance and quality assurance; ● raw material or active ingredient shortages from suppliers the third party has qualified for our product **candidates for development and for commercialization, if approved** ; ● the possible breach of the manufacturing agreement by the third party; ● manufacturing delays if our third- party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us; ● the possible misappropriation of our proprietary information, including our trade secrets and know- how; and ● the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. The facilities used by our contract manufacturers to manufacture our product candidates ~~is~~ **are** subject to registration requirements, and inspection by the FDA. A pre- approval inspection may be conducted after the submission of an application to the FDA. Although we will have oversight over our suppliers and manufacturers, we do not directly control the manufacturing operations and processes at these facilities, and therefore **,** rely on ~~,~~ our contract manufacturers to ensure full compliance with CGMP regulations with respect to the day- to- day operations related to the manufacture of our product candidates. Third- party manufacturers may, following an inspection, be subject to a Form FDA- 483 or similar inspectional findings, or a Warning Letter, or may not otherwise be able to comply with the CGMP regulations or similar regulatory requirements outside the United States. The failure of our third- party manufacturers to comply with applicable regulations directly impacts our compliance and could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions **,** and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Any ~~products~~ **product candidates** that we may develop **and commercialize, if approved,** may compete with other product candidates and products for access to manufacturing facilities. There may be a limited number of manufacturers that both operate under CGMP regulations and are capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any replacement manufacturers. The DEA restricts the importation of a controlled substance finished drug product when the same substance is commercially available in the United States, which could reduce the number of potential alternative manufacturers for IV ~~Tramadol~~ **tramadol** . Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to potentially commercialize any products that receive marketing approval on a timely and competitive basis. We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or potential commercialization of our products, producing additional losses and depriving us of potential product revenue. ~~35We~~ **We** rely on clinical data and results obtained by third parties that could ultimately prove to be inaccurate ~~or~~ **,** unreliable **, or unacceptable to regulatory authorities** . As part of our strategy to mitigate development risk, we seek to develop product candidates with a validated mechanism of action, and we utilize biomarkers to assess potential clinical efficacy early in the development process. This strategy necessarily relies upon clinical data and other results obtained by third parties that may ultimately prove to be inaccurate ~~or~~ **,** unreliable **, or unacceptable to regulatory authorities** . Further, such clinical data and results may be based on products or product candidates that are significantly different from our product candidates or future product candidates. If the third- party data and results we rely upon prove to be inaccurate, unreliable **, not acceptable by regulatory authorities,** or not applicable to our product candidates or future product candidate, we could make inaccurate assumptions and conclusions about our product candidates

and our research and development efforts could be compromised and called into question during the review or any marketing applications we submit. Risks Pertaining to Regulatory Approval ~~ProcessWe --~~ **Process The making, use, sale, importation, exportation, and distribution of controlled substances are subject to regulation by state, federal, and foreign law enforcement and other regulatory agencies. Controlled substances are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation, and distribution. Controlled substances are regulated under the Federal Controlled Substances Act of 1970 (" CSA ") and regulations of the DEA. IV Tramadol, which we currently have under development, will be subject to these regulations. The DEA regulates controlled substances as Schedule I, II, III, IV, or V substances. Schedule I substances by definition have a high potential for abuse and no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV, or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Various states also independently regulate controlled substances. Though state- controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs as well. While some states automatically schedule a drug when the DEA does so, in other states there must be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could impair the commercial attractiveness of such product. We or our collaborators must also obtain separate state registrations in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law. For any of our product candidates classified as controlled substances, we and our suppliers, manufacturers, contractors, customers, and distributors are required to obtain and maintain applicable registrations from state, federal, and foreign law enforcement and regulatory agencies and comply with state, federal, and foreign laws and regulations regarding the manufacture, use, sale, importation, exportation, and distribution of controlled substances. There is a risk that DEA regulations may limit the supply of the compounds used in clinical trials for our product candidates and the ability to produce and distribute our products for which we obtain regulatory approval in the volume needed to both meet commercial demand and build inventory to mitigate possible supply disruptions. Regulations associated with controlled substances govern manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, recordkeeping, reporting, handling, shipment, and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of product candidates including controlled substances. The DEA, and some states, conduct periodic inspections of registered establishments that handle controlled substances. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our product candidates, if approved, containing controlled substances and subject us to enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceedings. Because of their restrictive nature, these regulations could limit commercialization of any of our product candidates, if approved, that are classified as controlled substances, which would have a material adverse effect on our business, financial condition, cash flows and results of operations, and could cause the market value of our Securities to decline. If the DEA decides to reschedule tramadol from a Schedule IV controlled substance to a more restrictive Schedule, IV tramadol could lose its competitive advantage associated with having less burdensome regulatory requirements, and our related clinical development and regulatory approval could be delayed or prevented and, if approved, we could be subject to additional security requirements and quota system controls. In July 2014, the DEA classified tramadol as a Schedule IV controlled substance. In comparison, other opioids are classified by the DEA as Schedule II controlled substances. The regulatory burden associated with Schedule II drugs is substantially greater than that associated with Schedule IV drugs. If approved, IV tramadol will be the only intravenous Schedule IV opioid on the market. However, in the current environment where the opioid epidemic is a recognized problem in the United States, there is a possibility that the DEA could reschedule tramadol to a more restrictive classification (Schedule II or III). Such a rescheduling, or other similar action by DEA, would severely impair IV tramadol' s current competitive advantage over traditional opioids based on the less burdensome regulatory requirements and may affect our ability to potentially market IV tramadol. It could also delay or prevent clinical development and regulatory approval and, if approved, subject us to additional security requirements and quota system controls. We** may not receive regulatory approval for IV ~~Tramadol~~ **tramadol** , or our approval may be significantly delayed due to scientific or regulatory reasons. While we acquired BAER- 101 in connection with our acquisition of Baergic, **and rights to AJ201 from AnnJi,** we continue to pursue regulatory approval for IV ~~Tramadol~~ **tramadol** . However, in light of recently disclosed developments, there is doubt about our ability to obtain regulatory approval for IV ~~Tramadol~~ **tramadol** . In December 2019, we submitted an NDA for IV ~~Tramadol~~ **tramadol** and received the First CRL from the FDA in October 2020. In February 2021, we resubmitted the NDA for IV ~~Tramadol~~ **tramadol** . The FDA assigned a PDUFA goal date of April 12, 2021 for the resubmitted NDA for IV ~~Tramadol~~ **tramadol** . On June 14, 2021, we announced that we had received the Second CRL from the FDA regarding our NDA for IV ~~Tramadol~~ **tramadol** . We submitted **an** ~~a formal dispute resolution request (" FDRR ") with~~ the Office of Neuroscience of the FDA on July 27, 2021. On August 26, 2021, we received an Appeal Denied Letter from the Office of Neuroscience of the FDA in response to the FDRR submitted on July 27, 2021. On August 31, 2021, we submitted an FDRR with the Office of New Drugs of the FDA. On October 21, 2021, we received a written response from the Office of New Drugs of the FDA stating that the OND needs additional input from an Advisory Committee in order to reach a decision on the FDRR. On February 15, 2022, we had our Advisory Committee meeting with the FDA. In the final part of the public meeting, the Advisory Committee voted yes or no on the following

question: " Has the Applicant submitted adequate information to support the position that the benefits of their product outweigh the risks for the management of acute pain severe enough to require an opioid analgesic in an inpatient setting? " The results were 8 yes votes and 14 no votes. On March 18, 2022, we received an Appeal Denied Letter from the Office of New Drugs in response to the FDRR. Following the receipt of the Appeal Denied Letter, we submitted a Type A Meeting Request and related briefing document to the FDA on June 17, 2022. The meeting was granted by the ~~Division of Anesthesia, Analgesia, and Addiction Products (" DAAAP ")~~ on June 27, 2022, and scheduled for August 9, 2022. We submitted a briefing document presenting a study design that we believe has the potential to address the concerns around the safety risk of IV ~~Tramadol~~ **tramadol** in combination with other opioid analgesics for the management of moderate- to- moderately- severe pain in adults in a medically supervised healthcare setting that was discussed in detail at the previously disclosed Advisory Committee meeting on February 15, 2022 and in the Appeal Denied letter received on March 18, 2022. The meeting on August 9, 2022 was a collaborative discussion on the study design and **following** ~~potential path forward. At~~ the meeting, we ~~presented a study design for a single safety clinical trial that we believe could address the concerns regarding risks related to opioid stacking. The FDA stated that the proposed study design appears reasonable and agreed on various study design aspects with the expectation that additional feedback would be provided to us upon review of a more detailed study protocol. We intend to incorporate~~ **incorporated** the FDA' s suggestions from the meeting minutes and ~~submit~~ **submitted** a detailed study protocol that could form the basis for the submission of a complete response to the ~~second~~ **Second CRL** ~~Complete Response Letter for IV Tramadol~~ . Following the Type A Meeting, we submitted a ~~subsequent~~ request to the FDA and were granted a Type C Meeting to discuss a proposed study protocol to assess the risk of respiratory depression related to opioid stacking on IV ~~Tramadol~~ **tramadol** relative to an approved opioid analgesic. **In January 2024, we announced that we reached final agreement with the FDA on the Phase 3 safety study protocol and statistical analysis approach, including the primary endpoint, for IV tramadol.** If the FDA does not approve, or significantly delays the approval of, IV ~~Tramadol~~ **tramadol** , it could cause a material adverse effect on our business, financial condition **,** and results of operations. Even if one or more of our product candidates receives regulatory approval, which may not occur, it will remain subject to substantial regulatory scrutiny. Our product candidates and any other product candidates we may license or acquire will also be subject to ongoing regulatory and compliance requirements, including regular inspections by the FDA and other regulatory authorities. These requirements relate to, among others, labeling, packaging, storage, advertising, promotion, record- keeping and submission of safety and other post- market ~~36information --~~ **information** and reports, registration and listing requirements, ongoing CGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping of the drug. The FDA may also impose requirements for costly post- marketing studies or clinical trials and surveillance programs to monitor the safety or efficacy of the product. The FDA closely regulates the post- approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off- label use and off- label information and if we do not market our products for only their approved indications and on- label information, we may be subject to enforcement action for off- label marketing as well as false claims liability. Violations of the FDCA relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws. In addition, later discovery of previously unknown adverse events or other problems with our product, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including: ● restrictions on such product, operations, manufacturers **,** or manufacturing processes; ● restrictions or new requirements related to the promotion, labeling **,** or marketing of a product; ● restrictions on product distribution or use, including import and export restrictions; ● requirements to conduct post- marketing studies or clinical trials; ● Form FDA- 483 findings, ~~or~~ warning **letters, or untitled** letters; ● recall of the product, or withdrawal of the product from the market; ● refusal to approve pending applications or supplements to approved applications that we submit; ● fines, restitution **,** or disgorgement of profits; ● suspension or withdrawal of marketing or regulatory approvals; ● suspension of any ongoing clinical trials; ● refusal to permit the import or export of our product; ● product seizure; or ● injunctions or the imposition of civil or criminal penalties. The FDA' s policies, as well as policies of the DEA, ~~who~~ **which** has jurisdiction over controlled substances and opioids, **including IV tramadol,** may change and additional government regulations may be enacted that could prevent, limit **,** or delay regulatory approval of our product candidate. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained. We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business. A pharmaceutical product candidate cannot be marketed in the United States or many other countries until we have completed a rigorous and extensive regulatory review processes, including obtaining the approval of a brand name. Any brand names we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U. S. Patent and Trademark Office ~~, or~~ **(the** " USPTO " **)** . The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand name, we may be ~~37required --~~ **required** to adopt an alternative brand name for our product candidate. If we **have to** adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties **,** and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner **,** or at all, which would limit our ability to potentially commercialize our product candidate **, if approved** . Our current and future relationships with customers and third- party payors in the United States and elsewhere may be subject,

directly or indirectly, to applicable anti- kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens , and diminished profits and future earnings. 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 product candidates for which we obtain marketing approval. Our future arrangements with third- party payors, distributors, retailers, marketers , and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti- Kickback Statute, the federal False Claims Act, and similar state or foreign laws , which may constrain the business or financial arrangements and relationships through which we sell, market , and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U. S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state , and foreign healthcare laws and regulations that may affect our ability to operate include, but are not necessarily limited to: ● the federal Anti- Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving , or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid; ● federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent, making a false statement to avoid, decrease , or conceal an obligation to pay money to the federal government, or the knowing retention of an overpayment from government health care programs; ● the federal Health Insurance Portability and Accountability Act of 1996 ~~, or~~ **(“** HIPAA **”)** , which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; ● HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ~~, or~~ **("** HITECH **")** , and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain , or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security , and transmission of individually identifiable health information; ● the federal Open Payments program, which requires manufacturers of certain 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 “ payments or other transfers of value ” made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists ~~and~~ **,** chiropractors **, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse- midwives** , and certain teaching hospitals and applicable manufacturers to report annually to CMS ownership and investment interests held by the physicians and their immediate family members; and ● analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third party payors, including private insurers; state and foreign 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 otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. ~~38Efforts~~ -- **Efforts** to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. 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, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil , or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business, financial condition , and results of operations. 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. Any regulatory approval is limited to the specific labeled indication (s) 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 product **candidates** , our **potential** ability to effectively ~~potentially~~ market and sell our product **candidates** may be reduced and our business may be adversely affected. While physicians may choose to prescribe drugs for uses that are not described in the product’ s approved labeled indication, or for uses that differ from those tested in clinical studies, and thus the basis for approval by the regulatory authorities, our ability to promote the products is 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 United States generally do not regulate the practice of medicine by physicians with respect to their choice of treatments. Regulatory authorities do, however,

restrict communications by pharmaceutical companies in terms of their ability to promote off- label uses or disseminate off-label information. If our promotional activities fail to comply with these requirements, we may be subject to regulatory, compliance, or enforcement action by, these authorities. In addition, our failure to follow FDA requirements relating to promotion and advertising may result in a Warning Letter **or Untitled Letter** , cause the FDA to suspend or withdraw an approved product from the market, require a recall, require the issuance of corrective advertising, institute fines, or could result in disgorgement of money, operating restrictions, injunctions **,** or civil or criminal prosecution by the government, any of which could harm our reputation and business. If the **FDA does not conclude that** ~~DEA decides to reschedule Tramadol from~~ a **product candidate satisfies the requirements for the Section 505 (b) (2)** ~~Schedule IV controlled substance to a more restrictive Schedule, IV Tramadol could lose its competitive advantage, and our related clinical development and~~ regulatory approval **pathway, or if the requirements for such product candidate under Section 505 (b) (2) are not as we expect, the approval pathway for the product candidate will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful. 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 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 and for which the applicant has not obtained a right of reference. Section 505 (b) (2), if applicable to us under the FDCA, would allow an NDA we submit to FDA to rely in part on data in the public domain or the FDA' s prior conclusions regarding the safety and effectiveness of approved compounds, which** could **expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505 (b) (2) regulatory pathway as 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 these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We could need to obtain more additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would** be ~~delayed~~ **able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505 (b) (2) regulatory pathway would likely result in new competitive products reaching the market more quickly than** ~~or~~ **our** ~~prevented~~ **product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505 (b) (2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization in a timely manner, or at all** . In **addition** ~~July 2014~~ , **notwithstanding** the **approval of** ~~DEA classified Tramadol as~~ a ~~Schedule IV controlled substance~~ **number of products by the FDA under Section 505 (b) (2) over the last few years, certain brand- name pharmaceutical companies and others have objected to the FDA' s interpretation of Section 505 (b) (2). If the FDA' s interpretation of Section 505 (b) (2) is successfully challenged, the FDA may 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)** . In ~~comparison~~ **addition** , ~~other~~ -- **the pharmaceutical industry is** ~~opioids, which have a high~~ **highly competitive** ~~potential for abuse~~ , **and Section 505 (b) (2) NDAs** are ~~classified as Schedule I~~ **subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505 (b) (2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of** ~~and~~ - **an** ~~II controlled substances~~ **approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products** . If **successful, such petitions can significantly delay, or even prevent, the** ~~approved~~ **approval of** ~~, IV Tramadol will be~~ the **new product** ~~only intravenous Schedule IV opioid on the market~~ . However, ~~in~~ **even if** the **FDA ultimately denies such** ~~current environment where the opioid epidemic is~~ a **petition,** ~~recognized problem in~~ the ~~United States~~ **FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505 (b) (2) regulatory pathway** , there is **no guarantee this** ~~a possibility that the DEA could~~ **would** ~~reschedule Tramadol~~ **ultimately lead** to ~~a more restrictive classification~~ **faster product development or earlier approval. Moreover, even if our product candidates are approved under Section 505** (**b** ~~Schedule I, II or III~~) **(2)** ~~. Such a rescheduling~~ , **the approval may be subject to limitations on the indicated uses** ~~or~~ **for which the products may be marketed or to** other **conditions of approval** ~~similar action by DEA~~ , ~~would severely impair IV Tramadol' s current competitive advantage over traditional opioids and may affect our~~ - **or** ~~ability to potentially~~ **may contain requirements for costly post-** ~~market~~ **marketing** ~~IV Tramadol as a~~ **testing and surveillance to monitor the** ~~safe~~ **safety** ~~alternative pain management~~ **or efficacy of the** ~~product~~ **products** . Risks Pertaining to the Commercialization of Product ~~CandidatesWe~~ -- **Candidates We** are subject to new legislation, regulatory proposals **,** and managed care initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators **,** and raise capital. In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could prevent or delay marketing approval of our product candidate, restrict or regulate post- approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the " PPACA " or collectively, the " ACA "), substantially regulates the way healthcare is financed by both governmental and private insurers in the United States. Among other things, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15. 1 % to 23. 1 %; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non- deductible annual fee on pharmaceutical manufacturers or importers who sell certain " branded prescription drugs " to

specified federal government programs; implemented a new methodology under which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded the eligibility criteria for ~~39Medicaid~~ -- **Medicaid** programs; created 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 established a Center for Medicare and Medicaid Innovation (" CMMI ") at the CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Since its enactment, there have been executive, judicial **,** and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. ~~On January 20, 2017, President Donald Trump signed an executive order stating that the administration intended to seek prompt repeal of the Affordable Care Act, and, pending repeal, directed the U. S. Department of Health and Human Services and other executive departments and agencies to take all steps necessary to limit any fiscal or regulatory burdens of the Affordable Care Act. On January 28, 2021, President Joe Biden signed the Executive Order on Strengthening Medicaid and stated his administration' s intentions to reverse the actions of his predecessor and strengthen the Affordable Care Act. As part of this Executive Order, the Department of Health and Human Services, United States Treasury, and the Department of Labor are to review all existing regulations, orders, guidance documents, policies, and agency actions to consider if they are consistent with ensuring both coverage under the Affordable Care Act and if they make high- quality healthcare affordable and accessible to Americans. On March 11, 2021, President Biden signed into law the American Rescue Plan Act of 2021 to further strengthen Medicaid and the ACA and on April 5, 2022, President Biden signed the Executive Order on Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage in which he celebrated the significant progress across the U. S. in making healthcare more affordable and accessible. In this Executive Order, President Biden directed agencies " with responsibilities related to Americans' access to health coverage " to " review agency actions to identify ways to continue to expand the availability of affordable health coverage. " The continued expansion of the government' s role in the U. S. healthcare industry may further lower rates of reimbursement for pharmaceutical products. While we are unable to predict the likelihood of changes to the Affordable Care Act or other healthcare laws which may negatively impact our profitability, we continue to closely monitor all changes. President Biden intends to take action against drug prices which are considered " high. "~~ Drug pricing continues to be a subject of debate at the executive and legislative levels of U. S. government. The American Rescue Plan Act of 2021 signed into law by President ~~Joseph R.~~ Biden ~~Jr.~~ on March 14, 2021 includes a provision that ~~will eliminate~~ **eliminated** the statutory cap on rebates drug manufacturers pay to Medicaid beginning in January 2024. With the elimination of the rebate cap, manufacturers may be required to compensate states in an amount greater than what the state Medicaid programs pay for the drug. Additionally, the Inflation Reduction Act of 2022 contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U. S. Department of Health and Human Services that would require manufacturers to charge a negotiated " maximum fair price " for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the Inflation Reduction Act of 2022. The Inflation Reduction Act of 2022 could have the effect of reducing the prices we can charge and reimbursement we receive for our ~~products~~ **product candidates** , if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations **,** and growth prospects. The effect of Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical 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 additional federal, state **,** and foreign 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 limited coverage and reimbursement and reduced demand for our ~~products~~ **product candidates** , once approved, or additional pricing pressures. These and 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 receive for any current ~~product~~ or future product ~~candidate~~ **candidates** . Any reduction in reimbursement from Medicare or other government healthcare 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 ~~products~~ **product candidates, if approved** . Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance **,** or interpretations will be changed, or what the impact of such changes on the marketing approvals of any current or future product candidates, if any, may be. In addition, increased Congressional scrutiny of the ~~40FDA~~ -- **FDA** ' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. Public concern regarding the safety of opioid drug products such as IV ~~Tramadol~~ **tramadol** could delay or limit our ability to obtain regulatory approval for this product **candidate** , result in the inclusion of serious risk information in our labeling, negatively impact market performance, or require us to undertake other activities that may entail additional costs. In light of 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 controlled substance 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. Under the Food and Drug Administration Amendments Act of 2007 **(** ~~, or~~ " FDAAA " **)** , the FDA has authority 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 expanded the federal government' s clinical trial registry and results databank, resulting in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the 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 conduct additional preclinical studies or clinical trials prior to approving IV ~~Tramadol~~ **tramadol**, our ability to obtain approval of this product candidate will be delayed. If the FDA requires us to provide additional clinical or preclinical data following the approval of IV ~~Tramadol~~ **tramadol**, the indications for which this product candidate is approved may be limited or there may be specific warnings or limitations on production dosing, and our efforts to commercialize IV ~~Tramadol~~ **tramadol** may be otherwise adversely impacted. Rising public, medical, Congressional, and agency concern around the prescription of controlled substance drug products to patients and a growing movement to reduce the use of opioid drug products, to develop abuse- deterrent products, and to prevent dependence also could negatively impact our ability to commercialize and generate revenue from IV ~~Tramadol~~ **tramadol** if it is approved for marketing in the United States. Congress has enacted several laws intended to address opioid use disorder, including the Comprehensive Addiction and Recovery Act (**"** CARA **"**) in 2016, the 21st Century Cures Act (**"** Cures Act **"**) in 2016, and the Substance Use- Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the **"** SUPPORT Act **"**) in 2018. These laws primarily focus on funding for treatment, research, and education, but also include provisions intended to encourage reduction in opioid use, such as funding for research on non- opioid pain treatments. Other legislative and administrative measures at the state and federal level include, or may include in the future, restrictions and limitations on opioid prescribing, limitations on opioid doses dispensed per episode of care, labeling requirements specific to opioids, limitations on FDA approval of opioids, assessment of fees against opioid manufacturers, or reimbursement disincentives specific to opioids. **If we experience delays or difficulties in the enrollment of patients in any future clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented. We may not be able to initiate any future clinical trials for any current or future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Some of our competitors may have ongoing clinical trials for product candidates that treat the same indications as our current or potential future product candidates, and patients who would otherwise be eligible for any future clinical trials may instead enroll in clinical trials of our competitors' product candidates. Patient enrollment is affected by other factors, including: ● the severity of the disease under investigation; ● the eligibility criteria for a study; ● the perceived risks and benefits of the product candidate under study; ● the efforts to facilitate timely enrollment in clinical trials; ● the patient referral practices of physicians; ● the ability to monitor patients adequately during and after treatment; and ● the proximity and availability of clinical trial sites for prospective patients. Our inability to enroll a sufficient number of patients for any future clinical trials would result in significant delays and could require us to abandon any future clinical trials altogether. Enrollment delays in any future clinical trials may result in increased development costs for any current or future product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.** We expect intense competition for our **current or future** product candidates, and new products may emerge that provide different or better therapeutic alternatives for our targeted indications. The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of our product candidates **, if approved,** from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies **, including specialty and other large pharmaceutical companies, and OTC companies and generic manufacturers**. There can be no assurance that developments by others will not render our product candidates obsolete or noncompetitive. Furthermore, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render ~~on~~ **one** or more of our product candidates obsolete or noncompetitive. IV ~~Tramadol~~ **tramadol** will compete with well- established products with similar indications. Competing products available for the management of pain include other approved opioid agonists such as morphine, hydromorphone, **and** fentanyl ~~and~~ **. In 2020, the FDA also approved OLINVYK (** oliceridine ~~(approved in 2020 by the FDA~~ **, an intravenous opioid agonist for the management of moderate to severe acute pain in adults, where the pain is severe enough to require an intravenous opioid and for whom alternative treatments are inadequate**. Non- opioid products include **Combogesic (combination IV acetaminophen and ibuprofen),** Ofirmev (IV acetaminophen) and IV formulations of NSAIDs such as Dyloject (diclofenac), Toradol (ketorolac), Anjeso (meloxicam) **,** and Caldolor (ibuprofen). In addition, we also expect to compete with agents such as Exparel **(** ~~, a liposome injection of~~ bupivacaine ~~indicated for administration into the surgical site to produce postsurgical analgesia~~ **lipsome injectable suspension), Zynrelef (bupivacaine and meloxicam) and Xaracoll (bupivacaine implant)**. In addition to approved products, there are a number of product candidates in development for the management of acute pain. **In addition to** ~~The late- stage pain development pipeline is replete with~~ reformulations and fixed- dose combination products of already available therapies ~~. Among specific drug classes~~ , ~~opioid analgesics and NSAIDs represent the~~ **there** ~~greatest number of~~ **are also several novel** agents in ~~development. Most investigational opioids that have reached the later stages of~~ clinical development **such as VX** ~~are new formulations of already marketed opioids. 41Likewise, investigational NSAIDs — mostly lower dose injectable reformulations of already approved compounds — are another significant area of late - stage drug development in the postoperative pain space~~ **548 (Vertex Pharmaceuticals), LTG- 001 (Latigo Biotherapeutics), STC- 004 (SiteOne Therpaeutics), NTM- 001 (Neumentum) and CA- 008 (Concentric**

Analgesics) . BAER- 101 ~~competitors in the~~ **will compete with a number of selective and non- selective** GABA ~~-~~-A ~~space~~ **receptor agonists. The most commonly used therapies for anxiety and epilepsy** are ~~in~~ **benzodiazepines. Commonly prescribed benzodiazepine therapies are Valium (diazepam), Ativan (lorazepam), Alepam (oxazepam), Alodorm (nitrazepam), Euhypnos (temazepam), Xanax (alprazolam), Clonazepam (klonopin). There are** ~~the~~ **other selective GABA A receptor agonists in** ~~clinic~~ **clinical** ~~and include~~ **development such as darigabat (** Cerevel Therapeutics **), ENX101 (** ~~darigabat), RespireRx Pharmaceuticals (KRM- II- 81), Saniona AB (SAN711), and~~ Engrail Therapeutics **), and SAN711 (** ~~ENX101~~ **Saniona**). Although there are no approved therapies to treat SBMA, AJ201 competitors include Nido Biosciences (NIDO- 361) and pre- clinical programs from academic institutions. In Japan, Leuprorelin is approved for SBMA, but has not been developed for the indication in the United States. The **potential** commercial opportunity for our ~~products~~ **product candidates** could be significantly harmed if competitors are able to develop alternative formulations outside the scope of our in-licensed patents. Compared to us, many of our potential competitors have substantially greater: ● capital resources; ● development resources, including personnel and technology; ● clinical trial experience; ● regulatory experience; ● expertise in prosecution of intellectual property rights; and ● manufacturing, distribution **,** and sales and marketing experience. As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or potentially commercialize our product candidates. Our competitors may also develop drugs that are more effective, safe, useful **,** and less costly than ours and may be more successful than us in manufacturing and marketing their products. If **we are unable to compete effectively, our business, our business prospects, results of operations, financial condition, or cash flows may be materially adversely affected. If** the government or third- party payors fail to provide adequate coverage and payment rates for our product candidates **, if approved,** or any future products we may license or acquire in the future, if any, or if hospitals choose to use therapies that are less expensive, our potential revenue and prospects for profitability will be limited. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower- cost drugs **,** and may be incorporated into existing payments for other services. In both domestic and foreign markets, our sales of any future products will depend in part upon the availability of coverage and reimbursement from third party payors. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers **,** and other organizations. In particular, many U. S. hospitals receive a fixed reimbursement amount per procedure for certain surgeries and other treatment therapies they perform. Because this amount may not be based on the actual expenses the hospital incurs, hospitals may choose to use therapies which are less expensive when compared to our product candidates or future product candidates. Accordingly, our product candidates or any other product candidates that we may in- license or acquire, if approved, will face competition from other therapies and drugs for these limited hospital financial resources. We may need to conduct post- marketing studies in order to demonstrate the cost- effectiveness of any future products to the satisfaction of hospitals, other target customers **,** and their third- party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by implementation of recently promulgated regulations that permit importation of drugs from countries where they may be sold at lower prices than in the United States. Our future product might not ultimately be considered cost- effective. Adequate third- party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development. If none of our product candidates **, if approved,** achieves broad market acceptance, the potential revenues that we generate from sales will be limited. The commercial success of our product candidates or any or all of them, if approved, will depend upon its acceptance by the medical community, the ability to ensure that the drug is included in hospital formularies, and coverage and reimbursement for the drug by third ~~42party~~ **party** payors, including government payors. The degree of market acceptance of our product candidates or any other product candidate we may license or acquire would depend on a number of factors, including, but not necessarily limited to: ● the efficacy and safety as demonstrated in clinical trials; ● the safety and use of our product candidates in its intended patient population; ● the timing of market introduction of our product candidates as well as competitive products; ● the clinical indications for which the drug is approved; ● acceptance by physicians, major operators of hospitals and clinics **,** and patients of the drug as a safe and effective treatment; ● the safety of our product candidates seen in a broader patient group (i. e., real world use); ● the availability, cost **,** and potential advantages of alternative treatments, including less expensive generic drugs; ● the availability of adequate reimbursement and pricing by third party payors and government authorities; ● the relative convenience and ease of administration of our product candidates for clinical practices; ● the product labeling or product insert required by the FDA or regulatory authority in other countries, including any contradictions, warnings, drug interactions, or other precautions; ● the approval, availability, market acceptance **,** and reimbursement for a companion diagnostic, if any; ● the prevalence and severity of adverse side effects; ● the effectiveness of our sales and marketing efforts; ● changes in the standard of care for the targeted indications for our product candidates or future product candidates, which could reduce the marketing impact of any superiority claims that we could make following FDA approval; and ● potential advantages over, and availability of, alternative treatments. If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is not perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and potentially sell our product candidates and any other product candidates we may license or acquire in the hospital marketplace will also depend on pricing and cost effectiveness, including our ability to produce a product at a competitive price and achieve acceptance of the product onto hospital formularies, as well as our ability to obtain sufficient third- party coverage or reimbursement. Since many hospitals are members of group purchasing organizations, which leverage the purchasing power of a group of entities to obtain discounts based on the collective buying power of the group, our ability to potentially attract customers in the hospital marketplace will

also depend on our ability to effectively potentially promote our product candidates **, if approved,** to group purchasing organizations. We will also need to demonstrate acceptable evidence of safety and efficacy, as well as relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with our product candidates. If any of our product candidates is approved but does not achieve an adequate level of acceptance by physicians, health care payors **,** and patients, we may not potentially generate sufficient revenue from this product, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third- party payors on the benefits of our product candidates may require significant resources and may never be successful. ~~43If~~ **If** we are unable to establish sales ~~,~~and marketing capabilities or ~~to~~ enter into agreements with third parties to market and sell our product candidate, **if approved,** we may not be successful in commercializing our product candidates if and when they are approved. We currently do not have a marketing or sales organization for the marketing and sales of pharmaceutical products since we currently have no drug products for sale. In order to potentially commercialize any product candidate that receives marketing approval, we would need to build ~~out~~ **our** marketing, sales, managerial **,** and other non- technical capabilities **,** or enter into agreements with third party contract organizations to perform these services, and we may not be successful in doing so. In the event of successful development and regulatory approval of our product candidates or **any** ~~another~~ -- **other** product ~~candidate~~ **candidates , if approved, we may license or acquire** , we might have to build a targeted specialist sales force to market or co- promote the product. There are risks involved with establishing our own sales and marketing capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our potential efforts to successfully commercialize our future product, if any, using our own sales and marketing capabilities include, but are not necessarily limited to: ● our inability to recruit, train **,** and retain adequate numbers of effective sales and marketing personnel; ● the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products; ● the lack of complementary or other products to be offered by sales personnel, which may put us at a competitive disadvantage from the perspective of sales efficiency relative to companies with more extensive product lines; and ● unforeseen costs and expenses associated with creating an independent sales and marketing organization. As an alternative to establishing our own sales force, we may choose to partner with third parties that have well- established direct sales forces to sell, market **,** and distribute ~~our~~ **any** ~~products~~ **product candidates for which we receive marketing approval** . There are risks involved with partnering with third party sales forces, including ensuring adequate training on the product, regulatory, and compliance requirements associated with promotion of the product. We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for our product candidates or other product candidates we may license or acquire and may have to limit their commercialization **, if approved** . The use of our product candidates and any other product candidates we may license or acquire in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. For example, we may be sued if any **product candidate or** product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing **,** or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability **,** or a breach of warranties. Product liability claims might be brought against us by consumers, health care providers or others using, administering **,** or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: ● withdrawal of clinical trial participants; ● termination of clinical trial sites or entire trial programs; ● decreased demand for any product candidates or products that we may develop; ● initiation of investigations by regulators; ● impairment of our business reputation; ● costs of related litigation; ● substantial monetary awards to patients or other claimants; ~~44~~ ● loss of revenues; ● reduced resources of our management to pursue our business strategy; and ● the inability to commercialize our product candidates or future product candidates **, if approved** . We have limited product liability insurance coverage for our clinical trials. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. When needed, we intend to potentially expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business, financial condition **,** and results of operations. Risks Pertaining to Intellectual Property and Potential Disputes ~~ThereofIf~~ -- **Thereof If** we are unable to obtain and maintain patent protection for our technology and products **,** or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired. Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection in the United States with respect to our product candidates or any other product candidates that we may license or acquire and the methods we use to manufacture them, as well as successfully defending these patents and trade secrets against third party challenges. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product ~~candidate~~ **candidates** . We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them. The patent prosecution process is expensive and time- consuming, and we may not be able

to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. If our licensors or we fail to obtain or maintain patent protection or trade secret protection for our product candidates or any other product candidate we may license or acquire, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability. Moreover, should we enter into other collaborations we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance **,** and enforcement of our patents. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions **,** and has in recent years been the subject of much litigation. In addition, no consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the United States. The patent situation outside the United States is even more uncertain. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after a first filing, or in some cases at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In the event that a third party has also filed a U. S. patent application relating to our product candidates or a similar invention, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a material adverse effect on our U. S. patent position. As a result, the issuance, scope, validity, enforceability **,** and commercial value of our or any of our licensors' patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the federal courts of the United States have taken an increasingly dim view of the patent eligibility of certain subject matter, such as naturally occurring nucleic acid sequences, amino acid sequences **,** and certain ~~45methods~~ -- **methods** of utilizing same, which include their detection in a biological sample and diagnostic conclusions arising from their detection. Such subject matter, which had long been a staple of the biotechnology and biopharmaceutical industry to protect their discoveries, is now considered, with few exceptions, ineligible in the first place for protection under the patent laws of the United States. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents (if any) or in those licensed from third parties. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and affect the validity, enforceability, scope **,** or defense of our issued patents. The Leahy- Smith America Invents Act **(** ~~, or~~ the **"** Leahy- Smith Act ~~,~~ **")** includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO issues and administers regulations and procedures to govern administration of the Leahy- Smith Act, including the first- to- file provisions. The Leahy- Smith Act could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material, adverse effect on our business and financial condition. Moreover, we may be subject to a third- party pre- issuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, inter parties review, post- grant review **,** or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, Patent Trial and Appeal Board (" PTAB ") trial, proceeding **,** or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop **,** or commercialize current or future product candidates. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us **,** or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non- infringing manner. The issuance of a patent does not foreclose challenges to its inventorship, scope, validity **,** or enforceability. Therefore, our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated **,** or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. The patent rights that we have in- licensed covering the infusion time and pharmacokinetics, or " PK ", profile for IV ~~Tramadol~~ **tramadol** are limited to a specific IV formulation of centrally acting synthetic opioid analgesic, and our market opportunity for this product candidate may be limited by the lack of patent protection for the active ingredient itself and other formulations that may be developed by competitors. The active ingredients in IV ~~Tramadol~~ **tramadol** have been generic in the United States for a number of years. While we believe that the patent estate covering IV ~~Tramadol~~ **tramadol** (including but not limited to U. S. Patent Nos. 8, 895, 622; 9, 561, 195, 9, 566, 253 9, 962, 343, 10, 406, 122, 9, 693, 949, 9, 968, 551, 9, 980, 900,

10, 022, 321, 10, 537, 521, 10, 624, 842, 10, 751, 277, 10, 751, 278, 10, 751, 279, 10, 646, 433, 10, 729, 644, 10, 729, 645, and 10, 617, 635) provides strong protection, our market opportunity would be limited if a generic manufacturer could obtain regulatory approval for another IV formulation of tramadol and commercialize it without infringing our patents. We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming **,** and unsuccessful. Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent' s claims narrowly **,** or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, rendered unenforceable, or interpreted narrowly. ~~46We~~ **We** may become involved in other types of legal proceedings related to our intellectual property that could result in the invalidation or unenforceability of our patents and could be expensive and time consuming, regardless of the outcome. Any party can challenge the validity of our patents in post- grant proceedings at the PTAB, which include inter partes review and post- grant review proceedings. Although these proceedings are more limited, and therefore are often less expensive, than district court litigation, they can still require substantial resources. If the PTAB finds that our patents are unpatentable, we will be unable to enforce those patents against our competitors. Additionally, our competitors may bring other administrative challenges to our patents before the USPTO, including opposition, derivation, interference, ex parte reexamination, and inter partes reexamination proceedings. These proceedings may prevent our patent applications from issuing, or for patents that are already issued, an unsuccessful outcome will render the patent unenforceable. If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in any litigation would harm our business. Our ability to develop, manufacture, market **,** and potentially sell our product candidates or any other product candidates that we may license or acquire depends upon our ability to avoid infringing the proprietary rights of third parties. Numerous U. S. and foreign patents and pending patent applications, which are owned by third parties, exist in the general fields of pain treatment and neurologic disorder treatment and cover the use of numerous compounds and formulations in our targeted markets. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and our licensors may not be successful in defending intellectual property claims by third parties, which could have a material adverse effect on our **business, financial condition, and** results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time- consuming **,** and distracting to management. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates may infringe. There could also be existing patents of which we are not aware that one of our product candidates may inadvertently infringe. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we ~~infringe~~ **infringed** on their patents or misappropriated their technology, we could face a number of issues, including: ● infringement and other intellectual property claims which, with or without merit, can be expensive and time consuming to litigate and can divert management' s attention from our core business; ● substantial damages for past infringement which we may have to pay if a court decides that our product infringes on a competitor' s patent; ● a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do; ● if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and ● redesigning our processes so they do not infringe, which may not be possible or could require substantial funds and time. We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. A third party may hold intellectual property, including patent rights that are important or necessary to the development and potential commercialization of our product. It may be necessary for us to use the patented or proprietary technology of third parties to potentially commercialize our product, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business. We are currently party to license agreements under which we acquired rights to develop and market **AJ201** ~~IV Tramadol~~, BAER- 101 **,** and ~~AJ201~~ **IV tramadol**. The applicable license agreement for IV ~~Tramadol~~ **tramadol** will terminate on a product- by- product and country- by- country basis upon the expiration of the last licensed patent right, unless the agreement is earlier terminated. In addition to standard early termination ~~47provisions~~ -- **provisions**, the ~~License~~ **license** ~~Agreement~~ **agreement pertaining to IV tramadol,** included provisions allowing early termination by: (i) Revogenex Ireland Ltd. (" Revogenex ") if the FDA did not issue an approval or otherwise issues a " not approvable " notice for the NDA within 15 months after the NDA was filed with the FDA, although this termination right will be tolled if we are using commercially reasonable efforts in our negotiations with the FDA for approval and if we receive a " not approvable " notice, we will have a 15 month period to correct any issues and re- submit the NDA for approval, (ii) us if we reasonably determine prior to NDA approval that the development of IV ~~Tramadol~~ **tramadol** is not economically viable, or (iii) either Revogenex or us (provided we are using or have used commercially reasonable efforts to commercialize IV ~~Tramadol~~ **tramadol**) if, after the third anniversary date of the commercial launch, we fail to achieve annual net sales with respect to IV ~~Tramadol~~ **tramadol** of at least $ 20 million in any given calendar year, with certain exceptions. Baergic is similarly party to two license agreements related to BAER- 101, one with AstraZeneca AB and another with Cincinnati Children' s Hospital Medical Center. Both license agreements were entered into in December 2019. Baergic acquired an exclusive license from AstraZeneca AB to patent and related intellectual property rights pertaining to its proprietary GABA- A 2, 3 positive allosteric modulator, and also acquired from Cincinnati Children' s Hospital Medical Center patent and related intellectual property rights pertaining to GABA

inhibition for neurological disorders. Baergic is obligated to use commercially reasonable efforts to develop and commercialize the licensed products in the U. S. and European Union. Finally, we licensed rights to AJ201 from AnnJi under a license agreement we entered into in February 2023. Under this license agreement, we obtained an exclusive license from AnnJi to intellectual property rights pertaining to the molecule known as JM17, which activates Nrf1 and Nrf2, enhances androgen receptor degradation , and underlies AJ201, a clinical product candidate currently in a Phase 1b / 2a clinical trial in the U. S. for the treatment of spinal and bulbar muscular atrophy, also known as Kennedy' s Disease. The license is exclusive as to all oral forms of AJ201 for use in all indications (other than androgenetic alopecia and Alzheimer' s disease) in the United States, Canada, the European Union, the United Kingdom , and Israel. The license agreement also contains customary representations and warranties and provisions related to confidentiality, diligence, indemnification , and intellectual property protection. If we fail to comply with the terms of this license agreement, we could lose rights to develop and market AJ201. In the future, we may become party to licenses that are important for product development and potential commercialization. If we fail to comply with our obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture , or market any product or utilize any technology that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could materially and adversely affect the value of a product candidate being developed under any such agreement or could restrict our drug discovery activities. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. To the extent we operate in foreign jurisdictions, we may be exposed to increased risk associated with the potential theft of technology and intellectual property. Our U. S. patents can be enforced against those who make, use, offer to sell, or sell our licensed patented inventions within the U. S., or against those who import our licensed patented inventions within the U. S. We may depend on foreign intellectual property rights to prevent competitors from manufacturing and selling our products outside of the U. S. without our authorization. Foreign laws and regulations may not protect our patent rights and trade secret rights to the same extent as U. S. law. It is also possible that we may be required to compromise protections or waive rights in order to conduct business in a foreign jurisdiction. Such restrictions may limit our ability to profitably compete in those markets. We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patent protection for our product candidates or future product candidates, we also rely on trade secrets, including unpatented know- how, technology , and other proprietary information, to maintain our competitive position, particularly where ~~48we~~ **we** do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We limit disclosure of such trade secrets where possible , but we also seek to protect these trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who do have access to them, such as our employees, our licensors, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors , and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and may unintentionally or willfully disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive , and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. General Risk ~~FactorsOur~~ --- **Factors** ~~business and operations could be adversely affected by the effects of health epidemics, including the ongoing COVID- 19 pandemic. Any potential future clinical trials may experience delays in patient enrollment, potentially due to prioritization of hospital resources toward the COVID- 19 pandemic, or concerns among patients about participating in clinical trials during a public health emergency. During 2020 and 2021, the COVID- 19 pandemic affected the operations of government entities, such as the FDA, as well as contract research organizations, third- party manufacturers, and other third- parties upon whom we rely. As a result of " shelter- in- place " orders, quarantines or similar orders or restrictions to control the spread of COVID- 19, many companies, including our own, implemented work- from- home policies for their employees during 2020, 2021 and into 2022. The effects of these stay- at- home orders and work- from- home policies may be negatively impacting productivity, resulting in delays in our timelines. The extent of the impact on our operations depends in part on whether governments and businesses reinstate these restrictions as a result of a rising surge in COVID- 19 cases or a new variant of the virus. These and similar disruptions in our operations could negatively impact our business, operating results and financial condition, however, as of the date of this Annual Report on Form 10- K, we have not experienced a significant impact on our business resulting from government restrictions on the movement of people, goods, and services. The global pandemic of COVID- 19 continues to evolve rapidly, and the ultimate impact of the COVID- 19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full impact of potential delays or effects on our business, our ability to access the capital markets, or supply chains or on the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor**

~~the COVID- 19 situation closely.~~ Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn. Our results of operations could be materially negatively affected by economic conditions generally, both in the United States and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, including the invasion of Ukraine by military forces of the Russian Federation **and the war between Israel and Hamas in Gaza** , the availability and cost of credit, the U. S. mortgage market **,** and **the** residential real estate market in the United States have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence **,** and increased interest rate, have precipitated an economic recession and fears of a possible depression. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may further decline. We will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives. We are a listed and traded public company. As a public company, we incur significant legal, accounting **,** and other expenses under the Sarbanes- Oxley Act of 2002, as well as rules subsequently implemented by the SEC and the rules of the Nasdaq Stock Market, on which our common stock is listed. These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time- consuming and costly. For ~~49example --~~ **example** , these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees **,** or as executive officers. The Sarbanes- Oxley Act of 2002 requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. As a result, we are required to periodically perform an evaluation of our internal controls over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of the Sarbanes- Oxley Act. However, while we remain a non- accelerated filer, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To ~~achieve~~ **maintain** compliance with Section 404 ~~within the prescribed period~~ , we have ~~engaged~~ in **place** a process to document and evaluate our internal control over financial reporting. These efforts to comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources. While we anticipate maintaining the integrity of our internal controls over financial reporting and all other aspects of Section 404, we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future. If a material weakness is identified, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources, costly litigation **,** or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock. Our business and operations would suffer in the event of system failures. Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war **,** and telecommunication and electrical failures. Any system failure, accident **,** or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed clinical trials for our product candidates 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 results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidates may be delayed. The occurrence of a catastrophic disaster could damage our facilities beyond insurance limits or we could lose key data which could cause us to curtail or cease operations. We are vulnerable to damage and / or loss of vital data from natural disasters, such as earthquakes, tornadoes, power loss, fire, health epidemics and pandemics, floods **,** and similar events, as well as from accidental loss or destruction. If any disaster were to occur, our ability to operate our businesses could be seriously impaired. We have property, liability **,** and business interruption insurance that may not be adequate to cover losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business, financial condition **,** and prospects. Any of the aforementioned circumstances may also impede our employees' and consultants' abilities to provide services in- person and / or in a timely manner; hinder our ability to raise funds to finance our operations on favorable terms or at all; and trigger effectiveness of " force majeure " clauses under agreements with respect to which we receive goods and services, or under which we are obligated to achieve developmental milestones on certain timeframes. Disputes with third parties over the applicability of such " force majeure " clauses, or the enforceability of developmental milestones and related extension mechanisms in light of such business interruptions, may arise and may become expensive and time- consuming. We may become involved in securities class action litigation that could divert management' s attention and harm our business. The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and pharmaceutical companies. These broad market fluctuations may cause the market price of our stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years and due to the significant stock price decline we experienced

following the announcement of the First CRL. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management' s attention and resources, which could adversely affect our business. **Changes in tax laws or regulations that are applied adversely to us may have a material adverse effect on our business, cash flow, financial condition, or results of operations. New income, sales, use or other tax laws, statutes, rules, regulations, or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. For example, the United States recently passed the Inflation Reduction Act, which provides for a minimum tax equal to 15 % of the adjusted financial statement income of certain large corporations, as well as a 1 % excise tax on certain share buybacks by public corporations that would be imposed on such corporations. In addition, it is uncertain if and to what extent various states will conform to newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets, could result in significant one- time charges, and could increase our future U. S. tax expense.** ~~50Risks -- Risks~~ Pertaining to the Influence of ~~FortressFortress~~ **Fortress Fortress** controls a voting majority of our common stock. Pursuant to the terms of the Class A Preferred Stock held by Fortress, Fortress **is** ~~will be~~ entitled to cast, for each share of Class A Preferred Stock held by Fortress, the number of votes that is equal to 1. 1 times a fraction, the numerator of which is the sum of (A) the aggregate number of shares of outstanding common stock and (B) the whole shares of common stock into which the shares of outstanding the Class A Preferred Stock are convertible and the denominator of which is the aggregate number of shares of outstanding Class A Preferred Stock, or the " Class A Preferred Stock Ratio. " Thus, Fortress will at all times have voting control of us. Further, for a period of ten **(10)** years from the date of the first issuance of shares of Class A Preferred Stock, the holders of record of the shares of Class A Preferred Stock (or other capital stock or securities issued upon conversion of or in exchange for the Class A Preferred Stock), exclusively and as a separate class, shall be entitled to appoint or elect the majority of our directors. Accordingly, conflicts of interest may arise between Fortress and its affiliates, on the one hand, and us and our other stockholders, on the other hand. In resolving these conflicts of interests, Fortress may favor its own interests and the interests of its affiliates, over the interests of our other stockholders, which could cause a material adverse effect on our business, financial condition **,** and results of operations **. This concentration of voting power may also have the effect of delaying, preventing, or deterring a change in control of us even when such a change may be in the best interests of all stockholders, could deprive our stockholders of an opportunity to receive a premium for their shares of common stock as part of a sale of us or our assets, and might affect the prevailing market price of our common stock** . Fortress has the right to receive a significant grant of shares of our common stock annually, which would result in the dilution of your holdings of common stock upon each grant, which could reduce their value. Under the terms of the Amended and Restated Founders Agreement, which became effective September 13, 2016, Fortress is entitled to receive a grant of shares of our common stock equal to 2. 5 % of the gross amount of any equity or debt financing. Additionally, the holders of Class A Preferred Stock, as a class, are to receive an Annual Stock Dividend, payable in shares of common stock in an amount equal to 2. 5 % of our fully- diluted outstanding capital stock as of the business day immediately prior to the date such dividend is payable. Fortress currently owns all outstanding shares of Class A Preferred Stock ~~. At our Annual Meeting of Stockholders held on June 13, 2018, the Company' s stockholders approved an amendment to the Company' s Third Amended and Restated Certificate of Incorporation, amending the Class A Preferred dividend payment date from February 17 to January 1 of each year~~ . These potential future share issuances to Fortress and any other holder of Class A Preferred Stock will dilute your holdings in our common stock and, if our value has not grown proportionately over the prior year, would result in a reduction in the value of your shares. The Amended and Restated Founders Agreement has a term of 15 years and renews automatically for subsequent one- year periods unless terminated by Fortress or upon a Change in Control (as defined in the Amended and Restated Founders Agreement). We might have received better terms from unaffiliated third parties than the terms we receive in our agreements with Fortress. We entered into certain agreements with Fortress in connection with our separation from Fortress into an independent company, including the Management Services Agreement **(** ~~, or~~ the " MSA ~~,~~ " **)** and the Founders Agreement, and entered into the Contribution Agreement with Fortress in May 2022. While we believe the terms of these agreements are reasonable, they might not reflect terms that would have resulted from arm' s- length negotiations between unaffiliated third parties. The terms of the agreements relate to, among other things, payment of a royalty on product sales, the provision of employment and transition services **,** and the contribution to us of a majority of the outstanding equity securities of Baergic previously held by Fortress. We might have received better terms from third parties because, among other things, third parties might have competed with each other to win our business. The ownership by our executive officers and some of our directors of equity securities of Fortress and / or rights to acquire equity securities of Fortress might create, or appear to create, conflicts of interest. Because of their current or former positions with Fortress, some of our executive officers and directors own shares of Fortress common stock and / or options to purchase shares of Fortress common stock. Their individual holdings of common stock and / or options to purchase common stock of Fortress may be significant compared to their total assets. Ownership by our directors and officers, after our separation from Fortress, of common stock and / or options to purchase common stock of Fortress create or might appear to create conflicts of interest when these directors and officers are faced with decisions that could have different implications for Fortress than for us. For instance, and by way of example, if there were to be a dispute between Fortress and us regarding the calculation of the royalty fee due to Fortress under the terms of the Founders Agreement, then certain of our officers and directors may have and will appear to have a conflict of interest with regard to the outcome of such dispute. ~~51~~ **Fortress' current or future financial obligations and arrangements, or an event of default thereon, may change the ownership dynamic of us by Fortress. Any default or breach by Fortress under any current or future credit agreement or arrangements may have an adverse effect on our business. Fortress has pledged, as collateral to certain of its creditors, equity in the Company. If Fortress were to default on its obligations to any such creditor, that creditor, whose interests may not align with those of our other stakeholders, could acquire a**

controlling interest in the Company. In addition, Fortress' current credit agreement with Oaktree Capital (the " Oaktree Credit Agreement ") contains certain affirmative and negative covenants and events of default that apply in different instances to Fortress itself, its private subsidiaries, its public subsidiaries, or combinations of the foregoing. Although we are not a party to the Oaktree Credit Agreement, because Fortress controls our stockholder vote, Fortress may not permit us to effect certain actions which we feel would be in the Company' s best interests, but which Fortress cannot allow so as to remain in compliance with the Oaktree Credit Agreement.