Risk Factors Comparison 2024-02-28 to 2023-03-15 Form: 10-K

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

● **Risks Related to the Marketing of Approved Products •** Our success depends on the successful commercialization of our products. To the extent that our drug products are not commercially successful, our business, financial condition and results of operations will be materially harmed. ● • Our drug products may fail to receive the degree of market acceptance by physicians, patients, third- party ~~payers~~ **payors** or others in the medical community necessary for commercial success, which would negatively impact our business. ● • Our strategy of seeking to acquire or in- license innovative technical platforms or earlier stage drug development programs outside of the neuromuscular disease space may not be successful. ● • Our business may require additional capital. • ~~● The ongoing COVID- 19 pandemic and the worldwide attempts to contain it could harm our business and results of operations and financial condition and we could be adversely impacted by it.~~ ● Because the target patient ~~population~~ **populations** for FIRDAPSE ® ~~is~~ **and AGAMREE ® are** small, we must achieve significant market share and obtain relatively high per- patient prices for our products to achieve meaningful gross margins. ● • Because of risks associated with taking FYCOMPA ®, potential patients may be reluctant to start treatment with FYCOMPA ® or may discontinue use. Risks Related to the Development of Additional Drug Products and Indications ● • Failure can occur at any stage of our drug development efforts. ● • We rely on third parties to conduct our pre- clinical studies and clinical studies and trials, and if they do not perform their obligations to us we may not be able to obtain approval for additional indications. ● • We will need to continue to develop and maintain distribution and production capabilities or relationships to be successful. ● • We could be impacted by the viability of our suppliers. ● • We may encounter difficulties in managing our growth, which would adversely affect our results of operations. ● • Pressure on drug product third- party payor coverage, reimbursement and pricing may impair our ability to be reimbursed at prices or on terms sufficient to provide a viable financial outcome. ● • Our internal computer systems, or those of our contract research organizations and other key vendors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs. • ~~32~~ ● Our employees, sales agents and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. Risks Related to Government Regulation ● • The regulatory approval process is lengthy, and we may not be able to obtain all of the regulatory approvals required to manufacture and commercialize our drug products in which we are licensed to them. ● • If our pre- clinical studies or our clinical studies and trials are unsuccessful or significantly delayed, our ability to commercialize our products will be impaired. ● • We may face significant delays in our clinical studies and trials due to an inability to recruit patients for our clinical studies and trials or to retain patients in the clinical studies and trials we may perform. ● • If our third- party suppliers or contract manufacturers do not maintain appropriate standards of manufacturing in accordance with cGMP and other manufacturing regulations, our development and commercialization activities could suffer significant interruptions or delays. ● • Our drug products are subject to continuing regulatory review. If we fail to comply with continuing United States and applicable foreign regulations, we could lose those approvals, and our business would be severely harmed. ● • Enacted and future legislation or judicial action may increase the difficulty and cost for us to market our approved products or commercialize any other drug candidates we may acquire or license and affect the prices we may obtain. ● ~~35~~ **•** If we fail to obtain or subsequently maintain orphan drug exclusivity or regulatory exclusivity for FIRDAPSE ® and any other orphan drug candidates we may acquire or license, our competitors may sell products to treat the same conditions at greatly reduced prices, and our revenues would be significantly adversely affected. ● • Changes to the **ODA** ~~Orphan Drug Act~~ or successful legal challenges to the FDA' s interpretation of the **ODA** ~~Orphan Drug Act~~ may affect our ability to obtain or subsequently maintain orphan drug exclusivity or may affect the scope orphan drug exclusivity for our products. ● • Our operations and relationships with healthcare providers, healthcare organizations, customers and third- party payors are subject to applicable anti- bribery, anti- kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings. Risks Related to our Intellectual Property ● • If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets. ● • **Whether we will be successful in our litigation to enforce our patents against Paragraph IV challengers who have filed relating to FIRDAPSE ® and FYCOMPA ®. •** There is a risk that our patents may not protect our products from generic competition. ● • Our success will depend significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. ● • We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights. There are also general risk factors relating to us that you should consider that relate to our business and to our common stock. Risk Factors Our business involves a high degree of risk. You should carefully consider the risks and uncertainties described below, and all of the other information contained in this Form 10- K in assessing the risks relating to ownership of our common stock. The risks described below could cause our business, results of operations, financial condition and prospects to materially suffer and the market price of our stock to decline. Risks related to Our Business Our success depends on the successful commercialization of our products. To the extent that our drug products are not commercially successful, our business, financial condition and results of operations will be materially harmed. We received approval for FIRDAPSE ® for the treatment of Lambert- Eaton Myasthenic Syndrome (LEMS) from the FDA in November 2018 **;** ~~, and~~ in January 2023, we completed our acquisition of FYCOMPA ® for the treatment of (i) partial- onset seizures with or without ~~33~~ secondary generalized seizures in people with epilepsy four years of age and older, and (ii) for the treatment of primary generalized tonic- clonic seizures in people with epilepsy twelve years of age

and older from Eisai **; and in October 2023, we received approval for AGAMREE ® for the treatment of Duchenne Muscular Dystrophy (DMD)** . We invest a significant amount of effort and financial resources in the commercialization of these drug products in the U. S. ~~, and, in the case of FIRDAPSE ®, Canada.~~ The ability for us to generate net product revenues from our drug products will depend on the size of the markets, the numbers of competitors in such markets and numerous other factors, including: • successfully establishing and maintaining effective sales, marketing, and distribution systems in jurisdictions in which our drug products are approved for sale; • successfully establishing and maintaining commercial third- party manufacturers and having adequate commercial quantities of our drug products manufactured at acceptable cost and quality levels, including maintaining current good manufacturing practice (~~“~~cGMP ~~”~~) and quality systems regulation standards required by various regulatory agencies; • broad acceptance of our drug products by physicians, patients and the healthcare community; • the acceptance of pricing and placement of our drug products on ~~payers~~ **payors** ’ formularies and the associated tiers; • **36 •** effectively competing with other approved or used medicines and future compounds in development; • continued demonstration of safety and efficacy of our drug products in comparison to competing products; and • obtaining, maintaining, enforcing, and defending intellectual property rights and claims. Our drug products may fail to receive the degree of market acceptance by physicians, patients, third- party ~~payers~~ **payors** or others in the medical community necessary for commercial success, which would negatively impact our business. Our drug products may fail to gain sufficient market acceptance by physicians, patients, third- party ~~payers~~ **payors** , or others in the medical community. If any of our drug products do not achieve an adequate level of acceptance, we may not generate significant net product revenue or become profitable. The degree of market acceptance of our drug products is dependent on a number of factors, including but not limited to: • the efficacy and potential advantages compared to alternative treatments, including the convenience and ease, or duration of administration; • the prevalence and severity of any side effects; • the acceptability of the price of our drug products relative to other treatments; • the content of the approved product labels and our ability to make compelling product claims; • the effectiveness and adequacy of our and our collaboration partner’ s sales and marketing efforts; • the patients’ out- of- pocket costs in relation to alternative treatments; • the breadth and cost of distribution support; • the effectiveness of our patient assistance and support programs; • the availability of third- party ~~payer~~ **payor** coverage and adequate reimbursement; and • any restrictions on the use of our drug products together with other medications. Our business is subject to substantial competition. The biotechnology and pharmaceutical industries are highly competitive. Many of our competitors have substantially greater financial and other resources, larger research and development staffs and more experience developing products, obtaining FDA and other regulatory approvals of products and manufacturing and marketing products than we have. We compete against pharmaceutical companies that are developing or currently marketing therapies that will compete with us. In addition, we compete against biotechnology companies, universities, government agencies, and other research institutions in the development of pharmaceutical products. Our business could be negatively impacted if our competitors’ present or future offerings are more effective, safer or less expensive than ours, or more readily accepted by regulators, healthcare providers or third- party payors. Further, we may also compete with respect to manufacturing efficiency and marketing capabilities. For all of these reasons, we may not be able to compete successfully. Our strategy of seeking to acquire or in- license innovative technical platforms or earlier stage drug development programs outside of the neuromuscular disease space may not be successful. ~~34~~ We continue to seek to broaden and diversify our product portfolio through acquisitions of both early and late- stage products or companies or technology platforms in rare disease therapeutic categories outside of neuromuscular diseases. To accomplish these new priorities, we are employing a disciplined approach to evaluating assets and we believe that this strategic expansion will better position our company to build out a broader more diversified portfolio of drug candidates, which should add greater value to our company over the near and long- term. However, there can be no assurance that whatever product candidates or technology platforms we acquire, if any, will be successfully developed or commercialized. The process of proposing, negotiating and implementing a license or acquisition of a product candidate is lengthy and complex, and we may be unable to in- license or acquire the rights to any such products, product candidates or technologies from third parties for several reasons. Further, even if we identify acquisition or in- licensing targets, we may not be able to close those deals or we may determine after diligence not to pursue identified targets. The success of this strategy depends partly upon our ability to identify, select and acquire or in- license promising product candidates and technologies. **37** In addition, acquisitions and in- licenses may entail numerous operational, financial and legal risks, including: • exposure to known and unknown liabilities, including possible intellectual property infringement claims, violations of laws, tax liabilities and commercial disputes; • incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions; • higher than expected acquisition and integration costs; • difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel; • inability to maintain uniform standards, controls, procedures and policies; • restructuring charges related to eliminating redundancies or disposing of assets as part of any such combination; • large write- offs and difficulties in assessing the relative percentages of in- process research and development expense that can be immediately written off as compared to the amount that must be amortized over the appropriate life of the asset; • increased amortization expenses or, in the event that we write down the value of acquired assets, impairment losses; • potential failure of the due diligence process to identify significant problems, liabilities or other shortcomings or challenges of an acquired or licensed product candidate or technology, including problems, liabilities or other shortcomings or challenges with respect to intellectual property, product quality, revenue recognition or other accounting practices, partner disputes or issues and other legal and financial contingencies and known and unknown liabilities; and • entry into therapeutic modalities, indications or markets in which we have no or limited direct prior development or commercial experience and where competitors in such markets have stronger market positions. ~~The ongoing COVID- 19 pandemic and the worldwide attempts to contain it could harm our business and results of operations and financial condition and we could be adversely impacted by it. The COVID- 19 pandemic has had an impact on our business operations, and we continue to monitor applicable government modifications. We had to make modifications to our normal operations at~~

~~various points in time during the pandemic, including requiring our employees to work remotely. At present, our operations have returned mostly to being in- person, with some contact with doctors by our commercial sales force still being done remotely. Notwithstanding, the COVID- 19 pandemic, including the emergence of new COVID- 19 variants, including the delta and omicron variants, has in the past and may in the future affect the health and availability of our workforce as well as those of third parties whom we are relying upon to take similar measures. As a result, we have previously and may in the future experience disruptions to our business operations due to the COVID- 19 pandemic, and our business could be materially adversely affected by such disruptions, directly or indirectly. National, state and local governments in affected regions have implemented and may continue to implement varying safety precautions, such as quarantines, border closures, increased border controls, travel restrictions, shelter- in- place orders and shutdowns, business closures, cancellations of public gatherings and other measures. Organizations and individuals may continue to take additional steps to avoid infection, including limiting travel and staying home from work. These measures may continue to disrupt normal business operations both inside and outside of affected areas and have had significant impacts on healthcare and businesses worldwide. We cannot assess the impact on our business of the public concerns expressed by a vocal group of neuromuscular physicians and patients about the pricing of our product. We are also aware that the vocal group of neuromuscular physicians and a number of LEMS patients who have raised these issues in the past are continuing to raise concerns with the pricing of our product and with the appropriateness of the provisions in the Orphan Drug Act that grant us exclusivity for FIRDAPSE ®. A few of these patients continue to say negative things about us to the media, to other patients, to the FDA, and to politicians. We cannot assess the impact of these activities on our business. 35~~ Because the target patient population for ~~FIRDAPSE ® is~~ **several of our products are** small, we must achieve significant market share and obtain relatively high per- patient prices for ~~our~~ **those** products to achieve meaningful gross margins. ~~FIRDAPSE ®~~ **Our products** ~~targets~~ **target** ~~a disease~~ **diseases** with a small patient population. A key component of the successful commercialization of a drug product for these indications includes identification of patients and a targeted prescriber base for the drug product. Due to small patient populations, we believe that we would need to have significant market penetration to achieve meaningful revenues and identifying patients and targeting the prescriber base are key to achieving significant market penetration. Typically, drugs for conditions with small prevalence have higher prices in order to generate a return on investment, and as a result, the per- patient prices at which we sell ~~FIRDAPSE ®~~ **our products** are relatively high in order for us to generate an appropriate return for the investment in these product development programs and achieve meaningful gross margins, and **, in the case of FIRDAPSE ®,** high per patient prices could drive physicians to seek out compounding pharmacies to provide compounded amifampridine to fill their prescriptions rather than FIRDAPSE ®, thereby lowering the FIRDAPSE ® market share or penetration in the market. There can be no assurance that we will be successful in achieving a sufficient degree of market penetration and / or obtaining or maintaining high per- patient prices for FIRDAPSE ® for diseases with small patient populations. Further, even if we obtain significant market share for FIRDAPSE ®, because the potential target populations are very small, we may not be able to maintain profitability despite obtaining such significant market share. Additionally, patients who discontinue therapy or do not fill prescriptions are not easily replaced by new patients, given the limited patient population. Because of risks associated with taking FYCOMPA ®, potential patients may be reluctant to start treatment with FYCOMPA ® or may discontinue use. FYCOMPA **®** ' s ~~®~~ labeling has a boxed warning noting that some people taking the drug have undergone serious psychiatric and behavioral changes. These events occurred in people who had no history of such issues, as well as people who had such a history. The psychiatric changes included mood changes like euphoric mood, anger, irritability, aggression, belligerence, agitation, and anxiety, as well as psychosis (acute psychosis, hallucinations, delusions, paranoia) and delirium (delirium, confusional state, disorientation, memory impairment). Behavioral changes included physical assault and homicidal ideation and / or threats. While these side effects are rare, their existence may cause reluctance on the part of patients or providers to start or continue treatment. Other serious side effects include suicidal thoughts or behavior (like all anti- epileptic drugs), dizziness and gait disturbance, somnolence and fatigue, risk of falls, and increased risk of seizures if the drug is quickly withdrawn. In clinical trials, dizziness, somnolence, vertigo, aggression, anger, loss of coordination, blurred vision, irritability, and slurred speech were the side effects that most commonly led people to leave the trial. Use of FYCOMPA ® is also contraindicated in women who are pregnant or breastfeeding. **38** Risks Related to the Development of Drug Products Failure can occur at any stage of our drug development efforts. We will only obtain regulatory approval to commercialize our future drug candidates if we can demonstrate to the satisfaction of the FDA (or the equivalent foreign regulatory authorities) in adequate and well- controlled clinical studies and trials that the drug is safe and effective for its intended use, that the clinical and other benefits outweigh the safety risks and that it otherwise meets approval requirements. As we have experienced in the past, a failure of one or more pre- clinical or clinical trials or studies can occur at any stage of drug development. We may experience numerous unforeseen events during, or as a result of, testing that could delay or prevent us from obtaining regulatory approval for, or commercializing our drug candidates, including but not limited to: ~~•~~ regulators or Institutional Review Boards (IRBs) may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site; ~~•~~ conditions may be imposed upon us by the FDA regarding the scope or design of our clinical trials, or we may be required to resubmit our clinical trial protocols to IRBs for review due to changes in the regulatory environment; ~~•~~ the number of subjects required for our clinical trials may be larger, patient enrollment may take longer, or patients may drop out of our clinical trials at a higher rate than we anticipate; ~~•~~ we may have to suspend or terminate one or more of our clinical trials if we, regulators, or IRBs determine that the participants are being subjected to unreasonable health risks; ~~•~~ our third- party contractors, clinical investigators or contractual collaborators may fail to comply with regulatory requirements or fail to meet their contractual obligations to us in a timely manner; ~~•~~ the FDA may not accept clinical data from trials that are conducted at clinical sites in countries where the standard of care is potentially different from the United States; ~~•~~ our tests may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional testing; and ~~• 36 •~~ the costs of our pre- clinical and / or clinical trials may be greater than we anticipate. We rely on third parties to conduct our pre-

clinical studies and clinical studies and trials, and if they do not perform their obligations to us we may not be able to obtain approval for additional indications. We do not currently have the ability to independently conduct pre- clinical studies or clinical studies and trials, and we typically rely on third parties, such as third- party contract research and governmental organizations, medical institutions and clinical investigators (including academic clinical investigators), to conduct studies and trials for us. Our reliance on third parties for development activities reduces our control over these activities. These third parties may not complete activities on schedule or may not conduct our pre- clinical studies and our clinical studies and trials in accordance with regulatory requirements or our study design. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be adversely affected, and our efforts to obtain regulatory approvals for and commercialize our product candidates may be delayed. If we conduct studies with other parties, we may not have control over all decisions associated with that trial. To the extent that we disagree with the other party on such issues as study design, study timing and the like, it could adversely affect our drug development plans. Although we also rely on third parties to manage the data from our studies and trials, we are responsible for confirming that each of our studies and trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies will require us to comply with applicable regulations and standards, including Good Laboratory Practice (GLP) and Good Clinical Practice (GCP), for conducting, recording and reporting the results of such studies and trials to assure that the data and the results are credible and accurate and that the human study and trial participants are adequately protected. Our reliance on third- parties does not relieve us of these obligations and requirements, and we may fail to obtain regulatory approval for any additional indications if these requirements are not met. **39** We will need to continue to develop and maintain distribution and production capabilities or relationships to be successful. We are licensed in Florida as a virtual drug manufacturer, which means we have no in- house manufacturing capacity and we will be obligated to rely on contract manufacturers and packagers. We cannot be sure that we will successfully manufacture any product, either independently or under manufacturing arrangements, if any, with third **-** party manufacturers. Moreover, if any manufacturer should cease doing business with us or experience delays, shortages of supply or excessive demands on their capacity, we may not be able to obtain adequate quantities of product in a timely manner, or at all. Manufacturers, and in certain situations their suppliers, are required to comply with current NDA commitments and current good manufacturing practices (cGMP) requirements enforced by the FDA, and similar requirements of other countries. The failure by a manufacturer to comply with these requirements could affect its ability to provide us with product. Although we intend to rely on third- party contract manufacturers, we are ultimately responsible for ensuring that our products are manufactured in accordance with cGMP. In addition, if, during a preapproval inspection or other inspection of our third- party manufacturers' facility or facilities, the FDA determines that the facility is not in compliance with cGMP, any of our marketing applications that lists such facility as a manufacturer may not be approved or approval may be delayed until the facility comes into compliance with cGMP and completes a successful re- inspection by the FDA. Any manufacturing problem, natural disaster, or epidemic, affecting manufacturing facilities, or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we will be reliant on third parties to supply the raw materials needed to manufacture our products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to future contract manufacture caused by problems at suppliers could delay shipment of products, increase our cost of **sales** ~~goods sold~~ and result in lost sales. If our suppliers were to be unable to supply us with adequate supply of our drugs, it could have a material adverse effect on our ability to successfully commercialize our drug candidates. We could be impacted by the viability of our suppliers. We source ~~our products~~ **FIRDAPSE ®** from more than one supplier, and we have entered into contracts with our suppliers that contractually obligate them to meet our requirements. However, if our suppliers cannot or will not meet our requirements (for whatever reason), our business could be adversely impacted. We **are dependent on our licensing partners for supplies of FYCOMPA ® and AGAMREE ® Through our agreements with Eisai for FYCOMPA ® and Santhera for AGAMREE ®, we have agreed to purchase our supplies of each product through such companies. If either company were unable to supply sufficient supplies of drug product, our business would be adversely impacted, whether we would be required to work with these companies to resume supplies or whether we would be required to search for a sufficient third- party supplier. We** may encounter difficulties in managing our growth, which would adversely affect our results of operations. To manage future growth, we will likely need to hire, train, and manage additional employees. Concurrent with expanding our operational and marketing capabilities, we will also need to increase our product development activities. We may not be able to support, financially or otherwise, future growth, or hire, train, motivate, and manage the required personnel. Our failure to manage growth effectively could limit our ability to achieve our goals. ~~37~~ Our success in managing our growth will depend in part on the ability of our executive officers to continue to implement and improve our operational, management, information and financial control systems, and to expand, train and manage our employee base, and particularly to expand, train and manage a specially-trained sales force to market our products. We may not be able to attract and retain personnel on acceptable terms given the intense competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. Our inability to manage growth effectively could cause our operating costs to grow at a faster pace than we currently anticipate and could have a material adverse effect on our business, financial condition, results of operations and prospects. Pressure on drug product third- party payor coverage, reimbursement and pricing may impair our ability to be reimbursed at prices or on terms sufficient to provide a viable financial outcome. The commercial success of our drug products will depend substantially on the extent to which the cost of those products will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities (such as Medicare and Medicaid), private health coverage insurers and other third- party payors. **In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services (CMS). CMS decides whether and to what extent our products will be covered and reimbursed under**

Medicare and private payors tend to follow CMS to a substantial degree. If reimbursement is not available, or is available only to limited levels, we may not be able to continue to successfully commercialize our products. Even if coverage is provided, the approved reimbursement amount may not be high enough to establish and maintain pricing sufficient to realize a meaningful return on our investment. **40** The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell our product candidates profitably. These payors may not view our products as cost- effective, and coverage and reimbursement may not be available to our customers, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. **There have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. For example, in December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including an alternative rebate calculation for line extensions that is tied to the price increases of the original drug, and Best Price reporting related to certain value- based purchasing arrangements. Additionally, under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs on a unit of drug is eliminated. Elimination of this cap may, in some cases, require pharmaceutical manufacturers to pay more in rebates than they receive on the sale of products. Additionally, the Budget Control Act which, subject to certain temporary suspension periods, imposed 2 % reductions in Medicare payments to providers per fiscal year starting April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031, unless additional Congressional action is taken. Healthcare reforms that have been adopted, and that may be adopted in the future, could result in further reductions in coverage and levels of reimbursement for pharmaceutical products, increases in rebates payable under U. S. government rebate programs and additional downward pressure on pharmaceutical product prices. These** ~~Cost~~ **cost** - control initiatives could cause us to decrease the price we might establish for products, which could result in lower than anticipated product revenues. If the prices for our products decrease or if governmental and other third- party payors do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer. There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the drug and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services. In addition, increasingly, third- party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government- funded and private payors for any of our product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. The pricing of pharmaceutical products, in general, and of specialty drugs, in particular, has been a topic of concern in the United States Congress, where hearings have been held on the topic, and several bills have been introduced proposing a variety of actions to restrain the prices of drugs. **Several** ~~Healthcare~~ **healthcare** reform proposals recently culminated in the enactment of the ~~Inflation Reduction Act (~~IRA ~~)~~, which will eliminate, beginning in 2025, the coverage gap under Medicare Part D by significantly lowering the enrollee maximum out- of- pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10 % of Part D enrollees' prescription costs for brand drugs below the out- of- pocket maximum, and 20 % once the out- of- pocket maximum has been reached. The IRA ~~will~~ also ~~allow~~ **allows** ~~the Department of Health and Human Services (~~HHS ~~)~~ to **directly** negotiate the selling price of ~~certain~~ **a statutorily specified number of** drugs and biologics **each year** that ~~Centers for Medicare & Medicaid Services (~~CMS ~~)~~ reimburses under Medicare Part B and Part D **.** ~~(excluding drugs and biologics that are designated and approved for only~~ **Only** ~~one rare disease or condition), although only~~ high- expenditure single- source drugs that have been approved for at least 7 years (11 years for **single- source** biologics) ~~can~~ **are eligible to** be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. ~~The~~ **Negotiations for Medicare Part D products take place in 2024 with the** negotiated **price taking effect in 2026, and negotiations for Medicare Part B products will begin in 2026 with the negotiated price taking effect in 2028. In August 2023, HHS announced the ten Medicare Part D drugs and biologics that it selected for negotiations. HHS will announce the negotiated maximum fair** prices **by September 1, 2024, and this price cap** , which **cannot exceed** ~~will first become effective in 2026, will be capped at~~ a statutory ceiling price ~~. Beginning in October~~ **, will go into effect on January 1,** ~~2022~~ **2026 . A drug or biological product that has an orphan drug designation** for **only one rare disease or condition will be excluded from the IRA' s price negotiation requirements, but will lose that exclusion if it receives designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The IRA also imposes rebates on** Medicare Part D and ~~January 2023 for Medicare Part B, the IRA will also penalize drug manufacturers that increase prices of Medicare Part D and~~ Part B drugs **whose prices have increased** at a rate greater than the rate of inflation. **Manufacturers that fail to comply with the IRA may be subject to various penalties, including significant civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions may be subject to legal challenges. For example, the provisions**

related to the negotiation of selling prices of high- expenditure single- source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the biopharmaceutical industry and the pricing of our products and product candidates. It is unclear to what extent other statutory, regulatory, and administrative initiatives will be enacted and implemented in the future and to what extent these or any future legislation or regulations will have on our business, including market acceptance, and sales, of our products and product candidates. **41** We cannot predict how any such laws or regulations, or new laws or regulations that have yet to be proposed, will affect the pricing of our product, of orphan drugs generally, or of pharmaceutical products generally. ~~38~~ **At the state level in the United States, legislatures are increasingly enacting laws and implementing regulations designed to control pharmaceutical and biologic product pricing, including price constraints, restrictions on certain product access, reporting on price increases and the introduction of high- cost drugs. In some states, laws have been enacted to encourage importation of lower cost drugs from other countries and bulk purchasing. For example, the FDA released a final rule in September 2020 providing guidance for states to build and submit importation plans for drugs from Canada, and FDA authorized the first such plan in Florida in January 2024. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drug products that we successfully commercialize or put pressure on our product pricing. Legally mandated price controls on payment amounts by third- party payors or other restrictions on coverage or access could have a material adverse effect on our business, operations and financial condition.** Our internal computer systems, or those of our contract research organizations and other key vendors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs. Our internal computer systems and those of our contract research organizations and other key vendors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our drug candidates could be delayed. Our employees, sales agents and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of fraud or other misconduct by our employees, sales agents or consultants. Misconduct could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. 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 such 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 be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. Risks Related to Government Regulation The regulatory approval process is lengthy, and we may not be able to obtain all of the regulatory approvals required to manufacture and commercialize our drug products in which we are licensed to them. We will not be able to commercialize our products in other countries or for additional indications until we have obtained the requisite regulatory approvals from applicable governmental authorities. To obtain regulatory approval of a drug candidate for an indication, we must demonstrate to the satisfaction of the applicable regulatory agency that such drug candidate is safe and effective for that indication. The type and magnitude of the testing required for regulatory approval varies depending on the drug candidate and the disease or condition for which it is being developed. In addition, in the United States we must show that the facilities used to manufacture our drug candidates are in compliance with cGMP requirements. We will also have to meet similar regulations in any foreign country where we may seek to commercialize our drug candidates. In general, these requirements mandate that manufacturers follow elaborate design, testing, control, documentation, and other quality assurance procedures throughout the entire manufacturing process. The process of obtaining regulatory approvals typically takes several years and requires the expenditure of substantial capital and other resources. Despite the time, expense and resources invested by us in the approval process, we may not be able to demonstrate that our drug candidate is safe and effective for such indications, in which event we would not receive the regulatory approval required to market it. **42** If our pre- clinical studies or our clinical studies and trials are unsuccessful or significantly delayed, our ability to commercialize our products will be impaired. Before we can obtain future regulatory approval for the sale of our drug candidates for an indication, we may have to conduct, at our own expense, pre- clinical tests in animals in order to support the safety of our drug candidates. Pre- clinical testing is expensive, difficult to design and implement, can take several years to complete, and is uncertain as to outcome. Our pre- clinical tests may produce negative or inconclusive results, and on the basis of such results, we may decide, or regulators may require us, to halt ongoing clinical trials or conduct additional pre- clinical testing. In other countries where FIRDAPSE ® **, FYCOMPA ®, AGAMREE ®,** or any other product we may acquire or license may be marketed, we will also be subject to regulatory requirements governing human clinical studies, trials and marketing approval for drugs. The requirements governing

the conduct of clinical studies, trials, product licensing, pricing and reimbursement varies widely from country to country. ~~39~~ We may face significant delays in our clinical studies and trials due to an inability to recruit patients for our clinical studies and trials or to retain patients in the clinical studies and trials we may perform. We may encounter difficulties in our current and future clinical studies and trials recruiting patients, particularly since the conditions we are studying are rare, orphan conditions. The availability of approved therapies can also make enrollment difficult. We compete for study and trial subjects with others conducting clinical trials testing other treatments for the indications we are studying for our drug candidates. Further, unrelated third parties and investigators in the academic community have in the past and we expect will continue in the future to test our drug products and / or drug candidates. If these third- party tests are unsuccessful, or if they show significant health risk to the test subjects, our development efforts may also be adversely affected. Clinical trials in orphan diseases are often difficult to enroll given the small number of patients with these diseases. Completion of orphan clinical trials may take considerably more time than other trials, sometimes years, depending on factors such as type, complexity, novelty and intended use of a product candidate. As a result of the uncertainties described above, there can be no assurance that we will meet timelines that we establish for any of our clinical trials. If our third- party suppliers or contract manufacturers do not maintain appropriate standards of manufacturing in accordance with cGMP and other manufacturing regulations, our development and commercialization activities could suffer significant interruptions or delays. We rely, and intend to continue to rely, on third- party suppliers and contract manufacturers to provide us with materials for our clinical trials and commercial- scale production of our products. These suppliers and manufacturers must continuously adhere to cGMP **, DEA, and state regulations for controlled substances,** as well as any applicable corresponding manufacturing regulations outside of the United States. In complying with these regulations, we and our third- party suppliers and contract manufacturers must expend significant time, money and effort in the areas of design and development, testing, production, record- keeping, and quality control to assure that our products meet applicable specifications and other regulatory requirements. Failure to comply with these requirements could result in an enforcement action against us, including warning letters, the seizure of products, suspension or withdrawal of approvals, shutting down of production, and criminal prosecution. Any of these third- party suppliers or contract manufacturers will also be subject to inspections by the FDA **, DEA, state** and other regulatory agencies. If any of our third- party suppliers or contract manufacturers fail to comply with cGMP or other applicable manufacturing regulations **and requirements related to registration, security, recordkeeping and reporting of controlled substances** , our ability to develop ~~and~~ **,** commercialize **, manufacture and distribute** our products could suffer significant interruptions and delays. Reliance on third- party manufacturers entails risks to which we would not be subject if we manufactured the product ourselves, including: ~~•~~ reliance on the third **-** party for regulatory compliance and quality assurance; ~~•~~ reliance on the continued financial viability of the third parties; ~~•~~ limitations on supply availability resulting from capacity and scheduling constraints of the third parties; ~~•~~ impact on our reputation in the marketplace if manufacturers of our products fail to meet the demands of our customers; ~~•~~ the possible breach of the manufacturing agreement by the third **-** party because of factors beyond our control; and ~~•~~ the possible termination or nonrenewal of the agreement by the third **-** party, based on its own business priorities, at a time that is costly or inconvenient for us. **43** If any of our contract manufacturers fail to achieve and maintain appropriate manufacturing standards, patients using our products could be injured or die, resulting in product liability claims. Even absent patient injury, we may be subject to product recalls, product seizures or withdrawals, delays or failures in testing or delivery, cost overruns, or other problems that could seriously harm our business or profitability. Our drug products are subject to continuing regulatory review. If we fail to comply with continuing United States and applicable foreign regulations, we could lose those approvals, and our business would be severely harmed. We are and will continue to be subject to continuing regulatory review for our approved products, including the review of our required nonclinical and clinical post- marketing studies, and other clinical results which are reported after our drug candidates become commercially available approved drugs. As greater numbers of patients use a drug following its approval, side effects and other problems may be observed after approval that were not seen or anticipated during preapproval clinical studies and trials. In addition, the manufacturer, and the manufacturing facilities we use to make any approved drugs, will also be subject to periodic review and inspection by the FDA. The subsequent discovery of previously unknown problems with the drug, manufacturer or facility may result in restrictions on the drug, manufacturer or facility, including withdrawal of the drug from the market. If we fail to comply with applicable continuing regulatory requirements, we may be subject to fines, suspension, or withdrawal of regulatory approval, product recalls and seizures, operating restrictions, and criminal prosecutions. ~~40~~ Our product promotion and advertising are also subject to regulatory requirements and continuing regulatory review. In particular, the marketing claims we will be permitted to make in labeling or advertising regarding our marketed products will be limited by the terms and conditions of the FDA- approved labeling and available scientific data. We must submit copies of our advertisements and promotional labeling to the FDA at the time of initial publication or dissemination. If the FDA believes these materials or statements promote our products for unapproved indications, or with unsubstantiated claims, or if we fail to provide appropriate safety related information, the FDA could allege that our promotional activities misbrand our products. Specifically, the FDA could issue an untitled letter or warning letter, which may demand, among other things, that we cease such promotional activities and issue corrective advertisements and labeling to all recipients of the misbranded materials. The FDA also could take enforcement action including seizure of allegedly misbranded product, injunction, or criminal prosecution against us and our officers or employees. If we repeatedly or deliberately fail to submit such advertisements and labeling to the agency, the FDA could withdraw our approvals. Moreover, the Department of Justice can bring civil or criminal actions against companies and executives that promote drugs or biologics for unapproved uses, based on the FDCA, the False Claims Act, and other federal laws governing the marketing and reimbursement for such products under federally supported healthcare programs such as Medicare and Medicaid. Monetary penalties in such cases have often been substantial, and civil penalties can include costly mandatory compliance programs and potential exclusion of a company' s products from federal healthcare programs. Enacted and future legislation or judicial action may increase the difficulty and cost

for us to commercialize FIRDAPSE ® or any other drug candidates we may acquire or license and affect the prices we may obtain. In the United States, there have been a number of court cases, legislative and regulatory changes, and other potential changes relating to the healthcare system that restrict or regulate post- approval activities, which may affect our ability to profitably sell FIRDAPSE ® or any other drug candidates for which we obtain marketing approval. Legislative and regulatory proposals have been made to expand post- approval requirements, restrict sales and promotional activities for pharmaceutical products, and with respect to orphan drug designation and exclusivity. In addition, increased scrutiny by the United States Congress of the FDA' s approval process may subject us to more stringent product labeling and post- marketing testing and other requirements. Delays in feedback from the FDA may affect our ability to quickly update or adjust **the conditions of use reflected in** our label ~~in the interest of patient adherence and tolerability~~ . We cannot predict whether other legislative changes will be adopted or how such changes would affect the pharmaceutical industry generally and specifically the commercialization of FIRDAPSE ® and any other products we develop. If we fail to obtain or subsequently maintain orphan drug exclusivity or regulatory exclusivity for FIRDAPSE ® and any other orphan drug candidates we may acquire or in- license, our competitors may sell products to treat the same conditions at greatly reduced prices, and our revenues would be significantly adversely affected. 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. The company that first obtains FDA approval for a designated orphan drug for a given rare disease receives marketing exclusivity for use of that drug for the stated disease or condition for a period of seven years, with an additional six months of exclusivity if the product also qualifies for pediatric exclusivity. Orphan drug exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective, a subsequent product is deemed clinically superior, or if the manufacturer is unable to deliver sufficient quantity of the drug. Because the extent and scope of patent protection for some of our drug products may be particularly limited, orphan drug designation – and ultimately, orphan drug exclusivity – is especially important for our products that are eligible for orphan drug designation. For eligible drugs, we plan to rely on the orphan exclusivity period to maintain a competitive position. However, if we do not obtain orphan drug exclusivity for our drug candidates or we cannot maintain orphan exclusivity for our drug candidates, our competitors may then sell the same drug to treat the same condition and our revenues will be reduced. Also, without strong patent protection, competitors may sell a generic version upon the expiration of orphan exclusivity if our patent position is not upheld. **44** Even if we obtain orphan drug designation for our future drug candidates, we may not fulfill the criteria for exclusivity or we may not be the first to obtain marketing approval for any orphan indication. Further, even if we obtain orphan drug exclusivity for a particular product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition, and FDA can approve the same drug for a different patient population. Even after an orphan drug is approved, the FDA can subsequently approve a drug for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. The FDA can discontinue orphan drug exclusivity after it has been granted if the orphan drug cannot be manufactured in sufficient quantities to meet demand. Finally, there can be no assurance that the exclusivity provisions currently in the law may not be changed in the future and the impact of any such changes (if made) on us. The orphan drug exclusivity contained in the **ODA** ~~Orphan Drug Act~~ has been the subject of recent scrutiny from the press, from some members of Congress and from some in the medical community. There can be no assurance that the ~~41~~ exclusivity granted in the **ODA** ~~Orphan Drug Act~~ to orphan drugs approved by the FDA will not be modified in the future, and as to how any such change might affect our products, if approved. Changes to the **ODA** ~~Orphan Drug Act~~ or successful legal challenges to the FDA' s interpretation of the **ODA** ~~Orphan Drug Act~~ may affect our ability to obtain or subsequently maintain orphan drug exclusivity or affect the scope of orphan drug exclusivity for our products. There can be no assurance that the designation and / or exclusivity provisions currently in the law may not be changed in the future and the impact of any such changes (if made) on us. For example, the United States Congress could pass, and the President could sign, legislation to effectively overturn the decision of the U. S. Court of Appeals for the 11th Circuit overturning the FDA' s approval of RUZURGI ®, and such legislation, if passed and signed into law, could retroactively affect the outcome of the 11th Circuit **decision** . Notwithstanding, since we now hold the U. S. rights to RUZURGI ®, these legislative efforts will have no effect on our FIRDAPSE ® business. In that regard, in January 2023, the FDA reported that while it is complying with the 11th Circuit decision in Catalyst' s favor with respect to FIRDAPSE ®, going forward the FDA intends to continue to apply its regulations tying the scope of orphan drug exclusivity to the uses or indications for which a drug is approved with respect to other orphan drugs. We will not be affected by the FDA' s newly announced position, as the FDA' s announcement confirms the FDA' s previous decision to set aside the approval of RUZURGI ® as a result of the 11th Circuit' s decision. The orphan drug exclusivity contained in the **ODA** ~~Orphan Drug Act~~ has been the subject of recent scrutiny from the press, from some members of Congress and from some in the medical community. Furthermore, the FDA' s interpretations of the **ODA** ~~Orphan Drug Act~~ have been successfully challenged in court and future court decisions could continue that trend. There can be no assurance that the exclusivity granted in the **ODA** ~~Orphan Drug Act~~ to orphan drugs approved by the FDA will not be modified in the future, and as to how any such change might affect our products, if approved. Our operations and relationships with healthcare providers, healthcare organizations, customers and third- party payors are subject to applicable anti- bribery, anti- kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings. Our current and future arrangements with healthcare providers, healthcare organizations, third- party payors, customers, and patients expose us to broadly applicable anti- bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our drug candidates. In addition, we may be subject to patient data privacy and security regulation by the U. S. federal government and the states and the foreign governments in which we conduct our business. Restrictions under applicable federal and state anti- bribery and healthcare laws and regulations

include the following: • the Federal health care program Anti- Kickback Statute, which prohibits individuals and entities from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal and state healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • 45 • the federal criminal and civil false claims and civil monetary penalties laws, including the federal False Claims Act, which can be imposed through civil whistleblower or qui tam actions against individuals or entities, prohibits, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off- label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act; • HIPAA, which imposes criminal and civil liability, prohibits, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • HIPAA, as amended by HITECH, which impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect 42 to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information; • the federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children' s Health Insurance Program, with certain exceptions, to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, certain types of advanced care practice nurses and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members, with the information made publicly available on a searchable website; • the U. S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U. S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers; and • certain state and local laws that, among other things, require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; require drug and therapeutic biologics manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures; require manufacturers to report price increases that exceed a statutory threshold, as well as information on the reasons for the price increase; require manufacturers to report the introduction into the market of costly drugs; require the registration of pharmaceutical sales representatives; and govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. If we or our collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our products successfully and could harm our reputation and lead to reduced acceptance of our products by the market. These enforcement actions include, not only civil and criminal penalties, but also exclusion from participation in government- funded healthcare programs, and exclusion from eligibility for the award of government contracts for our products. Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm, any of which could adversely affect our financial results. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management' s attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources. 46 Risks Related to Our Intellectual Property If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets. We rely upon a combination of

patents, trademarks, trade secret protection, and confidentiality agreements to protect the intellectual property related to our drug development programs, products, and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the U. S. and other countries with respect to our drug candidates. We seek to protect our proprietary position by filing patent applications in the U. S. and abroad related to our development programs and product candidates. The patent prosecution process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The patent applications that we own or have licensed may fail to result in issued patents with claims that protect our drug products in the U. S. or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent 43 applications has been found, which can prevent a patent from issuing from a pending patent application or be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover our drug products, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. If the patent applications we hold or have in- licensed with respect to our development programs, products, and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current or any future drug products or candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize future drugs. Any such outcome could have a materially adverse effect on our business. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been and will continue to be the subject of litigation and new legislation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U. S. For example, many countries restrict the patentability of methods of treatment of the human body. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the U. S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result of these and other factors, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the U. S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. Moreover, we may be subject to a third- party pre- issuance submission of prior art to the U. S. Patent and Trademark Office (the " USPTO ") or become involved in opposition, derivation, reexamination, inter partes review, post- grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of defending our patents or enforcing our proprietary rights in post- issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the U. S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Generally, issued patents are granted a term of 20 years from the earliest claimed non- provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application (patent term adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension), or both. The scope of patent protection may also be limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. 47 Our success will depend significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the U. S., involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation, and administrative law proceedings, inter partes review, and post- grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our products, product candidates or other business activities may be subject to claims of infringement of the patent and 44 other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization. Also, there may be third- party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to

the use or manufacture of our products or product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our products or product candidates may infringe. In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes upon rights. If any third- party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our products or product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such products or product candidates unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third- party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable products or product candidates unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know- how and inventions. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our products or product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our products or product candidates, and we may do so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our products or product candidates, which could harm our business significantly. We cannot provide any assurances that third- party patents do not exist which might be enforced against our products or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties. We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights. Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third **-** party may also cause the third **-** party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the U. S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, enablement, written description, or patentable subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. **48** Third parties may also raise similar validity claims before the USPTO in post-grant proceedings, such as ex parte reexaminations, inter partes review, or post- grant review, or oppositions or similar proceedings outside the U. S., in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third **-** party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our products, or current or future product candidates. Such a loss of patent protection could harm our business. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the U. S. Our business could be harmed if in litigation the prevailing party does ~~45~~ not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees. 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 an adverse effect on the price of our common shares **. Risks associated with our pending Paragraph IV litigation As noted throughout this report, we are presently litigating several Paragraph IV challenges relating to two of our products, FIRDAPSE ® and FYCOMPA ®. If we are not successful in our litigation to enforce our patents against these Paragraph IV challengers, it could have a material adverse effect on our business and financial condition** . General Risk Factors Our business may require additional capital. We may need to raise additional capital in the future in order to fund our business (particularly to fund potential company or product acquisitions that are intended to expand our product offerings). If necessary, we would likely raise additional funds in the future through public or private equity offerings, debt financings,

corporate collaborations, or other means. We may also seek governmental grants to support our clinical and pre- clinical trials. However, there is no assurance that any such funding will be available, and, even if it is available, whether it will be available on terms that are favorable to us. We may also seek to raise additional capital to fund additional product development efforts, even if we have sufficient funds for our planned operations. Any sale by us of additional equity or debt securities convertible into additional equity could result in dilution to our stockholders. Further, to the extent that we raise funds through collaborative arrangements, it may be necessary to relinquish some rights to our technologies or grant sublicenses on terms that are not favorable to us. If we are not able to secure funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs, which could have an adverse effect on our business. The obligations incident to being a public company place significant demands on our management. As a public reporting company, we are required to comply with the Sarbanes- Oxley Act of 2002 and the related rules and regulations of the SEC, including periodic reports, disclosures and more complex accounting rules. As directed by Section 404 of the Sarbanes- Oxley Act, the SEC adopted rules requiring public companies to include a report of management on a company' s internal control over financial reporting in their Annual Report on Form 10- K. Based on current rules, we are required to annually report under Section 404 (a) of the Sarbanes- Oxley Act regarding our management' s assessment as to the effectiveness of our internal control over financial reporting. Further, under Section 404 (b) of the Sarbanes- Oxley Act, our auditors are required to report on their assessment as to the effectiveness of our internal control over financial reporting. If we or our auditors are unable to conclude that we have effective internal control over our financial reporting, investors could lose confidence in the reliability of our consolidated financial statements, which could result in a decrease in the value of our common stock. **49** Our business and operations could suffer in the event of system failures or security or data breaches due to cyber- attacks, or cyber intrusions, including ransomware, phishing attacks and other malicious intrusions. In recent years, cybersecurity threats have become a greater risk and focus for companies. In particular, ransomware attacks, where a hacker locks and threatens to delete or disclose the victim' s data unless a ransom is paid, has become a major risk. We and our third- party service providers are at risk of cyber- attacks or cyber intrusions via the Internet, computer viruses, break- ins, malware, ransomware, phishing attacks, hacking, denial- of- service attacks or other attacks and similar disruptions from the unauthorized use of, or access to, computer systems (including from internal and external sources). These types of incidents continue to be prevalent and pervasive across industries, including in our industry. In addition, we expect information security risks to continue to increase due to the proliferation of new technologies and the increased sophistication and activities of organized crime, hackers, terrorists and other external parties, including foreign state actors. We are increasingly dependent on information technology **(IT)** systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, process, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such information. The size and complexity of our **IT** ~~information technology~~ systems, and those of third- party vendors with whom we contract, and the volume of data we retain, make such systems potentially vulnerable to breakdown, malicious intrusion, security breaches, ransomware, phishing, and other cyber- attacks. Our information security systems and those of our third- party vendors are subject to laws and regulations, or may become subject to new laws and regulations, requiring that we enact certain measures to protect the privacy and security of certain information we collect or use in our business. A security breach or privacy violation that leads to disclosure or modification of, or prevents access to, personal information or other protected information, whether caused by internal or external parties, could harm our reputation, compel us to comply with federal and / or state breach notification laws and foreign law equivalents, subject us to notification requirements under certain agreements with third parties, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability ~~46~~ under laws and regulations that protect personal information, resulting in increased costs or loss of revenue. Similarly, the loss or unauthorized disclosure of clinical trial data from completed, ongoing or planned clinical trials could prevent us from obtaining regulatory approval or delay our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer negative impact to our reputation, financial loss and be subject to regulatory fines and penalties. In addition, breaches and other unauthorized data access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Moreover, the reliance on remote working technologies by our employees and third- party partners due to COVID- 19 and related public health safety measures and the prevalent use of mobile devices that access confidential and personal information increases the risk of data security breaches, which could lead to the loss of confidential information, personal information, trade secrets or other intellectual property. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities. While we have implemented security measures to protect our data security and **IT** ~~information technology~~ systems, such measures may not prevent such events. Significant disruptions of our **IT** ~~information technology~~ systems or breaches of data security could have a material adverse effect on our business, financial condition and results of operations. We are highly dependent on our small number of key personnel and advisors. We are highly dependent on our executive officers and key employees, and on our Board of Directors. The loss of the services of one or more of these individuals could significantly impede the achievement of our scientific and business objectives. **We** ~~Other than an employment agreement with Patrick J. McEnany, our Chairman, President and Chief Executive Officer with respect to his services, we~~ have no employment or retention agreements with any of our other officers or key employees. If we lose the services of any of our existing executive officers or key employees, or if we were unable to recruit qualified replacements on a timely basis for persons who leave our employ, our efforts to develop our drug candidates might be significantly delayed. We do not carry key- man insurance on any of our personnel. We face a risk of product liability claims and may not be able to obtain adequate insurance. Our business exposes us to potential liability risks that

may arise from the clinical testing, manufacture, and / or sale of our pharmaceutical products. Patients have received substantial damage awards in some jurisdictions against pharmaceutical companies based on claims for injuries allegedly caused by the use of pharmaceutical products used in clinical trials or after FDA approval. Liability claims may be expensive to defend and may result in large judgments against us. We currently carry liability insurance that we believe to be adequate. Our insurance may not reimburse us for certain claims or the coverage may not be sufficient to cover claims made against us. We cannot predict all of the possible harms or side effects that may result from the use of our current drug candidates, or any potential future products we may acquire and use in clinical trials or after FDA approval and, therefore, the amount of insurance coverage we currently hold may not be adequate to cover all liabilities we might incur. If we are sued for any injury allegedly caused by our products, our liability could exceed our ability to pay the liability. Whether or not we are ultimately successful in any adverse litigation, such litigation could consume substantial amounts of our financial and managerial resources, all of which could have a material adverse effect on our business, financial condition, results of operations, prospects and stock price. **50** Business or economic disruptions or global health concerns could seriously harm our development efforts and increase our costs and expenses. Broad- based business or economic disruptions could adversely affect our ongoing or planned research and development activities. Global health concerns, such as the COVID- 19 pandemic, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the suppliers, clinical trial sites, regulators and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. It is also possible that global health concerns such as the COVID- 19 pandemic could disproportionately impact the hospitals and clinical sites in which we conduct any of our clinical trials, which could have a material adverse effect on our business and our results of operation and financial condition. The trading price of the shares of our common stock has been and could in the future be highly volatile. The market price of our common stock has fluctuated in the past and is likely to fluctuate in the future. Market prices for biopharmaceutical companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include: • developments concerning our clinical studies and trials and our pre- clinical studies; ~~• 47 •~~ status of regulatory requirements for approval of our drug candidates; • adverse publicity regarding the pricing our drug products; • announcements of product development successes and failures by us or our competitors; • new products introduced or announced by us or our competitors; • adverse changes in the abilities of our third- party manufacturers to provide drug or product in a timely manner or to meet FDA requirements; • challenges to our intellectual property which could affect our products, such as the currently pending litigation involving Paragraph IV challenges to FIRDAPSE ® **and FYCOMPA ®** ; • changes in reimbursement levels; • changes in financial estimates by securities analysts; • actual or unanticipated variations in operating results; • changes in laws regarding FDA approval; • expiration or termination of licenses (particularly our **FIRDAPSE ®** License Agreement ~~for FIRDAPSE ®~~), research contracts, or other collaboration agreements; • conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries; • intellectual property, product liability or other litigation against us; • changes in the market valuations of similar companies; • changes in pharmaceutical company regulations or reimbursements for pharmaceutical products as a result of healthcare reform or other legislation; • changes in economic conditions; and • sales of shares of our common stock, particularly sales by our officers, directors and significant stockholders, or the perception that such sales may occur. **51** In addition, equity markets in general, and the market for emerging pharmaceutical and life sciences companies in particular, have experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. Further, changes in economic conditions in the United States, Europe, or globally could impact our ability to grow profitably. Adverse economic changes are outside our control and may result in material adverse impacts on our business or financial results. These broad market and industry factors may materially affect the market price of our shares, regardless of our own development and operating performance. In the past, following periods of volatility in the market price of a company' s securities, securities class- action litigation has often been instituted against that company. Any such litigation that we become involved in could cause us to incur substantial costs and divert our management' s attention and resources, which could have a material adverse effect on our business, financial condition, and results of operations. Delaware law and our certificate of incorporation and by- laws contain provisions that could delay and discourage takeover attempts that stockholders may consider favorable. Certain provisions of our certificate of incorporation and by- laws, and applicable provisions of Delaware corporate law, may make it more difficult for or prevent a third - party from acquiring control of us or changing our Board of Directors and management. These provisions include: • the ability of our Board of Directors to issue preferred stock with voting or other rights or preferences; • limitations on the ability of stockholders to amend our charter documents, including stockholder supermajority voting requirements; • the inability of stockholders to act by written consent or to call special meetings; • requirements that special meetings of our stockholders may only be called by the Board of Directors; and • advance notice procedures our stockholders must comply with in order to nominate candidates for election to our Board of Directors or to place stockholders' proposals on the agenda for consideration at meetings of stockholders. In addition, Section 203 of the Delaware General Corporation Law generally prohibits us from engaging in a business combination with any person who owns 15 % or more of our common stock for a period of three years from the date such person acquired such common stock, unless Board or stockholder approval is obtained. These provisions could make it difficult for a third - party to acquire us, or for members of our Board of Directors to be replaced, even if doing so would be beneficial to our stockholders. ~~48~~ Any delay or prevention of a change of control transaction or changes in our Board of Directors or management could deter potential acquirers or prevent the completion of a transaction in which our stockholders could receive a substantial premium over the then current market price for their shares. Future sales of our common stock may cause our stock price to decline. As of ~~March 15~~ **February 26** , ~~2023~~ **2024** , we had ~~105~~ **117** , ~~654~~ **863** , ~~395~~ **258** shares of our

common stock outstanding, of which ~~6~~ **7** , ~~301~~ **296** , ~~895~~ **124** shares were held by our executive officers and directors **. This includes the 10 million shares of our common stock that we sold in a public offering that closed on January 9, 2024** . We also had outstanding: (i) stock options to purchase an aggregate of ~~12~~ **14** , ~~348~~ **414** , ~~580~~ **654** shares at exercise prices ranging from $ ~~0~~ **2** . ~~79~~ **11** to $ ~~21~~ **19** . **02** ~~05 per share~~ (~~8~~ **9** , ~~723~~ **025** , ~~519~~ **987** of which are currently exercisable); and (ii) restricted stock units for ~~594~~ **622** , ~~337~~ **816** shares of common stock (none of which are currently vested). Sales of shares, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. We do not intend to pay cash dividends on our common stock in the foreseeable future. We have never declared or paid any cash dividends on our common stock or other securities, and we currently do not anticipate paying any cash dividends in the foreseeable future. Accordingly, investors should not invest in our common stock if they require dividend income. Our stockholders will not realize a return on their investment unless the trading price of our common stock appreciates, which is uncertain and unpredictable. **We may fail to meet our publicly announced guidance or other expectations about our business and future operating results, which would cause our stock price to decline. We release earnings guidance from time to time in our quarterly and annual earnings releases, or otherwise, regarding our future performance that represents our management' s estimates as of the date of release. This guidance includes forward- looking statements based on projections prepared by our management. Projections are based upon a number of assumptions and estimates that, while presented with numerical specificity, are inherently subject to significant business, economic and competitive uncertainties and contingencies on our business, many of which are beyond our control and are based upon specific assumptions with respect to future business decisions, some of which will change. For example, in light of our acquisition of an exclusive license for North America for vamorolone in July 2023, you are cautioned not to place undue reliance on any guidance issued prior to such acquisition. 52 The principal reason that we release guidance is to provide a basis for our management to discuss our business outlook with analysts and investors. Furthermore, analysts and investors may develop and publish their own projections of our business, which may form a consensus about our future performance. Our actual business results may vary significantly from such guidance or that consensus due to a number of factors, many of which are outside of our control. Furthermore, if we make downward revisions of our previously announced guidance, if we withdraw our previously announced guidance, or if our publicly announced guidance of future operating results fails to meet expectations of securities analysts, investors or other interested parties, the price of our common stock would likely decline. Guidance is necessarily speculative in nature, and it can be expected that some or all of the assumptions underlying the guidance furnished by us will not materialize or will vary significantly from actual results. Accordingly, our guidance is only an estimate of what management believes is realizable as of the date of release. Actual results may vary from our guidance, and the variations may be material. In light of the foregoing, investors are urged not to rely upon our guidance in making an investment decision regarding our common stock. Any failure to successfully implement our operating strategy or the occurrence of any of the events or circumstances set forth under the header " Item 1A – Risk Factors " from our filings with the SEC could result in the actual operating results being different from our guidance, and the differences may be adverse and material.** Item 1B. Unresolved Staff Comments None. Item ~~2~~ **1C** . ~~Properties~~ **Cybersecurity Risk management and strategy** We ~~currently operate~~ **recognize the critical importance of developing, implementing, and maintaining robust cybersecurity measures to safeguard our information systems and protect the confidentiality, integrity, and availability of our data. Managing Material Risks & Integrated Overall Risk Management We have integrated cybersecurity risk management into our broader risk management framework to promote a company- wide culture of cybersecurity risk management. This integration ensures that cybersecurity considerations are a part of our decision- making processes at every level. Our risk management team works closely with our Information Technology (IT) team including our IT and cybersecurity vendors to continuously evaluate and address cybersecurity risks in alignment with** our business ~~in 10, 700 square feet~~ **objectives and operational needs. Engage Third- parties on Risk Management Recognizing the complexity and evolving nature** of **cybersecurity threats** ~~leased office space in Coral Gables~~ , ~~Florida~~ **we engage with a range of external experts in evaluating and testing our risk management systems. These partnerships enable us to leverage specialized knowledge and insights, ensuring our cybersecurity strategies and processes remain at the forefront of industry best practices** . Our **collaboration with** ~~current annual rent in the~~ **these** ~~new space~~ **third- parties includes regular audits, threat assessments, and consultation on security enhancements. Oversee Third- party Risk Because we are aware of the risks associated with third- party service providers, we implement stringent processes to oversee and manage these risks. We conduct thorough security assessments of all third- party providers before engagement and maintain ongoing monitoring to ensure compliance with our cybersecurity standards. The monitoring includes quarterly assessments by our Chief Legal and Compliance Officer (CLCO) and our Chief Operating Officer (COO) and on an ongoing basis by our IT professionals. This approach** is **designed to mitigate risks related to data breaches or other security incidents originating** ~~approximately $ 0. 5 million. Item 3. Legal Proceedings Paragraph IV Patent Litigation In January 2023, we received Paragraph IV Certification Notice Letters~~ from ~~three generic drug manufacturers advising us~~ **third- parties. Risks from Cybersecurity Threats We have not encountered cybersecurity challenges** that ~~they had each submitted an Abbreviated New Drug Application (ANDA) to the FDA seeking authorization from the FDA to manufacture, use or sell a generic version of FIRDAPSE ® in the United States. The notice letters each allege that our six patents listed in the FDA Orange Book covering FIRDAPSE ® are not valid, not enforceable, and / or will not be infringed by the commercial manufacture, use or sale of the proposed product described in these ANDA submissions. Under the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, we had 45 days from receipt of the notice letters to commence patent infringement lawsuits against these generic drug manufacturers in a federal district court to trigger a stay precluding FDA from approving any ANDA until May 2026 or entry of judgment holding the patents invalid, unenforceable, or not infringed, whichever occurs first,~~

~~and in that regard, after conducting the necessary due diligence, we filed lawsuits on March 1, 2023 in the U. S. Federal District Court for the District of New Jersey against each of the three generic drug manufacturers who notified us of their ANDA filings. We intend to vigorously protect and defend our intellectual property for FIRDAPSE ® and, although there can be no assurance, we believe that our patents will protect FIRDAPSE ® from generic competition for the life of our patents. Canadian Litigation On March 11, 2022, we announced that we had received a favorable decision from the Canadian court setting aside, for the second time, the decision of Health Canada approving RUZURGI ® for the treatment of LEMS patients. In its ruling, the court determined that the Minister of Health' s approach to evaluating whether FIRDAPSE ®' s data deserved protection based on FIRDAPSE ®' s status as an innovative drug, which protects by regulation the use of such data as part of a submission seeking an NOC for eight years from approval of the innovative drug, was legally flawed and not supported by the evidence. The Minister of Health appealed that decision, and, in January 2023, the Canadian Appellate Court overturned the trial court' s decision. Thereafter, the Minister of Health reissued an NOC for RUZURGI ® in Canada and, as a result, RUZURGI ® is once again available for sale in Canada. While there can be no assurance, we do not believe that the reissuance of an NOC for RUZURGI ® in Canada will~~ have ~~a material~~ **materially impaired** ~~adverse effect on~~ our ~~results of~~ operations **or financial standing** . ~~49~~ **53**