Risk Factors Comparison 2025-03-24 to 2024-04-01 Form: 10-K

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Our operations and financial results are subject to various risks and uncertainties, including those described below that could adversely affect our business, financial condition, results of operations, cash flows and the trading price of our common stock. You should carefully consider the following risks, together with all of the other information in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. Risks Relating to Our Business We ~~may experience difficulties integrating Quince and EryDel' s operations and realizing the expected benefits of the EryDel Acquisition. The success of the EryDel Acquisition will depend in part on our ability to realize the expected operational efficiencies and associated cost synergies and anticipated business opportunities and growth prospects from the EryDel Acquisition in an efficient and effective manner. We may not be able to fully realize the operational efficiencies and associated cost synergies or leverage the potential business opportunities and growth prospects to the extent anticipated or at all. Challenges associated with the integration may include those related to retaining and motivating executives and other key employees, blending corporate cultures, eliminating duplicative operations, and making necessary modifications to internal control over financial reporting and other policies and procedures in accordance with applicable laws. Some of these factors are outside our control, and any of them could delay or increase the cost of our integration efforts. The integration process could take longer than anticipated and could result in the loss of key employees, the disruption of each company' s ongoing businesses, increased tax costs, inefficiencies, and inconsistencies in standards, controls, information technology systems, policies and procedures, any of which could adversely affect our ability to maintain relationships with employees or third parties, or our ability to achieve the anticipated benefits of the transaction, and could harm our financial performance. If we are unable to successfully integrate certain aspects of the operations of EryDel, including relevant human resource functions, or experience delays, we may incur unanticipated liabilities and be unable to fully realize the potential benefit of future revenue and other anticipated benefits resulting from the arrangement, and our business, results of operations and financial condition could be adversely affected. We~~ are substantially dependent on the success of our lead drug candidate, ~~EryDex~~ **eDSP** . Our business and future success depends on our ability to successfully develop, obtain regulatory approval for and successfully commercialize our lead drug candidate, ~~EryDex~~ **eDSP** , which is under clinical development for A- T. ~~EryDex~~ **eDSP** is our only drug candidate in late- stage clinical development, and our business currently depends heavily on its successful development. **The** ~~In the previous~~ Phase 3 ATTeST trial ~~, the trial~~ did not meet ~~the~~ **its** primary efficacy endpoint. The trial saw statistically significant results in the age group of six to nine years old **. We** ~~and we expect to initiate~~ **initiated** the NEAT ~~study~~ **clinical trial** in this population in the second quarter 2024 ~~. We~~ **, and** expect to announce the results of the NEAT ~~study~~ **clinical trial** in the ~~second half~~ **fourth quarter** of 2025, but cannot guarantee that the results of this study will be positive or that they will allow further development in this therapeutic indication. ~~EryDex~~ **eDSP** will require additional clinical and non- clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We cannot be certain ~~EryDex~~ **eDSP** will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. In addition, because ~~EryDex~~ **eDSP** is our most advanced drug candidate, and because our other drug candidates are based on the same AIDE platform technology, if ~~EryDex~~ **eDSP** encounters safety or efficacy problems, developmental delays or regulatory issues or other problems, our development plans and business would be significantly harmed. We have no drug candidates approved for commercial sale, we have never generated any revenue from sales, and we may never be profitable. We have no drug candidates approved for sale, have never generated any revenue from sales, have never been profitable and do not expect to be profitable in the foreseeable future. We have incurred net losses in each year since our inception. For the years ended December 31, **2024 and** 2023 ~~and 2022~~ , our net losses were $ **56. 8 million and $** 31. 4 ~~million and $ 51. 7~~ million, respectively. We had an accumulated deficit of $ ~~319~~ **376** . ~~6~~ **5** million as of December 31, ~~2023~~ **2024** . Before we are able to generate any revenue, we will need to commit substantial funds to the anticipated clinical and development activities related to ~~EryDex~~ **eDSP** , and we may not be able to obtain sufficient funds on acceptable terms, if at all. Any additional debt financing or additional equity that we raise may contain terms that are not favorable to us and / or result in dilution to our stockholders. We expect that it could take several years, if ever, before we may have a drug candidate ready for commercialization. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we pursue our current strategic direction, and seek regulatory approvals for any drug candidates, prepare for and begin the commercialization of any approved drug candidates, and add infrastructure and personnel to support our drug development efforts and operations as a public company. We anticipate that any such losses could be significant for the next several years. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Further, these net losses have fluctuated significantly in the past and are expected to continue to significantly fluctuate from quarter- to- quarter or year- to- year. To become and remain profitable, we must develop and eventually commercialize a drug with significant revenue. ~~We~~ **However, we** may never succeed in developing a commercial drug. On January 25, 2022, the..... force us to cease our operations. We expect to explore partnership and licensing opportunities to support the future development of ~~EryDex~~ **eDSP** and other drug candidates. We may also encounter other unforeseen expenses, difficulties, complications, delays and other known and unknown challenges as we pursue our current strategic direction. There are numerous risks and uncertainties, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to generate revenues or achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis

and we will continue to incur substantial research and development and other expenditures to develop and market additional drug candidates. **There is substantial doubt regarding our ability to continue as a going concern.** We ~~and assess our future viability.Drug development is a highly uncertain undertaking and involves a substantial degree of risk.To date,we have only initiated two late- stage clinical trials,one of which was initiated by EryDel,and we have not obtained marketing approval for any drug candidate,manufactured a commercial scale drug candidate,arranged for a third party to do so on our behalf,or conducted sales and marketing activities necessary for successful drug candidate commercialization.Our short operating history as a company makes any assessment of our future success and viability subject to significant uncertainty.We~~ will **need** ~~encounter risks and difficulties frequently experienced by clinical stage biotechnology companies in rapidly evolving fields,and we have not yet demonstrated an ability~~ to **raise** ~~overcome such risks and difficulties successfully.If we do not address these risks and difficulties successfully,our business will suffer.We will require~~ substantial additional funding **,which may not be available on acceptable terms,** to finance our operations and evaluate future drug candidates.If we are unable to raise this ~~funding~~ **additional capital** when needed or on acceptable terms,we may be forced to delay, **limit,** reduce **,terminate** or eliminate our drug development programs or other operations.Since our inception,we have used substantial amounts of cash to fund our operations **.We** ~~,and we~~ expect our expenses to increase substantially in the foreseeable future in connection with our ongoing activities, ~~particularly as we evaluate~~ **including completion of the Phase 3 NEAT clinical trial** and ~~develop drug candidates~~ **potential NDA submission,assuming positive study results** .In addition,if we obtain marketing approval for **eDSP or** any future drug candidates,we expect to incur significant commercialization expenses related to sales,marketing,manufacturing and distribution. **As of December 31,2024,we had $ 40.8 million in cash,cash equivalents and short- term investments.Based on our available cash resources and current operating plan,there is substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that our financial statements for the year ended December 31,2024 are issued.Our existing capital resources,including term loans we received under the EIB Loan,will not be sufficient to enable us to complete our clinical development for eDSP.We will need to raise substantial additional funds in the future in order to complete the development of eDSP and seek regulatory approval thereof,to expand our manufacturing capabilities,and to commercialize eDSP,if approved by the FDA.** Further development of ~~EryDex~~ **eDSP** will require us to incur significant additional expenses.Moreover,we expect to require substantial additional funding to finance such payments and to advance the development and optimize the commercialization of ~~EryDex~~ **eDSP** ,and there can be no assurance that such additional funding will be available on terms that are acceptable to us,or at all. ~~If adequate funds are not available on a timely basis,we may not be able to effectively implement our strategic plan.Accordingly,we will need to obtain substantial additional funding in order to fully execute on our corporate strategy.As of December 31,2023,we had $ 75.1 million in cash,cash equivalents and investments.Our balance sheet includes publicly- traded corporate debt securities.We may be required to recognize impairments in the value of these investments if the relevant companies are materially adversely affected,become unable to repay debt securities when due,or experience credit rating downgrades,or if the public trading price of these securities decreases.~~ We believe that our existing capital resources will be sufficient to fund our projected operations,which would include anticipated clinical and development activities related to **eDSP** ~~EryDel' s lead asset~~ through the Phase 3 NEAT clinical trial ~~,into 2026~~ .However,changing circumstances may cause us to increase our spending significantly faster than we currently anticipate,and we may need to spend more money than currently expected because of circumstances beyond our control.We may need to raise additional funds sooner than we anticipate if we choose to expand more rapidly than we presently anticipate **and our efforts to raise additional funding may divert our management from their day- to- day activities,which may adversely affect our ability to develop our proprietary AIDE technology platform and Phase 3 lead asset,eDSP,to progress development of our product candidates or to advance our manufacturing processes** .The amount and timing of our future funding requirements will depend on many factors,some of which are outside of our control,including but not limited to:• the rate of progress in the development of and the conduct of clinical trials with respect to our product candidates;• our ability to successfully identify partnership and licensing opportunities to support the future development of ~~EryDex~~ **eDSP** ;• the outcome,costs and timing of seeking and obtaining FDA and any other regulatory approvals;• ~~the number and characteristics of drug candidates that we acquired or pursue;•~~ our ability to manufacture sufficient quantities of our drug candidates and devices;• our need to expand our research and development activities;• the costs associated with securing and establishing commercialization and manufacturing capabilities;• ~~the costs of acquiring,licensing or investing in businesses,drug candidates and technologies;•~~ our ability to maintain,expand and defend the scope of our intellectual property portfolio,including the amount and timing of any payments we may be required to make,or that we may receive,in connection with the licensing,filing,prosecution,defense and enforcement of any patents or other intellectual property rights;• our need and ability to retain management and hire scientific and clinical personnel;• the effect of competing drugs and drug candidates and other market developments;• our need to implement additional internal systems and infrastructure,including financial and reporting systems;• the costs to grow our organization and increase the size of our facilities to meet our anticipated growth;• the economic and other terms,timing of and success of any collaboration,licensing or other arrangements into which we may enter in the future;and • our ability and timing of future milestones payments to EryDel shareholders and repayment of obligations in respect of the EIB ~~Facility~~ **Loan** .Additional funding may not be available to us on acceptable terms or at all. ~~Any~~ **Moreover,the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities,whether equity or debt,by us,or the possibility of** such ~~funding~~ **issuance,** may **cause the market price of our common stock to decline.The sale of additional equity or convertible securities would dilute all of our stockholders.The incurrence of indebtedness would** result in ~~dilution~~ **increased fixed payment obligations and we may be required** to **agree to certain restrictive** ~~stockholders,imposition of debt~~ covenants and ~~repayment obligations,or~~ other **operating** restrictions that ~~may affect~~ **could adversely impact our ability to conduct** our business. ~~We also could~~ **Additionally,the EIB Loan may prevent or limit our ability to incur additional indebtedness.As a result of geopolitical events,including the conflicts in**

Ukraine,inflation,high interest rates and other conditions,the global credit and financial markets have experienced volatility and disruptions.If we are unable to obtain funding on a timely basis,or to generate sufficient revenues,if at all,from collaboration arrangements,we may be required to **:• significantly curtail,delay or discontinue one or more of our research or development programs,the development of our technology,including our AIDE platform technology,the commercialization of any product candidates or cease operations altogether;•** seek ~~funds through arrangements with collaborative~~ **collaborators** ~~partners or~~ **for one or more of our product candidates at an earlier stage than** otherwise **would be desirable or on terms** that ~~may require us to~~ **are less favorable than might otherwise be available;•** relinquish **or license on unfavorable terms our** rights to ~~some of our~~ technologies or ~~drug~~ **product** candidates ~~or~~ **that we** otherwise **would seek to develop or commercialize ourselves;or • forego expansion of our operations or refrain from pursuing business opportunities.If we** ~~agree --~~ **are unable** to ~~terms unfavorable~~ **continue as a going concern,we may have** to ~~us~~ **cease operations and liquidate our assets** . ~~The terms of~~ **We may receive less than the value at which** ~~the~~ **those assets are carried** ~~EIB Facility place restrictions~~ on our ~~operating and~~ financial **statements** ~~flexibility.In connection with the EIB Facility~~ , ~~we are subject to operating restrictions and covenants that restrict our ability to finance our operations,engage in business activities or expand or fully pursue its business strategies.For example,unless we get approval from EIB,the EIB Facility limits our ability to,among other things:• incur additional debt or provide guarantees in respect of debt;• incur liens;• make investments,acquisitions,loans or advances;• sell assets;• make distributions to equity holders,including dividends and distributions on,and redemptions,repurchases or retirement of,our capital stock;• enter into certain hedging transactions;• enter into fundamental changes,including mergers and consolidations;• enter into transactions with affiliates;• change the nature of our business;and • change our management.In addition,the EIB Facility requires that we meet certain reporting and operating covenants,including an~~ **and** ~~obligation to maintain~~ **investors may lose all or** a ~~certain minimum unrestricted~~ **part of their investment.We have and** may be required to make milestone payments to **(i)** the EryDel ~~Shareholders~~ **shareholders** ~~or~~ pursuant to the **terms of the EryDel Acquisition or (ii) additional remuneration payments to** EIB ~~Facility~~ **pursuant to the EIB Loan** in connection with our development and commercialization of ~~EryDex~~ **eDSP** , which could adversely affect the overall profitability of ~~EryDex~~ **eDSP** , if approved. In connection with the EryDel Acquisition, we **have and** may be required to make additional payments to EryDel ~~Shareholders~~ **shareholders** of up to an aggregate of $ 485. 0 million in potential cash payments, comprised of up to $ 5. 0 million upon the achievement of ~~a specified development milestone~~ **first patient dosed in the Phase 3 NEAT clinical trial, which was achieved in the second quarter of 2024** , $ 25. 0 million at NDA acceptance, up to $ 60. 0 million upon the achievement of specified approval milestones, and up to $ 395. 0 million upon the achievement of specified on market and sales milestones, with no royalties paid to EryDel. These milestone obligations could impose substantial additional costs on us, divert resources from other aspects of our business, and adversely affect the overall profitability of ~~EryDex~~ **eDSP** , if approved. We may need to obtain additional financing to satisfy these milestone payments, and cannot be sure that any additional funding, if needed, will be available on terms favorable to us, or at all. ~~Additionally, in connection with the EIB Facility, we are also required to make additional payments to the EIB consisting of (i) interest payments on the outstanding loans thereunder, (ii) payments based on a percentage of the revenue derived from the acquisition of EryDel USA, Inc~~ **In** ~~. on July 21, 2023, which will be payable annually with respect to the immediately preceding fiscal year commencing on~~ June ~~30, 2027~~ **2024** , **we enrolled** ~~and (iii) repayments of the principal amount of the loans under the EIB Facility upon the occurrence of certain events. The occurrence of certain events of default under the EIB Facility, including failure to make payments as they~~ **the first patient in** ~~become due (subject to a grace period of three --~~ **the** (3) business days) to..... the Development of Our Drug Candidates The Phase 3 NEAT clinical trial **and paid the cash milestone payment** of **$ 5 million to the former** ~~EryDex~~ **EryDel shareholders in accordance with the Purchase Agreement. We owe no further payments to EryDel shareholders** for **development- related milestones. The remaining potential contingent payments in connection with the EryDel Acquisition pertain to regulatory, on market and sales milestones. We are required to make payments to EIB calculated based on a percentage of the revenue derived from the acquisition of EryDel on October 23, 2023, which will be payable annually on each June 30th. The additional remuneration is payable for seven years, during the period January 1, 2026, through December 31, 2032, with the first such payment becoming payable on June 30, 2027. The amount of additional remuneration to be paid is equal to 2. 5 % of revenue up to 125. 0 million euros, plus 1. 85 % of revenue between 125. 0 and 250. 0 million euros, plus 1. 0 % of revenue in excess of 250. 0 million euros, multiplied by a varying percentage based on how many tranches have been drawn. The varying percentage is equal to 30. 0 % in the event tranche** A - T will be conducted under a..... issue essential to determining safety or efficacy has been **drawn** ~~identified after testing has begun; • a sponsor fails to follow a protocol that was agreed upon with the FDA; or • the relevant data~~ , **50** ~~assumptions, or information provided by the sponsor in a request for SPA change, are found to be false statements or misstatements, or are found to omit relevant facts~~ . **0 % in the event tranche** A ~~documented SPA may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. An SPA, however, does not guarantee that a trial will be successful, and our execution of the Phase 3 NEAT clinical trial may be delayed and even if successful may not result in approval by the FDA. We, or any future development partner with whom we enter into a related agreement, are required to conduct clinical and nonclinical trials in accordance with the study plan and protocols and applicable regulatory requirements. The FDA or comparable regulatory authorities outside the U. S., including in the EU, may disagree with the design or implementation of our or any of our future development partners' clinical trials. We or any of our future development partners may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities outside the U. S., including in the EU, that a product candidate is safe and effective for any indication. In addition, we are responsible for ensuring that each of our nonclinical studies and clinical trials are conducted in accordance with the study plan and protocols and applicable regulatory requirements and that drug candidates are manufactured and tested in accordance with applicable GMP requirements and other~~

~~applicable regulatory requirements. If we or any future development partner are unable to demonstrate that our candidate drugs were manufactured and clinical trials were conducted in accordance with applicable regulations we may be unable to submit appropriate evidence to support applications for drug approval and the authorities may reject or related applications. Clinical drug development is a lengthy, expensive and uncertain process. The results of preclinical studies and early clinical trials are not always predictive of future results. Any drug candidate that we may advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval. The research and development of drugs is extremely risky. Only a small percentage of drug candidates that enter the development process ever receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidate may not be further developed or have favorable results in later studies or trials. Clinical trial failure may result from a multitude of factors including, but not limited to, flaws in study design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. The Phase 3 ATTeST clinical trial conducted by EryDel failed to meet the primary endpoint and was potentially negatively affected by missing date during the COVID- 19 pandemic. Several companies in the pharmaceutical industry have suffered setbacks in the advancement of their drug candidates into later- stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding results in earlier preclinical studies or clinical trials. In addition, data obtained from preclinical trials and clinical trials are susceptible to varying interpretations, and regulatory authorities may not interpret our data as favorably as we do, which may further delay, limit or prevent development efforts, clinical trials or marketing approval. Furthermore, as more competing drug candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. If we are unable to complete preclinical studies or clinical trials of any future drug candidates, due to safety or efficacy concerns, or if the results of these trials are not sufficient to convince regulatory authorities of their safety or efficacy, we will not be able to obtain marketing approval for commercialization on a timely basis or at all. Even if we are able to obtain marketing approval for our current and any future drug candidates, those approvals may be for indications or dose levels that deviate from our desired approach or may contain other limitations that would adversely affect our ability to generate revenue from sales of those drug candidates. Results in earlier clinical trials may not be indicative of the results that may be obtained in registrational clinical trials, which may delay or prevent obtaining regulatory approval. Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical studies and early clinical trials may not be predictive of results in larger clinical trials, and previous results from early or small clinical trials may not be replicated or show as favorable an~~ **and B** outcome in further clinical trials, even..... those events may occur. Other products have been ~~approved by~~ **drawn, 80. 0 % in** the ~~regulatory authorities for which safety concerns~~ **event tranche A, B and C** have been **drawn** ~~uncovered following approval. Such safety concerns have led to labeling changes~~ , ~~restrictions on distribution through use of a REMS, or comparable foreign strategy, or withdrawal of products from the market, and any of our drug candidates may be subject to similar risks. Although to date we have not seen evidence of significant safety concerns with our drug candidates in the patient populations currently undergoing clinical trials with EryDex, if approved, may experience previously unreported adverse reactions, and it is possible that the FDA or other regulatory authorities may ask for additional safety data as a condition of, or in connection with, our efforts to obtain approval of our drug candidates. If safety problems occur or are identified after our products, if any, reach the market, we may make the decision or be required by regulatory authorities to amend~~ -- **and 100. 0 % in** the ~~labeling of our products, recall our products, or even~~ **event all** ~~withdraw approval for~~ **four tranches** our products. If we are not..... our beliefs and estimates. These estimates have been derived from a variety of sources,..... may not have access to the raw **drawn** materials and other components, necessary for..... profitability despite obtaining such significant market share . If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any drug candidates we may develop and for which we obtain approval, we may not be successful in commercializing those drug candidates if and when they are approved. We do not have a sales or marketing infrastructure and have no experience in the sale, marketing, or distribution of pharmaceutical drug candidates, if approved, or devices. To achieve commercial success for any approved drug candidate for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing, and commercial support infrastructure to sell, or participate in sales activities with collaborators for, some of our drug candidates if and when they are approved. There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, factors that may inhibit our efforts to commercialize any drug candidates, if and when approved, whether alone or in collaboration with others: • our inability to recruit and retain adequate numbers of effective sales, marketing, coverage or reimbursement, customer service, medical affairs, and other support personnel; • the inability of sales personnel to obtain access to physicians or our failure to educate adequate numbers of physicians on the benefits of any future approved drug candidates; • the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors; • the inability to price our drug candidates, if approved, at a sufficient price point to ensure an adequate and attractive level of profitability; • the pricing of our products, particularly as compared to alternative treatments; • availability of alternative effective treatments for indications our candidates are intended to treat and the relative risks, benefits and costs of those treatments; • restricted or closed distribution channels that make it difficult to distribute our drug candidates, if approved, to segments of the patient population; • the lack of complementary drug candidates, if approved, to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive drug candidate lines;

and • unforeseen costs and expenses associated with creating an independent commercialization organization. If the commercial launch of a future drug candidate, if approved, for which we recruit a sales force and establish marketing and other commercialization 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 commercialization personnel. If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our sales revenue or the profitability of sales revenue may be lower than if we were to market and sell any drug candidates, if approved, we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our drug candidates, if approved, or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our drug candidates, if approved, effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our drug candidates if approved in the future. ~~If~~ **We may encounter difficulties in managing our growth and expanding our operations successfully. As we seek to advance our** product ~~liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our drug~~ candidates **through clinical trials and** , if approved **, through commercialization, we** ~~. We face an inherent risk of product liability as a result of the clinical testing of our drug candidates and~~ will ~~face an even greater risk when and if we~~ **need to expand our development, regulatory, quality assurance, manufacturing,** ~~commercialize~~ **commercialization , compliance, and administration capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to increase the responsibilities on members of management and manage** any **future growth effectively** ~~drug candidates, if approved~~ . **Our** ~~For example, we may be sued if our drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, early access program, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a~~ failure to **effectively manage** ~~warn of dangers inherent in the product, negligence, strict liability or~~ **our growth** ~~a breach of warranties. Product liability claims may be brought against us by participants enrolled~~ in **this regard** our clinical trials, patients, health..... to protect against potential product liability claims could prevent ~~or inhibit the commercialization of drug candidates we develop, alone or with potential collaborators. Our insurance policies may have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle~~ us **from successfully implementing** ~~to indemnification against losses, such indemnification may not be available or~~ **our** ~~adequate should any claim arise~~ **strategy and maintaining the confidence of investors in our company** . We may be exposed to a variety of international risks that could materially adversely affect our business. Our business is subject to risks associated with conducting business internationally. Some of our suppliers and clinical trial centers are located outside of the United States. We may enter into agreements with third parties for the development and commercialization of drug candidates in international markets. We also plan to seek regulatory approval of our drug candidates outside of the United States. International business relationships will subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including: • differing regulatory requirements for drug approvals internationally; • rejection or qualification of foreign clinical trial data by the competent authorities of other countries; • price controls on our drug products; • complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property; • potential third- party patent rights in countries outside of the United States; • different United States and foreign drug import and export rules; • different reimbursement systems and different competitive drugs indicated to treat the indications for which our drug candidates are being developed; • the potential for so- called " parallel importing, " which is what occurs when a local seller, faced with relatively high local prices, opts to import goods from another jurisdiction with relatively low prices, rather than buying them locally; • the potential for so- called " parallel exporting, " which is what occurs when a local seller buys goods meant for the locals and sells the goods for a higher price in another country, potentially causing or aggravating supply problems; • unexpected changes in tariffs, trade barriers and regulatory requirements; • economic weakness, including inflation, bank failures, or political instability, particularly in non- U. S. economies and markets, including several countries in Europe; • compliance with tax, including withholding of payroll taxes, employment, immigration and labor laws for employees living or traveling abroad; • regulatory and compliance risks that relate to anti- corruption compliance and record- keeping that may fall within the purview of the U. S. Foreign Corrupt Practices Act, its accounting provisions or its anti- bribery provisions or provisions of anti- corruption or anti- bribery laws in other countries; • taxes in other countries; • financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations; • foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; • workforce uncertainty in countries where labor unrest is more common than in the United States; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; • business interruptions resulting from geo- political actions, including war and terrorism, public health crises, such as pandemics and epidemics, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires; and • compliance with evolving and expansive international data privacy laws, such as the EU GDPR. Any of these factors could harm our ongoing international clinical operations and supply chain, as well as any future international expansion and operations and, consequently, our business, financial condition, prospects and results of operations. For example, the UK has voluntarily departed from the EU, commonly referred to as " Brexit. " We do not know to what extent Brexit will impact the business and regulatory environment in the UK, the EU, or other countries. Changes impacting our ability to conduct business in the UK, or other EU countries, or changes to the regulatory regime in those countries, may impact certain portions of

our research and general business operations in the UK and the EU. ~~The United Kingdom' s withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business, which could reduce the price of our common shares. Following Brexit, the UK and the EU signed a EU- UK Trade and Cooperation Agreement, or TCA, which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. This agreement provides details on how some aspects of the UK and EU' s relationship will operate going forwards however there are still uncertainties. The TCA primarily focuses on ensuring free trade between the EU and the UK in relation to goods, including medicinal products. Among the changes that have occurred are that Great Britain (England, Scotland and Wales) is treated as a " third country, " a country that is not a member of the EU and whose citizens do not enjoy the EU right to free movement. Northern Ireland continues to follow many aspects of the EU regulatory rules, particularly in relation to trade in goods. As part of the TCA, the EU and the UK recognize GMP inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The UK has unilaterally agreed to accept EU batch testing and batch release. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the UK must be retested and re- released when entering the EU market for commercial use. As it relates to marketing authorizations, Great Britain has a separate regulatory submission process, approval process and a separate national marketing authorization. Northern Ireland continues, however, to be covered by the marketing authorizations granted by the European Commission. For example, the scope of a marketing authorization for a medicinal product granted by the European Commission or by the competent authorities of EU Member States no longer encompasses Great Britain (England, Scotland and Wales). In these circumstances, a separate marketing authorization granted by the UK competent authorities is required to place medicinal products on the market in Great Britain. Northern Ireland continues, however, to be covered by the marketing authorizations granted by the European Commission. On February 27, 2023, the UK Government and the European Commission reached a political agreement on the so- called " Windsor Framework ". The Framework is intended to revise the Northern Ireland Protocol to address some of the perceived shortcomings in its operation. The agreement was adopted at the Withdrawal Agreement Joint Committee on March 24, 2023. If the changes are adopted in the form proposed, medicinal products to be placed on the market in the UK will be authorized solely in accordance with UK laws. Northern Ireland would be reintegrated back into a UK- only regulatory environment under the authority of the MHRA with respect to all medicinal products. The implementation of the Windsor Framework would occur in stages, with new arrangements relating to the supply of medicinal products into Northern Ireland anticipated to take effect in 2025. A significant proportion of the regulatory framework in the UK applicable to medicinal products is currently derived from EU Directives and Regulations. The potential for UK legislation to diverge from EU legislation following Brexit could materially impact the regulatory regime with respect to the development, manufacture, import, approval, and commercialization of our drug candidates in the UK or the EU. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. All of these changes could increase our costs and otherwise adversely affect our business. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our drug candidates in the UK or the EU and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our drug candidates into the EU. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the UK or the EU for our drug candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import / export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non- tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.~~ We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants, and the loss of such persons could negatively impact the operations of the company. We may not be able to attract or retain qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses or any other circumstances that would cause them no longer to provide their professional services to us in the near future. If we are not able to attract and retain necessary personnel and consultants 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. In addition, we may need to adjust the size of our workforce as a result of changes to our expectations for our business, which can result in diversion of management attention, disruptions to our business, and related expenses. In addition, we previously announced a reduction in force, impacting a number of employees. Any further reduction in force may yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended reduction in force, the distraction of employees, reduced employee morale and could adversely affect our reputation as an employer, which could make it more difficult for us to hire new employees in the future and increase the risk that we may not achieve the anticipated benefits from the cost reduction program. Our industry has experienced a high rate of turnover of management personnel in recent years. Potential changes in management could be disruptive to our business and may also result in our loss of unique skills and loss of knowledge about our business. Such turnover may also result in the departure of other existing employees or partners. Replacing executive officers, key employees and consultants may be difficult and may take an extended period because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize drug candidates successfully. Competition to hire

and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel and consultants. Our failure to retain or replace key personnel or consultants could materially harm our business. Additionally, the members of our management team have limited experience managing a public company, interacting with public company investors, and complying with the increasingly complex laws, rules and regulations that specifically govern public companies, which could cause our management to have to expend time and resources helping them become familiar with such requirements. We may lose our ability to implement our business strategy successfully and could be seriously harmed. Any of our executive officers or key employees or consultants may terminate their employment at any time. We have scientific and clinical advisors and consultants who assist us in formulating our research, development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. Non- compete agreements are not permissible or are limited by law in certain jurisdictions and, even where they are permitted, these individuals typically will not enter into non- compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing drug candidates or technologies that may compete with ours. Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could significantly harm our business. We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non- U. S. regulators, provide accurate information to the FDA and non- U. S. regulators, comply with health care fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee 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. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. **Risks Related to the Development of** Our ~~insurance policies Drug Candidates The Phase 3 NEAT clinical trial of eDSP for A-~~ T ~~is being~~ **will be** conducted under a protocol negotiated with FDA by EryDel and our execution of the trial may be ~~slow~~ **delayed** ,may not be successful,and may not result in NDA approval,with adverse results for our business and share price. ~~We~~ **With the acquisition of our Phase 3 lead asset,EryDex,we intend to** ~~initiated -~~ **initiate** the Phase 3 NEAT clinical trial in the first half of 2024.The NEAT protocol is the subject of an SPA,agreement with FDA.The FDA may revoke or alter its SPA agreement under the following circumstances:• public health concerns emerge that were unrecognized at the time of the protocol assessment,or the director of the review division determines that a substantial scientific issue essential to determining safety or efficacy ~~has been~~ are expensive and ~~only protect intended use.Clinical trials are expensive and~~ can take many years to complete,and their outcomes are inherently uncertain.We cannot guarantee that any future clinical trials will be conducted as planned or completed on schedule,if at all.Failure can occur at any time during the clinical trial process.For example,on ~~January 25~~ **March 8** , ~~2022~~ **2023** ,the FDA placed a ~~full~~ **partial** clinical hold on the IND for ~~atuzaginstat (COR388)~~ **eDSP related to extractables and leachables of new components used in the treatment kit.The FDA subsequently lifted the partial clinical hold on September 23,2023** .Additionally,the Phase ~~2 /~~ 3 **ATTeST** study **conducted by EryDel** ~~with COR388 in Alzheimer' s disease~~ failed to meet the primary endpoint. ~~COR388 is one of~~ **Failure to commence or complete,or delays in,** our ~~assets that has since been out- licensed.On March 8,2023 The FDA placed~~ **planned** ~~a partial~~ clinical ~~hold on~~ **trials would prevent** us from ~~have never conducted a registrational clinical trial and have limited experience in preparing,submitting and prosecuting regulatory filings,and have not submitted an NDA or comparable foreign applications.Failure to commence or complete,or delays in,our planned clinical trials would prevent us from~~ or delay us in seeking approval for,and if approved,commercializing our drug candidates,and failure to successfully complete any of these activities in a timely manner for any of our drug candidates could have a material adverse impact on our business and financial performance.The commencement,enrollment and completion of clinical trials can be delayed or suspended for a variety of reasons,including:• inability to obtain sufficient funds required for a clinical trial;• inability to reach agreements on acceptable terms with prospective CROs and trial sites,the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;• **difficulty recruiting and enrolling patients to participate in clinical trials for a variety of reasons,including ability to find patients with a rare disease,meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indications as our drug candidates;•** clinical holds,other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;• discussions with the FDA or non- U.S.regulators regarding the scope or design of our clinical trials;• inability to identify and maintain a sufficient number of trial sites,many of which may already be engaged in other clinical trial programs,including ~~some~~ some ~~business risks~~ **that may be for the same indications targeted by our drug candidates; • inability to obtain approval from IRBs or positive ethics committee opinions to conduct a clinical trial at their respective sites; • severe or unexpected drug- related adverse effects experienced by patients** , which **have resulted and may result** in **a full or partial** clinical ~~trials~~ **hold by the FDA or non- U.S.regulators;• inability to timely manufacture sufficient quantities of the drug candidate or devices required** for a ~~variety of reasons,including ability to find patients with a rare disease,meeting the enrollment criteria for our~~

~~study and competition from other~~ clinical trial ~~programs for the same indications as our drug candidates~~ ;• inability to retain enrolled patients after a clinical trial is underway;and • enrollment may be delayed or interrupted or patients may drop out of clinical trials due to or the fear of natural disasters,such as earthquakes,tsunamis,power shortages or outages,floods,or monsoons,public health crises,such as pandemics and epidemics,political crisis,such as terrorism,war,political instability or other conflict,cyberattacks,or other events outside of our control occurring at or around our clinical trials sites in the United States or Europe.In addition,the design of a clinical trial can determine whether its results ~~will~~ will ~~leave~~ **support approval of a drug and flaws in the design of a clinical trial may not become apparent until the clinical trial is well- advanced. Changes in regulatory requirements and guidance may also occur and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require** us **to resubmit** clinical ~~hold on September 23~~ **trial protocols to IRBs or ethics committees for re- examination** , ~~2023.Additionally~~ **which may impact the costs** , **timing or successful completion of a clinical trial** ~~the Phase 3 ATTeST study conducted by EryDel failed to meet the primary endpoint~~ .Even if any future clinical trials are completed as planned,we cannot be certain that their results will support the safety and effectiveness of our potential drug candidates for their targeted indications or support continued clinical development of such drug candidates.Our ongoing and any future clinical trial results may not be successful.In addition,even if such trials are successfully completed,we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do,and more trials could be required before we submit our drug candidates for approval.Moreover,results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction.To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application,we may be required to ~~expend significant resources,which exposed~~ -- **expend** ~~to~~ significant **resources, which may** ~~uninsured liabilities. We do~~ not ~~carry insurance~~ **be available to us, to conduct additional trials in support of potential approval of our drug candidates. If we are required to conduct preclinical studies, clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete preclinical studies, clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety of efficacy concerns, we may: • be delayed in obtaining marketing approval** for **our drug candidates; • not obtain marketing approval at** all ~~categories of risk~~ **or regulatory authorities may suspend, vary or withdraw marketing approvals for approved products; • obtain approval for indications, dosages or patient populations** that **are not as broad as intended** ~~our~~ -- **or desired; • obtain approval with labeling that** ~~business may encounter. Some of the policies we currently maintain include~~ **includes** ~~general liability~~ **significant use or distribution restrictions or safety warnings** , ~~products liability and directors' and officers' insurance~~ **including boxed warnings; • be subject to additional post- marketing testing requirements; or • have the medicine removed from the market after obtaining marketing approval. Drug development costs will also increase if we experience delays in testing or in obtaining marketing approvals** . We do not know **whether any clinical trials will begin as planned** , ~~however~~ **will need to be amended or will be completed on schedule, or at all. Significant preclinical studies and clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates, could allow our competitors to bring drug candidates to market before we do, and could impair our ability to successfully commercialize our drug candidates** , if ~~we~~ **approved, any of which may harm our business and results of operations. In addition, many of the factors that cause, or lead to a delay in the commencement or completion of, clinical trials may also ultimately lead to termination or suspension of a clinical trial. Any of these occurrences may harm our business, financial condition and prospects significantly. Any termination of any clinical trial of our drug candidates** will ~~be able~~ **harm our commercial prospects and our ability** to ~~to~~ generate revenues.Our drug candidates may cause or have attributed to them undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential.Undesirable side effects caused by our drug candidates or that may be identified as related to our drug candidates by investigators conducting our clinical trials or even related to competing products in development that utilize a similar mechanism of action or act through a similar biological disease pathway could cause us or regulatory authorities to interrupt,delay,or halt clinical trials and could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims.AEs and SAEs that emerge during treatment with our drug candidates or other compounds acting through similar biological pathways may be deemed to be related to our drug candidate.This may require longer and more extensive Phase 3 clinical development,or regulatory authorities may increase the amount of data and information required to approve,market, **or** maintain ~~insurance with adequate levels of coverage~~ **our drug candidates and could result in negative labeling or a restrictive REMS or comparable foreign strategy** . ~~Any significant uninsured~~ **This may also result in an** ~~liability~~ -- **inability** ~~may require us~~ to ~~pay substantial amounts~~ **obtain approval of our drug candidates. The occurrence of any or all of these events may cause the development of our drug candidates to be delayed or terminated** , which ~~would~~ **could materially and** adversely affect our **business** ~~financial position~~ and prospects.Our drug candidates have in the past and may in the future be deemed to cause AEs and SAEs.Clinical trials of our drug candidates may not uncover all possible AEs that patients may experience.Clinical trials are conducted in representative samples of the potential patient population,which may have significant variability.By design,clinical trials are based on a limited number of subjects and are of limited duration of exposure to the product,to determine whether the drug candidate demonstrates the substantial evidence of efficacy and safety necessary to obtain regulatory approval.As with the results of **any statistical sampling, we cannot be sure that all side effects of our drug candidates may be uncovered. It may be the case that only with a significantly larger number of patients exposed to the drug candidate for a longer duration may there be a more complete safety profile be identified. Further, even larger clinical trials may not identify rare SAEs, and the duration of such studies may not be sufficient to identify when those events may occur. Other products have been approved by the regulatory authorities for which safety concerns have been uncovered following approval. Such safety concerns have led to labeling changes,**

restrictions on distribution through use of a REMS, or comparable foreign strategy, or withdrawal of products from the market, and any of our drug candidates may be subject to similar risks. Although to date we have not seen evidence of significant safety concerns with our drug candidates in the patient ~~operations~~ **populations currently undergoing clinical trials with eDSP, if approved, may be associated with previously unreported adverse reactions, and it is possible that the FDA or other regulatory authorities may ask for additional safety data as a condition of, or in connection with, our efforts to obtain approval of our drug candidates** . ~~Failure~~ **If safety problems occur or are identified after our products,if any,reach the market,we may make the decision or be required by regulatory authorities to amend the labeling of our products,recall our products,or even withdraw approval for** our products.If we are not able to successfully demonstrate a favorable differentiation between ~~EryDex~~ **eDSP** and currently available corticosteroids,our business would be harmed and our ability to generate revenue from that class of drugs would be severely impaired.Our business model is to pursue the development of off- patent drugs for which we would directly pursue the development of a red blood cell encapsulated formulation through the FDA' s 505 ~~(b) (2) regulatory pathway.In order to receive sufficient reimbursement and utilization,our drug candidates,will require showing differentiation against currently available generic products.If we are not able to differentiate EryDex from currently available corticosteroids by showing~~ (**b** ~~or perceived failure~~) **(2)** ~~to comply with health and data protection laws and regulations~~ - **regulatory** ~~could lead~~ **pathway. In order** to ~~government enforcement actions~~ **receive sufficient reimbursement and utilization** , ~~which could include civil or~~ **our** ~~criminal penalties~~ **drug candidates** , ~~private litigation, and / or adverse publicity and could negatively affect~~ **will require showing differentiation against currently available generic products. If we are not able to differentiate eDSP from currently available corticosteroids by showing a safety** ~~our~~ - **or** ~~operating results and~~ **efficacy benefit that is reflected in the approved label, our** business **would be harmed and our ability to generate revenue from that class of drugs would be severely impaired** . ~~In~~ **Because the potential rare disease target patient populations of EryDex are small, and the addressable patient population even smaller, we may not be able to effectively complete clinical trials or commercialize the drug candidate and we must be able to successfully identify patients and acquire a significant market share to achieve profitability and growth. If the market opportunities for our drug candidates are smaller than we believe** ~~the~~ **they** ~~ordinary course of~~ **are, our revenue may be adversely affected, and our** business **may suffer. eDSP is in development for rare disease. Our projections regarding** , ~~we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, " process ") personal data and other~~ -- **the** ~~sensitive information, including proprietary~~ **number of people affected by these rare** and **ultra** ~~confidential business data, trade secrets, intellectual property, sensitive third~~ - ~~party data, business plans, transactions, financial information and (collectively, " sensitive data "). As a result, we and our collaborators are~~ **rare diseases** or may become subject to various federal..... are being considered in various other states , as well as ~~at~~ the ~~federal and local levels~~ **subset who may benefit from treatment** , **are based on our beliefs** and ~~we expect more states~~ **estimates** ~~to pass similar laws in the future~~ . These ~~developments may further complicate compliance efforts~~ **estimates, derived from various sources including scientific literature, patient foundations,** and ~~increase legal risk and compliance costs~~ **market research, may prove to be incorrect or contain errors. Furthermore, new studies may change the estimated incidence or prevalence of these diseases, reducing the number of patients who might benefit from treatment. As a result, we cannot accurately predict the number of patients who could be eligible** for **treatment** ~~us and the collaborators upon whom we rely~~ . ~~In addition, we~~ **The limited size of the potentially addressable patient population** may **hinder our ability to enroll a sufficient number of participants in** ~~obtain health information from third parties (including research institutions from which we obtain~~ clinical ~~trial~~ **trials** ~~data) that are subject to privacy and security requirements under the federal HIPAA as amended by the HITECH. Depending on the facts and circumstances~~ - , **delaying** we could be subject to civil,....., risks of noncompliance and penalties for - **or preventing** ~~noncompliance. For example, the EU' s GDPR imposes numerous requirements for the collection, use and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how~~ their **successful completion** ~~personal information is used, the obligation to notify regulatory authorities and affected individuals of personal data breaches, extensive internal privacy governance obligations, and obligations to honor expanded rights of individuals in relation to their personal information (for example, the right to access, correct and delete their data)~~ . **Additionally** In addition, the GDPR generally maintains..... laws, or breached our contractual obligations , even if we **obtain** ~~are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our business. Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations. In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and~~ regulatory ~~changes and proposed changes regarding the healthcare system that could prevent or delay marketing~~ approval ~~of~~ **for EryDex or other** drug candidates, **achieving** ~~restrict or regulate post- approval activities, and affect our ability to profitably sell any drug candidates for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, including in the EU, there is~~ significant **market share** interest in promoting changes in healthcare systems..... business. Other healthcare reform measures that may ~~be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products that we successfully commercialize or to successfully commercialize our drug candidates, if approved~~ --- **prove challenging** . In addition to the PPACA,....., which began in 2013 and, due to ~~subsequent legislative amendments to the statute, will remain in effect until 2032, unless additional Congressional action is taken. New laws may result in additional reductions in Medicare and other~~ -- **the small target** ~~healthcare funding, which may adversely affect customer demand and affordability for our drug candidates and, accordingly, the results of our financial operations~~ **populations** . **This** ~~Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed drug candidates, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among~~

~~other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, in July 2021, the Biden administration released an executive order, " Promoting Competition in the American Economy, " with multiple provisions aimed at prescription drugs. In response to Biden' s executive order, on September 9, 2021, the Department of Health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, the IRA will, among other things (i) allow HHS to negotiate the price of certain high- expenditure, single- source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the " negotiated fair price " under the law and (ii) impose rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration' s October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. 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~~ **limitation** ~~from other countries and bulk purchasing. We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved drug candidate. Any reduction in reimbursement from Medicare or other government- funded 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~~ **realizing a meaningful return on our investment or achieving profitability, even with substantial market penetration. Our effort to identify patients who may benefit from our treatments is in its early stages and may become increasingly difficult over time. If we are** ~~able~~ **unable** to **locate and reach a sufficient number of patients, our ability to enroll them in clinical trials or** generate **meaningful sales upon commercialization will be adversely affected. Financial assistance programs, which provide support to patients unable to afford treatment, could also negatively impact our profitability if a significant portion of patients continues to rely on these programs upon approval of our drugs. If eDSP is approved for a narrowly defined subset of patients, such as those with A- T between six and nine years old, this could further constrain an already small potential market. As a result, our** revenue, ~~attain profitability~~ **growth prospects, and overall business could suffer if market opportunities** ~~or~~ **for** ~~commercialize~~ our drug candidates **are smaller than anticipated** ~~, once marketing approval is obtained~~ . ~~Our~~ **Additionally, if we fail to successfully identify and reach patients, our** ability to **achieve profitability** ~~successfully commercialize any drugs that we develop depends in part on the extent to which coverage~~ and **growth** ~~adequate reimbursement are available from government health administration authorities, private health insurers, and other organizations. Our ability to successfully commercialize any drugs that we develop depends in part on the extent to which coverage and adequate reimbursement are available from government health administration authorities, private health insurers, and other organizations. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, each individually decide which medications they~~ will pay for and establish reimbursement levels..... charged for medical products. We cannot be sure that coverage or reimbursement will be..... and our overall financial condition. Further **further compromised** , coverage policies and third- party..... timely and efficient development of medicinal products . Interim, top- line and preliminary data from our future clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose preliminary or top- line data from our future clinical studies, which are based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top- line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top- line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top- line data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from future clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information

we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the top- line data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our drug candidates may be harmed, which could harm our business, operating results, prospects or financial condition. Even if we obtain regulatory approval for a drug candidate, it will remain subject to extensive ongoing regulatory review and requirements. If any of our future drug candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, conduct of post- marketing studies, and submission of safety, efficacy, and other post- market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. Manufacturers and manufacturers' facilities are required to comply with extensive requirements imposed by the FDA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to ~~cGMPs~~ **GMPs** regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with ~~cGMP~~ **GMP** and adherence to commitments made in any NDA. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We also are required to register our establishments and list our products with the FDA and certain state agencies. We and any third ~~-~~party manufacturers or suppliers must continually adhere to federal regulations setting forth ~~cGMP~~ **GMP** (for drugs) and QSR (for medical devices), and their foreign equivalents, which are enforced by the FDA and other national regulatory bodies through their facilities inspection programs. In complying with ~~cGMP~~ **GMP** and foreign regulatory requirements, we and any of our third- party manufacturers or suppliers will be obligated to expend time, money and effort in production, record- keeping and quality control to ensure that our products meet applicable specifications and other requirements. QSR requirements also impose extensive testing, control and documentation requirements. State regulatory authorities and the regulatory agencies of other countries have similar requirements. In addition, we will be required to comply with regulatory requirements of the FDA, state regulatory agencies and the regulatory agencies of other countries concerning the reporting of AEs and device malfunctions, corrections and removals (e. g., recalls), promotion and advertising and general prohibitions against the manufacture and distribution of adulterated and misbranded devices. Failure to comply with these regulatory requirements could result in enforcement actions, including, but not limited to, significant civil fines, product seizures, injunctions and / or criminal prosecution of responsible individuals and us. Any such actions would have a material adverse effect on our business, financial condition and results of operations. Manufacturers and manufacturers' facilities are required to comply with extensive requirements imposed by the FDA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to ~~cGMPs~~ **GMPs** regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with ~~cGMP~~ **GMP** and adherence to commitments made in any NDA or comparable foreign application. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Any regulatory approvals that we receive for our potential drug candidates will be subject to limitations on the approved indicated uses for which the drug candidate may be marketed and promoted or to the conditions of approval (including the potential for a requirement to implement a Risk Evaluation and Mitigation Strategy) or contain requirements for potentially costly post- marketing testing. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in drug development or commercialization, or increased costs to assure compliance. The FDA and other agencies, including the Department of Justice, as well as foreign regulatory authorities closely regulate and monitor the post- approval marketing and promotion of drug candidates to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. We will have to comply with requirements concerning advertising and promotion for our potential drug candidates and any products for which we receive approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the drug candidate' s approved label. As such, we may not promote our potential drug candidates for indications or uses for which they do not have approval. In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct- to- consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product' s Summary of Product Characteristics, or SmPC, which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off- label and is prohibited in the EU. The holder of an approved NDA or equivalent foreign application must submit new or supplemental applications and obtain approval for certain changes to the approved drug candidate labeling, or manufacturing process. We could also be asked to conduct post- marketing clinical trials to verify the safety and efficacy of our potential drug candidates in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post- marketing clinical trial to confirm clinical benefit for our drug candidates. An unsuccessful post- marketing study or failure to complete such a study could result in the withdrawal of marketing approval. If a regulatory authority discovers previously unknown problems with a drug or device, such as AEs of unanticipated severity or frequency, or problems with the facility where the drug candidate is manufactured, or disagrees with the promotion, marketing or labeling of a drug candidate, including if approved,

such regulatory authority may impose restrictions on that drug candidate, an approved drug, or us, including requiring withdrawal of the approved drug from the market. If we fail to comply with applicable regulatory requirements, a regulatory authority or enforcement authority may, among other things: • issue warning or untitled letters that would result in adverse publicity; • impose civil or criminal penalties; • suspend, vary or withdraw regulatory approvals; • suspend any of our ongoing clinical trials; • mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners; • require us to enter into a consent decree or permanent injunction, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance; • refuse to approve pending applications or supplements to approved applications submitted by us; • impose restrictions on our operations, including closing our contract manufacturers' facilities; • seize or detain drug candidates or approved drugs; or • require a drug candidate or approved drugs recall. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our drug candidates. If regulatory sanctions are applied or if regulatory approval is suspended, varied or withdrawn, the value of our company and our operating results will be adversely affected. Non- compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties **. A Fast Track designation by the FDA, such as the Fast Track designations received for eDSP, does not guarantee marketing approval and may not lead to a faster development, regulatory review or approval process. In June 2024, the FDA granted Fast Track designation for our eDSP System for the treatment of patients with A- T. Fast Track designation provides opportunities for frequent interactions with FDA review staff, as well as eligibility for priority review, if relevant criteria are met, and rolling review of the sponsor' s NDA. Fast Track designation is intended to facilitate and expedite development and review of an NDA to address unmet medical needs in the treatment of serious or life- threatening conditions. However, Fast Track designation does not accelerate conduct of clinical trials or mean that the regulatory requirements are less stringent, nor does it ensure that any potential eDSP NDA will be approved or that any approval will be granted within any particular timeframe. In addition, the FDA may withdraw Fast Track designation for any indication if it believes that the designation is no longer supported by data emerging from the eDSP clinical development program** . We may be unable to obtain and retain orphan drug designations for some of our drug candidates or to maintain the benefits associated with orphan drug designation status, including market exclusivity, which may cause our revenue, if any, to be reduced. Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200, 000 in the United States, or a patient population greater than 200, 000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug in the United States will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user- fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. In the EU, the European Commission, following an opinion from the EMA' s Committee for Orphan Medicinal Products may grant orphan drug designation to promote the development of products (i) that are intended for the diagnosis, prevention, or treatment of a life- threatening or chronically debilitating conditions; (ii) either such conditions affect not more than five in 10, 000 persons in the EU community, or without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition. In the EU, orphan drug designation provides a range of potential incentives for medicinal products that have been granted an orphan designation by the European Commission, including protocol assistance, access to the centralized authorization procedure and fee reductions. If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan product exclusivity or if the FDA finds that the holder of the orphan product exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. A product may obtain orphan drug exclusivity for each indication that has been designated upon approval of the indication, subject to the qualifications above. Any orphan drug exclusivity granted for second or subsequent indications applies only to those subsequent indications and does not block approval of a product for the first indication once the initial period of exclusivity has expired. Moreover, even if one of our drug candidates receives orphan product exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. In the EU, upon grant of a marketing authorization, orphan medicinal products are entitled to a ten- year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory

review and approval process. The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application; (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products. We have received orphan drug designation by the FDA and European Commission for ~~EryDex~~ **eDSP** for the treatment of A- T. We may seek orphan drug designation in the United States, the EU and other European countries for additional orphan indications in which there is a medically plausible basis, including other rare diseases. In the future, exclusive marketing rights in the United States, if granted, may be limited if we seek approval for an indication broader than the orphan drug designated indication and may be lost if the FDA later determines that the request for the orphan drug designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we have sought or intend to seek orphan drug designation, we may never receive approval for such designations ,coverage policies and third- party payor reimbursement rates may change at any time.Therefore,even if favorable coverage and reimbursement status is attained,less favorable coverage policies and reimbursement rates may be implemented in the future.In the EU,coverage and reimbursement status of any drug candidates for which we obtain regulatory approval are provided for by the national laws of EU member states.The requirements may differ across the EU member states.The EU provides options for EU Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use.An EU Member State may approve a specific price for the medicinal product,it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market.Many EU Member States also periodically review their reimbursement procedures for medicinal products,which could have an adverse impact on reimbursement status.Moreover,in order to obtain reimbursement for our products in some European countries,including some EU Member States,we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies.This HTA of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States,including those representing the larger markets.The HTA process is the procedure to assess therapeutic,economic and societal impact of a given medicinal product in the national healthcare systems of the individual country.The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States.The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.In December 2021,Regulation No 2021 / 2282 on HTA amending Directive 2011 / 24 / EU,was adopted in the EU.This Regulation,which entered into force in January 2022 and ~~began on~~ **will apply as** of January ~~12,~~ 2025, ~~through a phased implementation.The Regulation~~ is intended to boost cooperation among EU Member States in assessing health technologies,including new medicinal products,and ~~provides~~ **providing** the basis for cooperation at EU level for joint clinical assessments in these areas.The Regulation foresees a three- year transitional period and **will** ~~permits~~ **permit** EU Member States to use common HTA tools,methodologies,and procedures across the EU,working together in four main areas,including joint clinical assessment of the innovative health technologies with the most potential impact for patients,joint scientific consultations whereby developers can seek advice from HTA authorities,identification of emerging health technologies to identify promising technologies early,and continuing voluntary cooperation in other areas.Individual EU Member States will continue to be responsible for assessing non- clinical (e.g.,economic,social,ethical) aspects of health technologies,and making decisions on pricing and reimbursement.If we are unable to maintain favorable pricing and reimbursement status in EU Member States for drug candidates that we may successfully develop and for which we may obtain regulatory approval,any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.In light of the fact that the United Kingdom has left the EU,Regulation No 2021 / 2282 on HTA will not apply in the United Kingdom.However,the UK MHRA is working with UK HTA bodies and other national organizations,such as the Scottish Medicines Consortium,the National Institute for Health and Care Excellence,and the All- Wales Medicines Strategy Group,to introduce new pathways supporting innovative approaches to the safe, **timely and efficient development of medicinal products** . If we fail to comply with healthcare laws, we could face substantial penalties and our business, operations and financial condition could be adversely affected. Our operations are subject to various federal and state fraud and abuse and other healthcare laws. The laws that may impact our operations include: • federal Anti- Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act; • federal civil and criminal false claims laws, including the False Claims Act, and civil monetary penalty laws, which impose criminal and civil penalties, including through civil " qui tam " or " whistleblower " actions, against individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other

third- party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation; • the federal HIPAA, which created new federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; • HIPAA, as amended by HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and their subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization; • the federal Physician Payment Sunshine Act, created under the PPACA, and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program to report annually to the U. S. Department of Health and Human Services under the Open Payments Program, information related to payments or other transfers of value made to physicians, (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; • federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and • analogous state and foreign laws and regulations, such as state and foreign anti- kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third- party payor, including commercial 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 government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state and foreign laws that require the registration of sales representatives; state and foreign laws that require drug manufacturers to file reports with states or foreign regulatory authorities regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; 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 may not have the same effect, thus complicating compliance efforts. Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti- bribery laws of European countries, national sunshine rules, regulations, industry self- regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities, including compensating physicians with stock or stock options, could, despite our efforts to comply, be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our drug candidates, if approved, outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above and comparable risks, among other foreign laws ~~. We are subject to substantial government regulation that is subject to change and could force us to make modifications to how we develop, manufacture, market, and price our products in the future. The medical device industry is regulated extensively by governmental authorities, principally the FDA in the U. S. and corresponding state and foreign regulatory authorities. The majority of our manufacturing processes are required to comply with quality systems regulations, including cGMP requirements that cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging and shipping of our products. Failure to comply with applicable medical device regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspensions of production, refusal of the FDA or other regulatory authorities to grant pre- market clearances or approvals for our products, withdrawals, or suspensions of future or current clearances or approvals and criminal prosecution. In addition, our products are subject to pre- clearance requirements by the FDA and similar foreign regulatory authorities that govern a wide variety of product activities from design and development to labeling, manufacturing, promotion, sales, and distribution. Compliance with these regulations may be time consuming, burdensome, and expensive for us. The failure to obtain, or the loss or suspension of any such pre- approval, would negatively affect our ability to sell our products and harm our anticipated revenues. Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we sell our products in foreign countries, we may be subject to rigorous regulation in the future. Regulatory changes could result in restrictions on our ability to~~

~~carry on or expand our operations, higher than anticipated costs or lower than anticipated revenue. The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our potential drug candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State' s decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial approved, clinical study development may proceed. The CTR foresees a three- year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials in relation to which application for approval was made on the basis of the Clinical Trials Directive before January 31, 2023, the Clinical Trials Directive will continue to apply on a transitional basis until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025. Compliance with the CTR requirements by us and our third- party service providers, such as CROs, may impact our developments plans. In light of the entry into application of the CTR on January 31, 2022, we may be required to transition clinical trials for which we have obtained regulatory approvals in accordance with the CTD to the regulatory framework of the CTR. Transition of clinical trials governed by the CTD to the CTR will be required for clinical trials which will have at least one site active in the EU on January 30, 2025. A transitioning application would need to be submitted to the competent authorities of EU Member States through the Clinical Trials Information Systems and related regulatory approval obtained to continue the clinical trial past January 30, 2025. This would require financial, technical and human resources. If we are unable to transition our clinical trials in time, the conduct of those clinical trials may be negatively impacted. It is currently unclear to what extent the UK will seek to align its regulations with the EU in the future. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency, or MHRA, launched an eight- week consultation on reframing the UK legislation for clinical trials. The UK Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation. These resulting legislative amendments will determine how closely the UK regulations will align with the CTR. Failure of the UK to closely align its regulations with the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and / or make it harder to seek a marketing authorization for the Company' s drug candidates on the basis of clinical trials conducted in the United Kingdom. In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our drug candidates in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status. 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 future marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations~~ . If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We and any contract manufacturers and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and radioactive materials. Our operations also produce hazardous waste. 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. 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. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third- party facilities. We also could incur significant costs associated with civil or criminal fines and penalties. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, drug development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. 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. We do not carry specific hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Our business activities may be subject to the FCPA and similar anti- bribery and anti- corruption laws. Our business activities may be subject to the FCPA and similar anti- bribery or anti- corruption laws,

regulations or rules of other countries in which we may operate, including the UK Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non- U. S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non- U. S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our drug candidates in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition ~~enrolled in~~ our clinical trials,patients,health care providers or others using,administering our drug candidates or selling our drug candidates,if approved.Claims could also be asserted under state consumer protection acts.If we cannot successfully defend ourselves against product liability claims,we may incur substantial liabilities or be required to limit testing and commercialization of our drug candidates.Even successful defense would require significant financial and management resources.Regardless of the merits or eventual outcome,liability claims may result in:• decreased or interrupted demand for our drug candidates;• withdrawal of clinical trial participants and inability to continue clinical trials;• initiation of investigations by regulators;• costs to defend the related litigation;• a diversion of management' s time and our resources;• substantial monetary awards to trial participants or patients;• drug recalls,withdrawals or labeling,marketing or promotional restrictions;• termination of clinical trial sites or entire trial programs;• injury to our reputation and significant negative media attention;• loss of revenue;• exhaustion of any available insurance and our capital resources;• the inability to commercialize any drug candidate,if approved;and • a decline in our share price.Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product **liability claims** . Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize potential future drug candidates. We may consider collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of drug candidates depending on the merits of retaining or divesting some or all commercialization rights. We will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time- consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so chose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us. Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that: • collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations; • collaborators may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive drug candidates, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing; • collaborators could independently develop, or develop with third parties, drug candidates that compete directly or indirectly with our drug candidates; • a collaborator with marketing, manufacturing and distribution rights to one or more drug candidates may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities; • we could grant exclusive rights to our collaborators that would prevent us from collaborating with others; • collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability; • disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future drug candidates or that results in costly litigation or arbitration that diverts management attention and resources; • collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future drug candidates; • collaborators may own or co- own intellectual property covering our drug candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and • a collaborator' s sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings. Risks Relating to Our Intellectual Property If we are unable to obtain and maintain sufficient intellectual property protection for our current drug candidates, any future drug candidates, and other proprietary technology we develop, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize drug candidates similar or identical to ours, and our ability to successfully commercialize our current drug candidate, if approved, any future drug candidates, and other proprietary technologies if approved, may be adversely affected. Our commercial success will depend in part on obtaining and maintaining a combination of patent protection, trade secret protection and confidentiality

agreements to protect the intellectual property related to our current and future drug candidates and the methods used to manufacture them, as well as successfully defending these patents against third- party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our drug candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the issued patents that we currently own, or in patents that may issue from the applications we currently or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected. Others may have filed, and in the future are likely to file, patent applications covering drug candidates that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in- licensed by us, or that we or our licensors will not be involved in interference, opposition or invalidity proceedings before U. S. or non- U. S. patent offices. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our current or future drug candidates and proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations. For example: • others may be able to make compounds that are similar to our drug candidates but that are not covered by the claims of our patents; • we might not have been the first to make the inventions covered by our pending patent applications; • we might not have been the first to file patent applications for these inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies; • any patents that we obtain may not provide us with any competitive advantages; • we may not develop additional proprietary technologies that are patentable; or • the patents of others may have an adverse effect on our business. Should any of these events occur, they would significantly harm our business, results of operations and prospects. We have applied, and we intend to continue applying, for patents covering aspects of our current drug candidates and device, any future drug candidates, any future improvements on the device or other proprietary technologies and their uses that we deem appropriate. However, we may not be able to apply for patents on certain aspects of our current or future drug candidates, proprietary technologies and their uses in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent coverage we obtain may not be sufficient to prevent substantial competition. Without patent protection on our current or future drug candidates, our ability to assert our patents to stop others from using or selling our current or future drug candidates may be limited. Due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all of our current or future drug candidates or methods involving the use of these candidates in a particular patent application. We plan to pursue divisional patent applications or continuation patent applications in the United States and other countries, where applicable, to obtain claim coverage for inventions which were disclosed but not claimed in a particular parent patent application. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our actual or potential future collaborators will be successful in protecting our current drug candidates, any future drug candidate, and other proprietary technologies and their uses by obtaining, defending, and enforcing patents. These risks and uncertainties include the following: • the U. S. Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction; • patent applications may not result in any patents being issued; • patents that may be issued or in- licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage; • our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our drug candidates; • other parties may have designed around our claims or developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same compounds, compositions of matter, or methods, or formulations, or by claiming subject matter that could dominate our patent position; • any successful opposition to any patents owned by or licensed to us could deprive us of rights necessary to prevent others from practicing our technologies or to successfully commercialize any drug candidates that we may develop; • because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our current drug candidates, any future drug candidates, and other proprietary technologies and their uses; • an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of applications we may in- license which have an effective filing date before March 16, 2013; • there may be significant pressure on the U. S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and • countries other than the United States may have patent laws less favorable to patentees than those upheld by U. S. courts, allowing foreign competitors a better opportunity to create, develop and market competing drug candidates in those countries. The patent

prosecution process is also 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. Although we enter into non- disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection for such output. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, 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 filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. We may also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or feasible. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know- how. We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court, and we may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights. Third parties, including competitors, may infringe, misappropriate or otherwise violate our patents, patents that may issue to us in the future, or the patents of our licensors that are licensed to us. To counter infringement or unauthorized use, we may need to choose to file infringement claims, which can be expensive and time- consuming. We may not be able to prevent, alone or with our licensors, infringement, misappropriation, or other violation of our intellectual property, particularly in countries where the laws may not protect those rights as fully as in the United States. If we choose to go to court to stop another party from using the inventions claimed in any patents we obtain, that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party for any number of reasons. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements for patentability, including lack of novelty, obviousness or non- enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in non- U. S. patent offices and may result in the revocation, cancellation, or amendment of any non- U. S. patents we hold in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents, or those of our licensor' s, invalid. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more drug candidates. Such a loss of patent protection would have a material adverse impact on our business. These lawsuits are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. In addition, there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the claimed inventions. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party' s activities do not infringe our rights to such patents. In addition, the U. S. Supreme Court has recently modified some tests used by the USPTO in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of challenge of any patents we obtain or license. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications, or those of our licensor' s. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non- exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our current and any future drug candidates to market. Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace. Furthermore, because of the substantial amount of discovery required in

connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their drug candidates. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor' s or potential competitor' s drug candidate. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. In addition, proceedings to enforce or defend our patents, including those of our licensor' s, could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our drug candidates are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our drug candidates, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights. If we initiate lawsuits to protect or enforce our patents, or litigate against third party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel. We may infringe the intellectual property rights of others, which may prevent or delay our drug development efforts and stop us from commercializing or increase the costs of commercializing our drug candidates. Our success will depend in part on our ability to operate without infringing the intellectual property rights of third parties. We cannot guarantee that our drug candidates, or manufacture or use of our drug candidates, will not infringe third- party patents. Furthermore, a third party may claim that we or our manufacturing or commercialization collaborators are using inventions covered by the third party' s patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our drug candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. There is a risk that a court would decide that we or our commercialization collaborators are infringing the third party' s patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our commercialization collaborators may not have a viable way around the patent and may need to halt commercialization of the relevant drug candidate. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages for having violated the other party' s patents. If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, our collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. In the future, we may agree to indemnify our collaborators against certain intellectual property infringement claims brought by third parties. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of drug candidates or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. Any claims of patent infringement asserted by third parties would be time consuming and could: • result in costly litigation; • divert the time and attention of our technical personnel and management; • cause development delays; • prevent us from out- licensing or commercializing ~~EryDex~~ **eDSP**, or our other drug candidates until the asserted patent expires or is finally held invalid, unenforceable, or not infringed in a court of law; • require us to develop non-infringing technology, which may not be possible on a cost- effective basis; • require us to pay damages to the party whose intellectual property rights we may be found to be infringing, which may include treble damages if we are found to have been willfully infringing such intellectual property; • require us to pay the attorney' s fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; and / or • require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all. If we are sued for patent infringement, we would need to demonstrate that our drug candidates or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity or unenforceability is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management' s time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity or enforceability of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non- infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid or unenforceable, we may incur substantial monetary damages, encounter significant delays in bringing our drug candidates to market and be precluded from manufacturing or selling our drug candidates. We do not routinely conduct independent reviews of pending patent applications of and patents issued to third parties. We cannot be certain that others have not filed patent applications for technology covered by our pending applications, or that we were the first to invent the technology, because: • some patent applications in the United States may be maintained in secrecy until the patents are issued; • patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived; • pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our drug candidates or the use of our drug candidates; • identification of third- party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims; • patent applications in the United States are typically not published until 18 months

after the priority date; and • publications in the scientific literature often lag behind actual discoveries. Furthermore, the scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our drug candidates. Further, we may incorrectly determine that our technologies, or drug candidates are not covered by a third- party patent or may incorrectly predict whether a third party' s pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our drug candidates. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours, and others may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our drug candidates and future approved products or impair our competitive position. Numerous third- party U. S. and foreign issued patents and pending patent applications exist in the fields in which we are developing drug candidates. There may be third- party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug candidates. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U. S. patent application on inventions similar to ours, we may have to participate in an interference proceeding 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 such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar inventions prior to our own inventions, resulting in a loss of our U. S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications, and may be entitled to priority over our applications in such jurisdictions. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, which might adversely affect our ability to develop and market our products. As the biotechnology industry expands and more patents are issued, the risk increases that our drug candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe existing or future third- party patents. Identification of third- party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our drug candidates in any jurisdiction. Numerous U. S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U. S. applications that will not be filed outside the U. S. can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third- party patent or may incorrectly predict whether a third- party' s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products. We cannot provide any assurances that third- party patents do not exist which might be enforced against our current technology, including our research programs, drug candidates, their respective methods of use, manufacture and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties, which could be significant. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patents and / or pending applications are due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and / or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm to pay these fees due to the USPTO and non- U. S. patent agencies. The USPTO and various non- U. S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms

and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. If we license intellectual property, we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business. We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers. We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and drug candidate could be significantly diminished. As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. 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. We may also be subject to claims that former employees, or other third parties have an ownership interest in our patents or other intellectual property. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, which could adversely affect our business. 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. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, and invention assignment agreements with employees, consultants and advisors, to protect our trade secrets and other proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA' s disclosure policies may change in the future, if at all. Costly and time- consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position. In addition, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer or third party with authorized access. Our security measures may not prevent an employee, consultant or customer from misappropriating our trade secrets and providing them to a competitor, and any recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our drug candidates that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time- consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions. 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, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Trade secrets could over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third- party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our drug candidates and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. In the future, we may need to obtain licenses of third- party technology that may not be available to us or are available

only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated. From time to time we may be required to license technology from third parties to further develop or commercialize our drug candidates. Should we be required to obtain licenses to any third- party technology, including any such patents required to manufacture, use or sell our drug candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third- party license required to develop or commercialize any of our drug candidates could cause us to abandon any related efforts, which could seriously harm our business and operations. Where we obtain licenses from or collaborate with third parties, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. We may also require the cooperation of our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business, in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, including making royalty and milestone payments, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license, or expiration of licensed patents or patent applications, could have a material adverse impact on our business. Our business would suffer if any such licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any exclusive licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, drug candidates identical to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor' s rights. In addition, while we cannot currently determine the amount of the royalty obligations, we would be required to pay on sales of future drug candidates, if any, the amounts may be significant. The amount of our future royalty obligations will likely depend on the technology and intellectual property we use in drug candidates that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize drug candidates, we may be unable to achieve or maintain profitability. Intellectual property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to make drug candidates that are similar to ours but that are not covered by the claims of the patents that we own; • we or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed; • we or future collaborators might not have been the first to file patent applications covering certain of our inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • it is possible that our pending patent applications will not lead to issued patents; • issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive drug candidates for sale in our major commercial markets; • we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our drug candidates; • we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable drug candidates or will provide us with any competitive advantages; • we cannot ensure that our commercial activities or drug candidates will not infringe upon the patents of others; • we cannot ensure that we will be able to successfully commercialize our drug candidates on a substantial scale, if approved, before the relevant patents that we own or license expire; • we may not develop additional proprietary technologies that are patentable; and • the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications; Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties. Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk- adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non- litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in- license needed technology or other drug candidates, or enter into development partnerships that would help us bring our drug candidates to market. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non- litigious action or solution. We may not be able to protect our intellectual property rights throughout the world. Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our drug candidates throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. As such, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing drug candidates made using our inventions in and into the United States or other jurisdictions. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the

enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing drug candidates in violation of our proprietary rights generally. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit, and in those countries, we and our licensors and licensees may have limited remedies if patents are infringed or if we or our licensors or licensees are compelled to grant a license to a third party, which could diminish the value of those patents. This could limit our potential revenue opportunities. Further, competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drug candidates and, further, may export otherwise infringing drug candidates to territories where we have patent protection but where enforcement is not as strong as that in the United States. These drug candidates may compete with our drug candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. In Europe, beginning June 1, 2023, European applications and patent may be subjected to the jurisdiction of the ~~Unified Patent Court (the "~~ UPC ~~")~~. Also, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty. As a single court system can invalidate a European patent, we, where applicable may opt out of the UPC and as such, each European patent would need to be challenged in each individual country. Geo- political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates. As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Our patent rights may be affected by developments or uncertainty in U. S. or non- U. S. patent statutes, patent case laws in USPTO rules and regulations or in the rules and regulations of non- U. S. patent offices. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs. Recent patent reform legislation in the United States and other countries, including the AIA, signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents ~~. The AIA includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost- effective avenues for competitors to challenge the validity of patents. These include allowing third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post- grant proceedings, including post- grant review, inter parties review, and derivation proceedings. After March 2013, under the AIA, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, Congress may pass patent reform legislation that is unfavorable to us~~. The U. S. Supreme Court has ruled on several patent cases in recent years, narrowing the scope of patent protection available in certain circumstances and weakening the rights of patent owners in certain situations. Depending on future actions by the U. S. Congress, the U. S. courts, the USPTO and the relevant law- making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets or other intellectual property as an inventor or co- inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our drug candidates or as a result of questions regarding co- ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and / or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Our licensors may have relied on third- party consultants or collaborators or on funds from third parties, such as the U. S. government, such that our licensors are not the sole and exclusive owners of the patents we in- licensed. If other third

parties have ownership rights or other rights to our in- licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. In addition, we may be unsuccessful in executing agreements assigning such intellectual property to us with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects. Patent terms may be inadequate to protect our competitive position on our drug candidates for an adequate amount of time, and if we do not obtain patent term extension for our drug candidates, our business may be materially harmed. Patent rights are of limited duration. In the United States, the natural expiration of a patent is generally 20 years after its first effective non- provisional filing date. In addition, although upon issuance a U. S. patent' s life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such drug candidates are commercialized. Even if patents covering our drug candidates are obtained, once the patent life has expired for a drug candidate, we may be open to competition from generic products. A patent term extension of up to five years based on regulatory delay may be available in the United States under the Hatch- Waxman Act. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single drug candidate. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the drug candidate as approved. Further, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug candidate approval and only those claims covering such approved drug candidate, a method for using it or a method for manufacturing it may be extended. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our drug candidate will be shortened and our competitors may obtain approval of competing drug candidates following our patent expiration, and our revenue could be reduced. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations. Moreover, any name we have proposed to use with our drug candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed drug candidate names, including an evaluation of potential for confusion with other drug candidate names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary drug candidate names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and / or unenforceable. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our drug candidates by obtaining and defending patents. We have pending U. S. and foreign patent applications in our portfolio; however, we cannot predict: • if and when patents may issue based on our patent applications; • the scope of protection of any

patent issuing based on our patent applications; • whether the claims of any patent issuing based on our patent applications will provide protection against competitors; • whether or not third parties will find ways to invalidate or circumvent our patent rights; • whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; • whether we will need to initiate litigation or administrative proceedings to enforce and / or defend our patent rights which will be costly whether we win or lose; • whether the patent applications that we own or in- license will result in issued patents with claims that cover our drug candidates or uses thereof in the United States or in other foreign countries; and / or • whether we may experience patent office interruption or delays to our ability to timely secure patent coverage to our drug candidates. We cannot be certain that the claims in our pending patent applications directed to our drug candidates and / or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. There can be no assurance that any such patent applications will issue as granted patents. One aspect of the determination of patentability of our inventions depends on the scope and content of the " prior art, " information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our drug candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our drug candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries. We may not be successful in obtaining or maintaining necessary rights to our drug candidates through acquisitions and in- licenses. Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in- license, or use these third- party proprietary rights. We may be unable to acquire or in- license any compositions, methods of use, processes or other third- party intellectual property rights from third parties that we identify as necessary for our drug candidates. The licensing and acquisition of third- party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third- party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third- party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third- party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or drug candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our drug candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to our drug candidates are controlled by our future licensors or collaboration partners. If any of our future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our drug candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those drug candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution. We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future drug candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our future licensors fail to prosecute, maintain, enforce, and defend such patents or patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our future drug candidates that are subject of such licensed rights could be adversely affected. Our future licensors may rely on third- party consultants or collaborators or on funds from third parties such that our future licensors are not the sole and exclusive owners of the patents we in- license. If other third parties have ownership rights to our future in- licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products **and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.** It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, drug candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected drug candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-

party patents do not exist which might be enforced against our current technology, manufacturing methods, drug candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties, which could be significant. Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • our right to sublicense patents and other rights to third parties; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; • our right to transfer or assign the license; • the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners; and • the priority of invention of patented technology. In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. In spite of our best efforts, our future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. From time to time, we may be required to license technologies relating to our therapeutic research programs from additional third parties to further develop or commercialize our drug candidates. Should we be required to obtain licenses to any third- party technology, including any such patents required to manufacture, use or sell our drug candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third- party license required to develop or commercialize any of our drug candidates could cause us to abandon any related efforts, which could seriously harm our business and operations. • collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or drug candidates; • a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities; • disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our future drug candidates or that results in costly litigation or arbitration that diverts management attention and resources; • collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current and future drug candidates; • collaborators may own or co- own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and We may encounter difficulties in managing our..... on our business and financial condition. Risks Relating to Owning Our Common Stock The market price of our common stock is likely to be volatile and could fluctuate or decline, resulting in a substantial loss of your investment. The market price of our common stock has been and may continue to be volatile and could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including: • our **ability** ~~integration efforts related~~ to **complete clinical development of eDSP, on a timely basis** ~~our~~ **or** ~~acquisition~~ **at all; • our ability to continue as a going concern, the sufficiency** of ~~EryDel~~ **our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements** ; • changes in our business strategy; • timing and results of clinical trials; • our ability to identify partnership and licensing opportunities to support the future development of ~~EryDex~~ **eDSP** ; • market opportunity for A- T and future indications; • any delays in manufacturing of drug supplies, results of preclinical studies and clinical trials for drug candidates; • regulatory actions with respect to our drug candidates or our competitors' drug candidates; • actual or anticipated fluctuations in our financial condition and operating results, including fluctuations in our quarterly and annual results; • announcement of actual or anticipated reduction in force, including our recent reduction in force; • announcements of technological innovations by us or our competitors; • overall conditions in our industry and the markets in which we operate; • addition or loss of significant customers, or other developments with respect to significant customers; • changes in laws or regulations applicable to our drug candidates **, including eDSP** ; • actual or anticipated changes in our growth rate relative to our competitors; • announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments; • additions or departures of key personnel; • competition from existing drug candidates or new drug candidates that may emerge; • issuance of new or updated research or reports by securities analysts; • ~~cash runway expectations; •~~ fluctuations in the valuation of companies perceived by investors to be comparable to us; • disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain intellectual property protection for our technologies; • announcement or expectation of additional financing efforts; • sales of our common stock by us or our stockholders; • share price and volume fluctuations attributable to inconsistent trading volume levels of our shares; • market conditions for pharmaceutical stocks in general; • **our ability to maintain compliance** ~~the expiration of contractual lock- up~~

~~agreements~~ with **Nasdaq minimum listing requirements** ~~our executive officers, directors and stockholders~~ ; • general economic and market conditions; and • ineffectiveness of our disclosure controls or internal controls. Furthermore, the stock markets have experienced price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of our common stock. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs and divert our management' s attention from other business concerns, which could seriously harm our business. We may be subject to securities class action and stockholder derivative actions. These, and potential similar or related litigation, could result in substantial damages and may divert management' s time and attention from our business and adversely impact our business, results of operations and financial condition. We may become the target of securities class actions or stockholder derivative claims. Securities- related class action litigation has often been brought against companies, including many biotechnology companies, which experience volatility in the market price of their securities. This risk is especially relevant for us because biotechnology companies often experience significant stock price volatility in connection with their product development programs. Any preclinical or clinical trial results that the investors may deem as unfavorable, volatility in our stock price and other matters affecting our business and operations may subject us to actual and threatened securities class actions or stockholder derivative claims. ~~In addition, we may be exposed to increased litigation from stockholders, customers, suppliers, consumers and other third parties due to the combination of EryDel' s and Novosteo' s business and ours following the EryDel and Novosteo Acquisitions, out- licensing of our legacy assets and NOV004.~~ These types of proceedings may result in substantial costs, divert management' s attention from other business concerns and adversely impact our business, results of operations and financial condition. Future sales of our common stock in the public market could cause our share price to fall. Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. Certain holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in Securities Act registration statements that we may file for ourselves or other stockholders. Once we register these shares, they can be freely sold in the public market. Moreover, we have also registered under the Securities Act shares of common stock that we may issue under our equity compensation plans. In addition, the issuance of shares under awards granted under existing or future employee equity benefit plans may cause immediate and substantial dilution to our existing stockholders. In the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline. **In addition, we have filed a shelf registration statement on Form S- 3, or the Shelf Registration Statement, which permits us to sell from time- to- time up to $ 200. 0 million of additional shares of our common stock or other securities in one or more offerings. In particular, we may offer and sell up to $ 75. 0 million shares of our common stock from time to time pursuant to the Controlled Equity OfferingSM Sales Agreement dated December 18, 2024, or the Sales Agreement, that we have entered into with Cantor Fitzgerald & Co. and H. C. Wainwright & Co., LLC. As of the filing date of this Annual Report, we have not sold any shares of our common stock pursuant to the Sales Agreement. Depending on market liquidity at the time, sales of our common stock pursuant to the Sales Agreement, or other sales of our common stock or other securities under the Shelf Registration Statement, may cause the trading price of our common stock to decline.** We have in the past and may in the future fail to ~~continue to~~ meet the **requirements for continued** listing **on** ~~standards of~~ Nasdaq **. If we fail to maintain compliance with the minimum listing requirements** , ~~and as a result~~ our common stock may be delisted, which could have a material adverse effect on the liquidity of our common stock. Our common stock currently trades on the Nasdaq. The Nasdaq has requirements that a company must meet in order to remain listed on Nasdaq. For example, Nasdaq ~~rules require us to maintain a minimum closing bid price of $ 1. 00 per share of our common stock. On December 4, 2023, we received a letter from the Listing Qualifications Staff, or the " Nasdaq Staff " of Nasdaq notifying us that for the last 30 consecutive business days, the bid price of our common stock had closed below $ 1. 00 per share, the minimum closing bid price required by the continued listing requirements of Nasdaq~~ Listing Rule 5450 (a) (1) **requires listed securities to maintain a minimum bid price** ~~. The notification received had no immediate effect on the listing~~ of **$ 1** ~~our common stock on the Nasdaq~~ . ~~In accordance with~~ **00 per share (the " Minimum Bid Price Requirement ") and** Nasdaq Listing Rule 5810 (c) (3) (A) **provides that a failure** ~~, we had 180 calendar days~~ to **meet** ~~regain compliance with~~ the ~~minimum~~ **Minimum** ~~bid~~ **Bid** ~~price~~ **Price** ~~requirement~~ **Requirement exists if the deficiency continues** ~~by having shares of our common stock maintain a minimum closing bid price of at least $ 1. 00 per share~~ for a ~~minimum~~ **period** of ~~10~~ **30** consecutive trading days. ~~On~~ **Additionally, in** December ~~29, 2023~~ **2022** , we received a ~~letter~~ **written notice** from the Nasdaq ~~Staff~~ **Listing Department** notifying us that **we were in noncompliance with** the ~~closing bid~~ **Minimum Bid** ~~price~~ **Price Requirement** ~~of our common stock had been at $ 1. 00 per share or greater for 10 consecutive business days, from December 11, 2023 to December 28, 2023,~~ and ~~accordingly,~~ we ~~had~~ regained compliance ~~with~~ **in April 2023. In December 2023, we again received a written notice from the** Nasdaq Listing ~~Rule 5450 (~~ **Department notifying us that we were in noncompliance with the Minimum Bid Price Requirement and regained compliance later in December 2023. In June 2024, we again received** a ~~) (1)~~ **written notice from the Nasdaq Listing Department notifying us that we were in noncompliance with the Minimum Bid Price Requirement and regained compliance later in November 2024** . There can be no assurance that we will continue to meet the ~~minimum~~ **Minimum** ~~bid~~ **Bid** ~~price~~ **Price** ~~requirement~~ **Requirement** , or any other Nasdaq requirements, in the future. **Furthermore** ~~In addition~~ , we may **also** be unable to meet other applicable Nasdaq listing requirements, including maintaining minimum levels of stockholders'

equity or market values of our common stock, in which case our common stock could be delisted. If our common stock were to be delisted, the liquidity of our common stock would be adversely affected, and the market price of our common stock could decrease. We have never paid dividends on our common stock and we do not intend to pay dividends for the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases. We have never declared or paid any dividends on our common stock and do not intend to pay any dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the operation of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments . Our stockholders may realize little or no value from the divestiture of our legacy assets,and as a result our stock price may decline,we could be subject to litigation,and our business may be adversely affected.We have sold our legacy small molecule protease inhibitor portfolio to Lighthouse,which is a newly organized,private development stage company in the start- up phase,and has only recently commenced its operations.There is currently no existing public market for the shares of Lighthouse' s common stock,and there can be no assurance that an active public market will ever develop.The absence of an active public market for these securities would make it difficult for us to sell the shares of Lighthouse' s common stock and realize any value from them.To date,Lighthouse' s operations have been primarily limited to organizing and staffing its company and completing the acquisition of our legacy assets.Accordingly,it is difficult if not impossible to predict Lighthouse' s future performance or to evaluate its business and prospects,or ability to develop our legacy assets.For these and other reasons,our stockholders may realize little or no value from the divestiture of our legacy assets.The divestiture of our legacy assets or previously announced change in our corporate strategy,including the termination of the license for NOV004,could result in litigation against us,including litigation arising from or related to the value,received in the sale of our legacy assets to Lighthouse.For example,some of our investors purchased shares of our common stock because they were interested in the opportunities presented by our small molecule protease inhibitor portfolio,others because they were interested in our bone- targeting drug platform.Thus,certain stockholders may have attributed substantial financial value to our legacy assets or NOV004.If our stockholders believe that the financial value which is or may be received by us or them from the divestiture of our assets is inadequate,our stock price may decline and litigation may occur.As a result of these and other factors,we may be exposed to a number of risks,including declines or fluctuations in our stock price,additional legal fees,and distractions to our management caused by activities undertaken in connection with resolving any disputes related to these transactions.The occurrence of any one or more of the above could have an adverse impact on our business and financial condition ~~.~~. General Risk Factors Our charter documents and Delaware law could prevent a takeover that stockholders consider favorable and could also reduce the market price of our stock. Our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it more difficult for stockholders to elect directors and take other corporate actions. These provisions include: • providing for a classified board of directors with staggered, three- year terms; • authorizing our board of directors to issue preferred stock with voting or other rights or preferences that could discourage a takeover attempt or delay changes in control; • prohibiting cumulative voting in the election of directors; • providing that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; • prohibiting the adoption, amendment or repeal of our amended and restated bylaws or the repeal of the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors without the required approval of at least 66. 67 % of the shares entitled to vote at an election of directors; • prohibiting stockholder action by written consent; • limiting the persons who may call special meetings of stockholders; and • requiring advance notification of stockholder nominations and proposals. These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, the provisions of Section 203 of the Delaware General Corporate Law, or the DGCL, govern us. These provisions may prohibit large stockholders, in particular those owning 15 % or more of our outstanding voting stock, from merging or combining with us for a certain period of time without the consent of our board of directors ~~. In addition, in April 2023, we implemented the Rights Agreement, also called a " poison pill, " that may have the effect of discouraging or preventing a change of control by, among other things, making it uneconomical for a third party to gain control of us through open market accumulation of shares without paying all stockholders an appropriate control premium or without the consent of our board of directors. The Rights will expire on April 5, 2024, unless the Rights are earlier redeemed or exchanged by the Company~~ . These and other provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and under Delaware law could discourage potential takeover attempts, reduce the price investors might be willing to pay in the future for shares of our common stock and result in the market price of our common stock being lower than it would be without these provisions. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' abilities to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that, unless we consent to the selection of an alternative forum, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for: • any derivative action or proceeding brought on our behalf; • any action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any of our directors, officers, employees or agents or our stockholders; • any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; and • any action asserting a claim against us that is governed by the internal- affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State

of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation also provides that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act. We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi- forum litigation. However, these provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees. While the Delaware Supreme Court recently determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring such a claim arising under the Securities Act against us, our directors, officers, or other employees in a venue other than in the federal district courts of the United States of America. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation, and this may require significant additional costs associated with resolving such action in other jurisdictions. Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third- party claims against us and may reduce the amount of money available to us. Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that: • we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person' s conduct was unlawful; • we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law; • we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification; • we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification; • the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and • we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents. ~~Our~~ **If our** internal ~~computer~~ **information** systems, ~~or~~ those **of** ~~used by our~~ third ~~- party research institution collaborators~~ **parties with whom we work** , ~~CROs~~ **or** ~~or~~ **our** ~~other contractors~~ **data are** or ~~consultants~~ **were compromised** , **we** ~~may fail or suffer security breaches, which~~ could **experience** ~~result in~~ adverse consequences including, but not limited to, regulatory investigations or actions, litigation, fines / penalties, disruptions of our business operations, reputational harm, and loss of revenue or profits. In the ordinary course of our business, we and the third parties upon which we rely process sensitive data, and, as a result, we and the third parties upon which we rely face a variety of evolving threats that could cause security incidents. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer " hackers, " " hacktivists, " individual threat actors, organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation- state- supported actors. Despite the implementation of security measures designed to detect and mitigate vulnerabilities, our internal ~~computer~~ **information** systems and those of **third parties with whom we work (such as** our CROs and other contractors and consultants ~~may be~~ **) are** vulnerable to damage from sources including, but not limited to, malicious code (e. g., computer viruses), malware, ransomware attacks, **social engineering attacks,** software or hardware failures **or bugs** , telecommunications failures **, data loss** , and unauthorized access (including as a result of personnel misconduct or error). In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Additionally, remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network. ~~Although~~ **It is difficult and costly** to ~~our knowledge~~ **detect, investigate, mitigate, contain and remediate security incidents. Our efforts to do so may not be successful. For example,** we have ~~not experienced any~~ **been the target of unsuccessful phishing attempts in the past, and expect** such **attempts will continue in the future. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.** ~~material~~ **Material information** system ~~failure~~ **failures** or security ~~breach~~ **breaches** ~~to date, if such an~~ **can** ~~event were to occur and~~ cause interruptions in our operations **which** ~~, it~~ could result in a material disruption of our development programs and our business operations, as well as adverse consequences including, but not limited to, investigations, fines / penalties, litigation, and reputational harm **, as well as triggering data breach notification obligations. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences** . For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on our third- party research institution collaborators for research and development of our drug candidates and other third parties for the manufacture of our drug candidates and to conduct clinical trials, and similar events relating to their computer systems could

also have a material adverse effect on our business. Our reliance on third- party service providers could also introduce new ~~cyber security~~ **cybersecurity** risks and vulnerabilities, such as supply- chain attacks. To the extent that any disruption or security breach **has in past or** were **in the future** to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our drug candidates could be delayed **. Additionally, future or past business transactions could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies** . We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, **or** that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. Our ability to utilize our federal net operating loss and tax credit carryforwards may be limited. Our net operating loss, or NOL, carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U. S. tax law. NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 taxable years under applicable U. S. federal tax law. Moreover, under the Tax Act as modified by the CARES Act, federal NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs may be limited to 80 % of taxable income for tax years beginning January 1, 2018 **. NOLs generated in Italy are subject to Italian tax laws and deductibility of such Italian NOLs may be limited to 80 % of taxable income** . Under Sections 382 and 383 of the Internal Revenue Code, limitations on a corporation' s ability to use its NOLs and tax credit carryforwards apply if a corporation undergoes an " ownership change, " which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three- year period. If we have experienced an ownership change at any time since our incorporation, we may already be subject to limitations on our ability to utilize our existing NOL carryforwards and other tax attributes to offset taxable income or tax liability. In addition, future changes in our stock ownership, which may be outside of our control, may trigger an ownership change. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. As a result, even if we earn net taxable income in the future, our ability to use our pre- change NOL carryforwards and other tax attributes to offset such taxable income or tax liability may be subject to limitations, which could potentially result in increased future income tax liability to us.