Risk Factors Comparison 2024-03-28 to 2023-03-30 Form: 10-K

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The following summarizes the principal factors that make an investment in the Company speculative or risky, all of which are more fully described in Part I, Item 1A, Risk Factors in this Annual Report on Form 10- K. This summary should be read in conjunction with the Risk Factors section and should not be relied upon as an exhaustive summary of the material risks facing our business. The occurrence of any of these risks could harm our business, financial condition, results of operations and / or growth prospects or cause our actual results to differ materially from those contained in forward- looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described in our public filings when evaluating our business. • Our short operating history and **shifts** ~~the acquisition of Anelixis Therapeutics, Inc.~~ in ~~September 2020~~ **our business strategy** may make it difficult to evaluate the success of our business to date and to assess our future viability. • Our financial condition raises substantial doubt as to our ability to continue as a going concern. If we become unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. • We have incurred significant operating losses since our inception and expect that we will continue to incur losses over the next several years and may never achieve or maintain profitability. • We will require additional funding to be able to complete the development of our lead drug candidate. If we are unable to raise such capital, or if we are unable to do so on acceptable terms, we will be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether. • **Issuances of our common stock, including common stock that may be issuable pursuant to outstanding warrants or other convertible securities as well as shares and warrants issued in connection with our recent Private Placement, could result in significant dilution and could cause our stock price to fall. •** Our product candidates are in the early stages of clinical development and may not be successfully developed. If we are unable to successfully develop and commercialize these or any other product candidate, or if we experience significant delays in doing so, our business will be materially harmed ~~. • The COVID- 19 pandemic has adversely affected and it or other public health crises, pandemics or epidemics could in the future adversely affect our business operations, which could have a material adverse effect on our business~~ . • Unfavorable global economic conditions could have a material adverse effect on our business. • ~~We maintain cash deposits in excess of federally insured limits.~~ Adverse ~~developments affecting~~ **conditions in the** financial ~~institutions~~ **markets** , including bank failures, could adversely affect our liquidity and financial performance. • Drug development involves a lengthy and expensive process with an uncertain outcome, including failure to demonstrate safety and efficacy to the satisfaction of the U. S. Food and Drug Administration (FDA) or similar regulatory authorities outside the United States. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development, formulation and commercialization of our product candidates. • The results of nonclinical studies and early clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials, and there is a risk that additional nonclinical and / or clinical safety studies will be required by the FDA or similar regulatory authorities outside the United States or that subsequent studies will not match results seen in prior studies. • Delays or difficulties in the enrollment of patients in clinical trials could delay or prevent our receipt of necessary regulatory approvals and increase expenses for the development of our product candidates. • If serious adverse events or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates. • Our future success depends on our ability to retain executives and key employees and to attract, retain and motivate qualified personnel in the future. • If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, or the approvals may be for a narrow indication, we may not be able to commercialize our product candidates, and our ability to generate revenue may be materially impaired. • Legislation regulating the pharmaceutical and healthcare industries may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain. • Our internal computer systems, or those of our third- party collaborators, service providers, contractors or consultants, may fail or suffer security breaches, disruptions, or incidents, which could result in a material disruption of our development programs or loss of data or compromise the privacy, security, integrity or confidentiality of sensitive information related to our business and have a material adverse effect on our reputation, business, financial condition or results of operations. • Even if any of our product candidates receives marketing approval, we may fail to achieve the degree of market acceptance by physicians, patients, third- party payers and others in the medical community necessary for commercial success. • If our current product candidates, or a future product candidate receives marketing approval and we, or others, later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, the ability to market the product could be compromised. • We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do. • The insurance coverage and reimbursement status of newly - approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue. • Our reliance on third parties for the manufacture of our product candidates for nonclinical and clinical trials, and for eventual commercialization, increases the risk that we will not have sufficient quantities of our product candidates or products at an acceptable cost and quality, which could delay, prevent or impair our development or commercialization efforts. • We depend on contract research organizations (“ CROs ”) and other contracted third parties to perform nonclinical and clinical testing and certain other research and development activities. As a result, the outcomes of the activities performed by these organizations will be, to a certain extent, beyond our control. • If we are unable to

obtain and maintain intellectual property protection for our technology and products or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired. • **Public health crises, including pandemics or epidemics, could adversely affect our business. •** Our stock price could be volatile, and the market price of our common stock may drop unexpectedly. • If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed. • Provisions in our corporate charter and under Delaware law could make an acquisition of the Company more difficult and may prevent attempts by our stockholders to replace or remove our current management. WEBSITE REFERENCES In this Annual Report on Form 10- K, we make references to our website at www. eledon. com. References to our website through this Form 10- K are provided for convenience only and the content on our website does not constitute a part of, and shall not be deemed incorporated by reference into, this Annual Report on Form 10- K. PART I Item 1. Business. Overview ~~Eledon Pharmaceuticals, Inc.~~ **We are a clinical stage biotechnology company using our immunology expertise in targeting the CD40 Ligand** (" ~~Eledon~~ **CD40L** " or ~~the~~ " ~~Company~~ **CD154** ") **pathway to** ~~is a clinical stage biopharmaceutical company focused on developing~~ --- **develop therapies to protect** ~~life- changing, targeted medicines for persons requiring an organ or cell based transplant~~ **transplanted organs and prevent rejection** , **and to treat** ~~living with autoimmune disease, or living with~~ amyotrophic lateral sclerosis (" ALS "). **Our** ~~The Company' s~~ lead compound in development is tegoprubart, an IgG1, anti- CD40L antibody with high affinity for **the** CD40 Ligand ~~(" CD40L ", also called " CD154 ")~~ , a well- validated biological target that we believe has broad therapeutic potential. ~~In September 2020, we acquired Anelixis Therapeutics, Inc. (" Anelixis "), the company that owned and controlled the intellectual property related to tegoprubart.~~ Tegoprubart is engineered to potentially both improve safety and provide pharmacokinetic, pharmacodynamic, and dosing advantages compared to other anti- CD40 approaches. The CD40L / CD40 pathway is recognized for its prominent role in immune regulation. CD40L is primarily expressed on activated CD4 T cells, platelets and endothelial cells while the CD40 receptor is constitutively expressed on antigen presenting cells such as macrophages and dendritic cells, as well as B cells. By blocking CD40L and not the CD40 receptor, tegoprubart inhibits both the CD40 and CD11 costimulatory signaling pathways, providing the potential for improved efficacy compared to anti- CD40 receptor approaches. Blocking CD40L also increases polarization of CD4 lymphocytes to Tregs, a specialized subpopulation of T cells that act to suppress an immune response, thus creating a more tolerogenic environment, which may play a therapeutic role in autoimmune diseases and in the prevention of allograft rejection after solid organ transplantation. **Figure 1: Mechanism overview of CD40L inflammatory signaling and tegoprubart site of action Figure 1: Interaction of CD40 with CD40L on immune cells mediates activation of the co- stimulatory immune pathway, controlling" cross talk " between the adaptive and innate immune systems. Blocking CD40L shifts polarization away from pro- inflammatory signaling to T- cell anergy, apoptosis, and polarization to a " T- reg " environment. (Source: Adapted from Kant et al., Principles of Immunosuppression in the Management of Kidney Disease: Core Curriculum 2022, AJKD.)** Tegoprubart is designed to negate the risk of thrombolytic events seen in the first generation of anti- CD40L antibodies by introducing structural modifications that have been shown in preclinical models to eliminate binding to the Fcγ receptors associated with platelet activation without altering the binding of tegoprubart to CD40L. In non- human primate studies, dosing of tegoprubart up to 200 mg / kg per week for 26 weeks, demonstrated no adverse events regarding coagulation, platelet activation or thromboembolism. **Strategy** Our business strategy is to optimize the clinical and commercial value of tegoprubart and become a global biopharmaceutical company with a focused immunology franchise. Our ~~original~~ strategy ~~was~~ **is** to develop tegoprubart ~~in up to four~~ - **for** ~~indications: the~~ **the prevention of allograft and xenograft rejection, and for the treatment of autoimmune diseases such as** ALS ~~, prevention of kidney allograft rejection, prevention of islet cell allograft rejection, and IgA Nephropathy (" IgAN ")~~ . We selected our indications based on preclinical and clinical data that was generated with either tegoprubart or historical anti- CD40L molecules. In January 2023, we announced our decision to prioritize resources on our kidney transplantation programs, **and** discontinue **the Company funding of** the islet cell transplantation program ~~,~~ and ~~deprioritize~~ the IgAN program. We ~~also~~ remain committed to further progressing ALS clinical development and are working with key stakeholders on potential next steps to do so. However, as described below, we are unable to continue our clinical development of tegoprubart for people with ALS without additional financing. ~~In January 2023, we entered into a collaborative research agreement with eGenesis, Inc., (" eGenesis"), under which eGenesis will gain access to tegoprubart for preclinical xenotransplantation studies in support of eGenesis' kidney, heart and islet cell xenotransplantation programs.~~ The following chart summarizes the status of our current clinical development programs **. Details for each program are outlined below. Acquisition In September 2020, we acquired Anelixis Therapeutics, Inc. (" Anelixis "), the company that owned and controlled the intellectual property related to tegoprubart. See Note 8 of the Notes to Financial Statements included in this Annual Report on Form 10- K, for further details of grants and licenses related to this acquisition** . Prior to our acquisition of Anelixis, we focused on developing medicines for patients with disorders of the ear, nose, and throat (" ENT "). In June 2020, we announced that our lead program did not achieve statistical significance for the primary efficacy endpoints in the treatment of acute otitis media. As a result of this failure to achieve the primary study endpoint, we suspended the clinical development of our legacy ENT assets while we assessed potential development strategies. Following the June 2020 announcement, we significantly curtailed development expenses as we sought to identify strategic alternatives that would maximize stockholder value. As a result of these activities, we acquired Anelixis and raised additional capital in September 2020, as described above. After acquiring Anelixis, we terminated our ENT activities and returned our product rights to the original license holders in July 2021. **Clinical Development of Tegoprubart for the Prevention of Allograft Rejection in** Kidney ~~transplantation~~ **Transplantation** ~~: prevention of allograft rejection~~ In January 2023, **we** ~~the Company~~ announced plans to prioritize and focus resources on ~~its~~ **our** kidney transplantation programs. **We are first focusing on** ~~Kidney~~ **kidney** transplantation **as this** is the most common type of solid organ transplantation in the ~~United States~~ **U. S.** with an estimated ~~240~~ **255** , 000 Americans living with a transplanted kidney. In ~~2019~~

2022 , an estimated ~~24~~ **25** , 000 kidneys were transplanted **in the U. S.** , of which up to 15 % were re- transplants in persons that had already received at least one other kidney. Over 90, 000 people in the U. S. wait 3- 5 years **on average** for a kidney transplant and **about** ~~in 2014, nearly~~ 5, 000 ~~Americans~~ **people in need of a kidney transplant** ~~died~~ **die each year while** waiting for a **suitable** kidney **. There remains a critical shortage of kidneys and other organs available for transplantation. There has been little innovation in immunosuppression therapy for organ transplant patients over the past 30 years. The standard of care immunosuppressive drugs used post- transplant have been shown to reduce the risk of organ rejection, but they are also associated** with **potentially toxic side effects. Organ** ~~another nearly 4, 000 becoming too sick to receive a~~ transplant **recipients require immunosuppression on a lifelong basis, and any disruption in the immunosuppression therapy can trigger transplant rejection** . Calcineurin inhibitors (" CNI " s) are a critical component of ~~many~~ **most** immunosuppressive regimens to prevent acute and long- term kidney transplant rejection. However, chronic exposure to ~~certain~~ CNIs ~~including~~ **(** tacrolimus **is the drug most commonly used)** is associated with **nephrotoxicity, hypertension,** new onset diabetes due to pancreatic beta cell toxicity, ~~nephrotoxicity~~ **as well as central nervous system (" CNS ") side effects** , ~~and cardiotoxicity~~ **like tremor** . Over time, these CNI side effects may significantly damage **the** transplanted kidneys or result in a requirement for reduced exposures to CNIs **which can lead to** ~~and~~ **an** ~~a~~ **increased risk of rejection. Moreover, other side effects, including CNS side effects like tremors, may** ~~resulting~~ **result in patients decreasing their adherence to their medicines. Today, an implanted kidney is expected to fail within 10- 15 years on average using currently available immunosuppression options. The fact that American transplant patients are on average in their 50s means that many of them will ultimately need a second or even third transplant procedure during their lifetime or a return to dialysis. The central role of CD40L signaling in generating pro- inflammatory responses makes it a highly attractive candidate for therapeutic intervention in the protection of transplanted organs and prevention of transplant rejection. Results from prior studies demonstrate that targeting and blocking CD40L has the** potential ~~decrease in~~ **for better efficacy and improved safety, including reduced risk of lymphopenia, diabetes, hypertension, and** ~~the~~ **other** ~~ability to prevent long~~ **side effects associated with standard** ~~term rejection~~ **of- care CNIs such as tacrolimus** . Tegoprubart seeks to address challenges associated with current immunosuppressive transplantation regimens using CNI- based therapies. The ability to prevent acute and chronic transplant rejection without the need for CNIs has the potential to transform the clinical management of preventing graft rejection by mitigating the adverse events associated with CNIs and improving long- term graft survival, **thus** potentially decreasing the need for repeat kidney transplants **and increasing organ availability for other patients on the wait list. By identifying and advancing novel strategies in immunosuppression including targeting the CD40L pathway, we may be able to help organs remain functional for longer and potentially throughout the natural lifespan of each recipient** . In aggregated data from the published studies referenced in Figure 1 below, non- human primates undergoing allograft renal transplantation receiving anti- CD40L monotherapy (e. g., 5c8, AI794, IDEC- 131) had longer average survival than both those receiving anti- CD40 monotherapy (e. g., 4D11, cH5D12, Chi220, ASKP1240), tacrolimus monotherapy or untreated controls (Figure ~~1~~ **2**). Figure ~~1~~ **2** : Inhibition of CD40L improved survival vs. CD40 inhibition in non- human primate kidney transplantation monotherapy studies Figure ~~1~~ **2** : Kaplan- Meir estimates of the probability of rejection free survival by treatment group from eleven published studies of allograft kidney transplant in non- human primates. **Sources: Perrin** ~~Median survival of untreated animals is 6 days (red line)~~ , ~~monotherapy anti CD40 treated animals 131 days (gray line), and monotherapy anti CD40L treated animals 352 days (blue line), log rank test P = 0. 0001. (Kirk, 1999; Preston, 2005; Montgomery, 2002~~ - **2022** ~~; Xu, 2001; Xu, 2002; Kanmaz, 2004; Kim 2017~~ ; Song, 2014; ~~Aoyagi~~ **Song** , ~~2009~~ **2016** ; ~~Imai~~ **Duan** , ~~2007~~ **2017** ~~; Haanstra~~ **. Note: In aggregated data from published studies** , ~~2003; Pearson~~ **NHPs receiving anti- CD40L (e. g.** , ~~2002; Cordoba 2015~~ **5c8, AI794, IDEC- 131**) **immunomodulation monotherapy post kidney transplantation had longer average survival than those receiving anti- CD40 monotherapy (e** . **g., 4D11, cH5D12, Chi220, ASKP1240), tacrolimus monotherapy or untreated controls. Tac = tacrolimus. Meta-** ~~Analysis~~ **analysis** is not based on head- to- head ~~comparison~~ **studies** . Differences between any individual programs may vary. ~~The Company~~ **We have** received regulatory approvals in Canada, the United Kingdom and Australia, for a Phase 1b clinical trial of tegoprubart ~~,~~ in up to ~~12~~ **24** subjects, replacing tacrolimus as an immunosuppressive regimen component in patients undergoing de novo kidney transplantation. **Each participant will receive rabbit antithymocyte globulin (ATG) induction and a maintenance regimen consisting of tegoprubart, mycophenolate mofetil, and corticosteroids. The primary endpoint of the study is safety. Other endpoints include glomerular filtration rate (eGFR), characterizing the pharmacokinetic profile of tegoprubart, and the incidence of biopsy proven rejection.** The first subject in the Phase 1b study was dosed in July 2022. **Better graft function as assessed by eGFR, has been associated with improved long- term patient and graft survival and is an early predictor of future graft failure. Historical studies have reported average eGFRs generally in the low 50 mL / min / 1. 73m2 range during the first year after kidney transplant using current standard of care immunosuppression. An eGFR of 50 indicates chronic kidney disease. We reported interim safety and efficacy results from the Phase 1b clinical trial in March 2023, and provided updated data in November 2023. At the time of the November 2023 update, results from 11 participants in the Phase 1b trial demonstrated that tegoprubart was generally safe and well- tolerated in patients undergoing kidney transplantation. There were no cases of hyperglycemia, new onset diabetes, tremor, or cytomegalovirus infection commonly seen with tacrolimus. One participant experienced a mild T cell mediated rejection (Banff score 1a) on day 99. This patient was treated for the rejection and remains in the study. There were no cases of graft loss or death. Aggregate mean eGFR was above 70 mL / min / 1. 73m2 at all reported time points after day 90.** In July 2022, **we** ~~the Company~~ received Investigational New Drug (IND) application clearance from the FDA for ~~a~~ **our** controlled, Phase 2 **BESTOW** trial of tegoprubart for the prevention of transplant rejection in persons receiving a kidney transplant. The **BESTOW** ~~Phase 2~~ study **is a multi- center, two- arm, active comparator, head- to- head superiority clinical study, and** will ~~be a multicenter, open- label, active control study~~ **enroll 120 participants undergoing kidney transplantation in the U. S. and other countries** to ~~assess~~

evaluate the safety **, pharmacokinetics,** and efficacy of tegoprubart compared ~~with~~ **to the calcineurin inhibitor** tacrolimus ~~in the preservation of allograft function after kidney transplantation~~ . The study **' s primary objective is to assess graft function as measured by estimated eGFR at 12 months post- transplant in participants treated with tegoprubart compared to tacrolimus. Secondary objectives** will ~~enroll approximately 120 participants (60 / arm) undergoing kidney~~ **include assessment of graft survival, biopsy- proven acute rejection, and the incidence of new onset diabetes mellitus after** transplant ~~and will run~~ **. The BESTOW study is running** in parallel to the ongoing Phase 1b clinical trial of tegoprubart in kidney transplantation. The **first subject in the BESTOW study was dosed in August 2023. In October 2023, the** Company ~~plans~~ **enrolled the first participant in a Phase 2 open- label extension (OLE) study which is designed** to ~~initiate~~ **evaluate the long- term safety, pharmacokinetics, and efficacy of tegoprubart in participants who have completed one year of treatment in the ongoing Phase 1b study, or BESTOW study. Clinical Development of tegoprubart for the Prevention of Allograft Rejection in Xenotransplantation While inhibition of CD40L has shown it may play an important role in immunosuppression in allograft kidney transplantation, this mechanism of action has also demonstrated that it may be a promising option in xenotransplantation (i. e., transplanting an organ from an animal to a human). In January 2023, we entered into a non- exclusive collaborative research agreement with eGenesis, Inc., (" eGenesis"), under which eGenesis gained access to tegoprubart for preclinical and clinical xenotransplantation studies in support of eGenesis' kidney, heart and islet cell xenotransplantation programs. Clinical Development of tegoprubart for the Prevention of Allograft Rejection in Islet cell transplantation (" ICT") Type 1 diabetes is a T cell mediated autoimmune disease with progressive loss of insulin producing pancreatic beta cells and affects over one million persons in the U. S. Of these individuals, an estimated 70, 000 people have a particularly hard to control type 1 diabetes called Brittle Diabetes (" BT1D ") which is in part characterized by large swings in blood glucose levels and impaired awareness of hypoglycemia. Impaired awareness of hypoglycemia for people with type 1 diabetes is associated with severe hypoglycemic events which can lead to significant symptoms and even death. Pancreatic islet cell transplantation is gaining attention as a therapeutic option for type 1 diabetes because it can restore physiological insulin secretion, minimize the risk of hypoglycemic unawareness, and reduce the risk of death due to severe hypoglycemia. The advances made in this field over the past decade have improved** patient ~~enrollment~~ **outcomes, and the procedure has been evolving from an experimental treatment to a clinical treatment option. A number of issues are believed to continue to hamper the overall success of ICT and to need to be addressed** in **order for** ~~the~~ **there** ~~third quarter~~ **to be widespread clinical acceptance. These include the acute loss** of **transplanted islets with current immunosuppressive treatments, particularly those with CNI- based therapies, due to islet cell toxicity and alloreactive immunologic responses to transplanted islets. Over time, the progressive loss of islet cells and decline in islet cell function often leads to the need for multiple donors in order for BTID patients to have optimal response to blood glucose levels and possibly achieve insulin independence. Tegoprubart seeks to address the challenges associated with current ICT immunosuppressive regimens using CNI- based therapies, by replacing the CNIs with tegoprubart. CD40L blockade may abolish many effector mechanisms of inflammation, prevent and intervene in the progression of autoimmunity, and instill transplant tolerance. Historical studies in nonhuman primate models of ICT have demonstrated that treatment with anti- CD40L antibodies induces long term islet cell function and graft survival, even as a monotherapy. Tegoprubart has shown pre- clinical, proof- of- concept efficacy in a non- human primate model of type 1 diabetes, where animals undergoing ICT maintained glucose control and sustained levels of C- peptide with chronic tegoprubart treatment for up to a year. Compared to combination immunosuppressive therapy including CNIs, tegoprubart monotherapy was more effective in preventing long term islet cell rejection, associated with better graft function, and showed an improved safety profile. In January** ~~2023~~ **2024** , ~~subject to financing~~ **we announced that tegoprubart will be utilized in an investigator- initiated trial, at the University of Chicago for pancreatic ICT in patients with type 1 diabetes** . ~~Amyotrophic Lateral Sclerosis~~ **This is a pilot study assessing the safety of using a monoclonal antibody against CD40 ligand to achieve a calcineurin inhibitor- free immunosuppression regimen in patients with type 1 diabetes mellitus and problematic hypoglycemia undergoing islet cell transplantation. The Company is not funding this trial but is supplying tegoprubart. Clinical Development of tegoprubart for ALS** ALS is a progressive, paralytic disorder characterized by degeneration of motor neurons in the brain and spinal cord. In the U. S., the incidence is estimated at approximately 5, 000 cases per year with a prevalence of approximately 30, 000 cases overall. Despite 3 approved drugs, in most cases, death from respiratory failure occurs between 3 to 5 years from diagnosis, with 50 % of patients living at least 3 years from diagnosis and only 20 % of patients living at least 5 years from diagnosis. While the exact pathogenic mechanism of ALS is still not fully understood, there is strong evidence indicating that neuroinflammation plays an important role in the disease' s pathogenesis. Neuroinflammation in ALS is characterized by the infiltration of lymphocytes and macrophages into the central nervous system, and the activation of microglia and reactive astrocytes. Reactive astrocytes and microglia as well as infiltrating lymphocytes, dendritic cells, monocytes, macrophages and immune complexes have been identified in cerebrospinal fluid and neural tissues in both animal models of ALS and at autopsy in ALS patients. Tegoprubart is designed to block CD40L binding to CD40, thereby potentially inhibiting neuroinflammatory pathways leading to disease progression in ALS. In vitro proof- of- concept studies have shown that tegoprubart binds to CD40L in human cells and blocks CD40L binding on antigen presenting cells and activated T cells. The potential for therapeutic benefit of CD40L blockage in treating ALS has been demonstrated in a SOD1 mouse model of ALS, where a murine anti- CD40L antibody, MR1, prolonged survival and delayed the onset of neurological disease progression. These pathophysiological manifestations are believed to be due to reduced immune cell infiltration of macrophages into skeletal muscle and their destroying denervated nerves. The plasticity of the nervous system to repair itself in the absence of this immune cell attack is believed to result in improved neuromuscular junction occupancy and improved muscle function. Blocking CD40L signaling also prevents pro- inflammatory polarization of lymphocytes, reduced neuroinflammation and improved motor neuron survival in rodent ALS models (Figure ~~2~~ **3**). Figure ~~2~~ **3** :

Blocking CD40L Improves Survival and Pathophysiology Associated with ALS Figure ~~2~~ **3** : Anti- CD40L (" MR1 ") treatment decreases CD68 macrophages, improves neuromuscular junction occupancy and improves motor neuron survival. (A) Quantification of reduction of CD68 macrophages by anti- CD40L treatment at day 100. (White bar, control IgG); gray bar (anti- CD40L – treatment); black bar (untreated age- matched non- transgenic mice) (B) Quantification of neuromuscular occupancy in SOD1 mice prior to overt symptoms (day 70) versus after symptom onset (day 85) treated with an IgG control antibody (vehicle) or anti- CD40L antibody. (C) Quantitative comparison of lumbar spinal cord motor neuron counts per mm2 in IgG vehicle control (White bar) versus anti- CD40L treated mice (grey bar) at day 100 (Lincecum, 2010). In 2018, the FDA granted orphan drug designation to tegoprubart for ALS. In 2019, we completed a single ascending dose Phase 1 study of tegoprubart in healthy volunteers and people ~~living~~ with ALS. In this study, the doses of tegoprubart studied were well tolerated in healthy adult subjects and adults with ALS. Tegoprubart demonstrated low anti- drug antibody responses that were not dose related, linear dose proportionality across the dose ranges, and a half- life of up to 26 days. In October 2020, we initiated a Phase 2a, open- label, multi- center study to evaluate the safety and tolerability of multiple doses of tegoprubart in adult subjects with ALS. Fifty- four subjects ~~living~~ with ALS were enrolled into the study in the United States and Canada at 13 ALS treatment sites. Ascending doses of tegoprubart were administered as IV infusions to four sequentially enrolling cohorts. The first two cohorts consisted of nine participants, and the last two cohorts of 18 participants each. All enrolled subjects received six infusions of tegoprubart over a 12 ~~–~~week period. Blood samples for target engagement, and exploratory biomarkers for inflammation and neurodegeneration were taken and analyzed. Participant- focused clinical outcomes were also assessed. In May 2022, we completed the Phase 2a study and ~~reported~~ **released** positive topline results ~~where . tegoprubart~~ **Tegoprubart** successfully met the primary endpoints of safety and tolerability. Fifty of the fifty- four subjects completed all six study infusions, and adverse events were typical of an ALS patient population. Tegoprubart was well- tolerated, and no drug- related serious adverse events were observed. No new safety signals emerged. Anti- drug antibodies (ADAs) were present in less than 5 percent of samples. All ADAs were of low titer and did not impact tegoprubart drug levels. Tegoprubart target engagement was demonstrated in all dose cohorts with increasing target engagement in a dose- dependent manner, plateauing at the 4 and 8 mg / kg dosing levels using CD40L and CXCL13 biomarkers related to T cell and B cell function, respectively. Tegoprubart exposure decreased inflammatory biomarker levels, in a dose dependent manner, in ~~over~~ 20 of 32 pro- inflammatory proteins. Pro- inflammatory biomarkers reduced included biomarkers also associated with IgA nephropathy and kidney transplant rejection, such as IgA, IgE, IgM, C3, CXCL9, and CXCL10. **We are** ~~The Company is~~ seeking to further progress ALS clinical development and ~~plans~~ - **plan** to work with key stakeholders on potential next steps to do so. However, we will be unable to continue our clinical development of tegoprubart for people with ALS without additional financing **specific for our ALS program** , and we can provide no assurances that we will be able to obtain financing on acceptable terms or at all. **Clinical Development of tegoprubart for IgA Nephropathy** In January 2023, the Company announced the deprioritization of its IgAN program **and all IgAN clinical development activities were discontinued in 2023** . IgAN is the leading cause of chronic glomerulonephritis, a state of inflammation producing damage to the filtering part of the kidney. Disease manifestation and clinical presentation involves renal dysfunction characterized by proteinuria with a slow relentless course. Approximately 30 %- 40 % of persons living with IgAN ultimately reach end stage renal disease (ESRD). The standard of care for ESRD is dialysis or kidney transplant, which represents a significant economic burden as well as a major impact on a patient' s quality of life. With an estimated prevalence of approximately 150, 000 persons in the United States, IgAN is one of the most common autoimmune glomerulonephropathies. In the United States, oral budesonide Tarpeyo was approved for use in IgAN by the FDA in December 2021 and Kinpeygo received conditional approval by the European Medicines Agency (" EMA ") in July 2022. ~~The pathophysiology of IgAN has been well characterized, and based on its mechanism of action, tegoprubart has the potential to impact the disease process both upstream, at the source of the immune complexes, and downstream in the kidney itself, where it may reduce inflammation in the glomeruli. By disrupting multiple steps in the IgAN' s pathophysiology, tegoprubart has the potential to affect the clinical course of the disease and improve outcomes for patients. The inhibition of CD40L has been shown to be effective in models of multiple glomerulonephritides, as measured by a reduction in proteinuria and were associated with a decrease in immune cell infiltrate into the glomeruli (Figure 3). Figure 3: Blocking CD40L Improves Survival and Pathophysiology Associated with Autoimmune Nephritis Figure 3: Effect of anti- CD40L in the SNF1 rodent model of Lupus. (A) The survival curves of anti- CD40L treated and HIg controls differ significantly (p < 0. 001 by Wilcoxon test). Control mice receiving HIgG control die rapidly with the onset of severe nephritis, and all but one are dead by age 12 months while all anti- CD40L treated mice are alive when the study is terminated at age 15. 5 months (Kalled, 1998). (B) Urine was monitored weekly for proteinuria. Proteinuria was scored as follows: 0. 5 (15 to 30 mg / dl); 1 (30 mg / dl); 2 (100 mg / dl); 3 (300 mg / dl) and 4 (> 20000 mg / dl). The proportion of mice with = > 3 proteinuria differed significantly between anti- CD40L treated and HIg controls at all timepoints (p < 0. 001 by x2 test). Controls that did not have = > 3 proteinuria at the start of treatment became 4 soon after, as opposed to anti- CD40L treated mice where the proteinuria levels of six of seven mice declined and only one mouse developed 3 proteinuria (Kalled, 1998). (C) MR1 treatment was associated with a significant reduction in the number of infiltrating macrophages. The number of infiltrating CD4 and CD8 cells was not statistically different from the Adriamycin alone group. Bars represent mean values standard deviation. * * P < 0. 01 vs. Adriamycin alone group (Kairatis, 2003).~~ In August 2022, **we** ~~the Company~~ received IND clearance from the FDA to evaluate tegoprubart for the treatment of IgAN. ~~Including the United States, the Company has now received regulatory clearances to initiate a phase 2a study in twelve countries.~~ The **Phase 2** global study ~~is~~ **was** a 96- week open- label, dose ranging trial, and ~~will include~~ **included both** ~~up to 42 subjects in~~ a high dose and a low dose cohort. The primary endpoint ~~is~~ **was** change in urinary protein: creatinine ratio ~~(UPCR)~~ at week twenty- four. Secondary endpoints ~~include~~ **included** change in estimated Glomerular Filtration Rate (eGFR) at week 96 as well as safety and tolerability. The first subject was dosed in May 2022. **In January 2023, we announced** ~~The Company does not plan to initiate~~ the **deprioritization of our IgAN program** ~~low dose cohort and only plans~~ to **focus resources on our**

kidney transplantation programs. We ~~report~~ **reported** ~~out~~ **interim** safety data from the **Phase 2** high dose cohort ~~,~~ in **March** 2023. **All IgAN** ~~Islet cell transplantation: prevention of allograft rejection Type 1 diabetes is a T cell mediated autoimmune disease with progressive loss of insulin producing pancreatic beta cells and affects over one million persons in the U. S. Of these individuals, an estimated 70, 000 people have a particularly hard to control type 1 diabetes called Brittle Diabetes (" BT1D ") which is in part characterized by large swings in blood glucose levels and impaired awareness of hypoglycemia. Impaired awareness of hypoglycemia for people with type 1 diabetes is associated with severe hypoglycemic events which can lead to significant symptoms and even death. Pancreatic islet cell transplantation may be a therapeutic option for type 1 diabetes because it can restore physiological insulin secretion, minimize the risk of hypoglycemic unawareness, and reduce the risk of death due to severe hypoglycemia. In November 2020, the Company received clearance from Health Canada to proceed with the initiation of a Phase 2a clinical trial of tegoprubart for people with type 1 diabetes undergoing islet cell transplantation. In November 2021, the Company received IND clearance from the FDA for a Phase 2a clinical trial of tegoprubart for up to six people with type 1 diabetes undergoing islet cell transplantation at the University of Chicago. In June 2022, the FDA granted orphan drug designation to tegoprubart for the prevention of allograft rejection in pancreatic islet cell transplantation. In August 2022, the Company announced the closure of the clinical site in Canada in order to concentrate resources in the United States. In January 2023, the Company announced that all~~ clinical development **activities were** ~~for tegoprubart in islet cell transplantation would be~~ discontinued **in** ~~. Collaboration Agreement with eGenesis for Xenotransplantation Studies In January~~ 2023 ~~, the Company entered into a collaborative research agreement with eGenesis, under which eGenesis will gain access to tegoprubart, for preclinical xenotransplantation studies in support of eGenesis' kidney, heart and islet cell programs . The competitive conditions faced by the Company are described in greater detail in Part I, Item 1A. Risk Factors in this Annual Report on Form 10- K under the caption " We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do. "~~ Intellectual Property Eledon' s success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, novel discoveries, product technologies and other know- how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. We seek to protect our product candidates by, among other methods, filing U. S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trademarks, trade secrets, know- how, continuing technological innovation and potential in- licensing opportunities to develop and maintain proprietary protection for our product candidates. Our intellectual property portfolio includes issued patents and patent applications directed toward (i) isolated antibodies and (ii) methods of treatment using the isolated antibodies that block the interaction of CD40L and CD40 to treat CD- 40L related diseases or disorders. We have exclusive rights to these patent families, of which two families are directed to tegoprubart and related antibodies. The first family is directed to methods for treating amyotrophic lateral sclerosis with antibodies and includes two issued United States patents and 14 issued foreign patents (Japan, Hong Kong, Belgium, Germany, Denmark, Spain, Finland, France, Great Britain, Ireland, Italy, the Netherlands, Sweden, and Switzerland). The second family is directed to tegoprubart. Tegoprubart is the current clinical candidate, with 13 pending applications, and issued / allowed patents including three issued United States patents, one allowed United States patent application, and 17 issued foreign patents (Australia, Belgium, Switzerland, China, Germany, Denmark, France, Great Britain, Ireland, Israel, Italy, Japan, Mexico, the Netherlands, Russia, Sweden, Singapore). The third family is directed to tegoprubart with 17 pending applications, including one pending United States patent application, and issued patents, including one issued United States patent and one issued Russian patent. In the first family, the patents are set to expire in December 2029, absent any term adjustments or extensions. In the second family, any issued patent would nominally expire in February 2036, absent any term adjustments or extensions. In the third family, any issued patent would nominally expire in May 2038, absent any term adjustments or extensions. Subsequent to our acquisition of Anelixis, we undertook a strategic review of the legacy ENT assets. We concluded this review and determined that the best path forward was to terminate license agreements associated with these ENT assets and return the rights to the original license holders, which we did in July 2021. There was no financial impact to returning these assets. Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country. Eledon also protects its proprietary information by requiring its employees, consultants, contractors, and other advisors to execute nondisclosure and assignment of invention agreements upon commencement of their respective employment or engagement. In addition, Eledon also requires confidentiality or service agreements from third parties that receive confidential information or materials. See Note ~~6~~ **8** . Commitments and Contingencies of the consolidated financial statements included elsewhere herein under the caption " Grants and Licenses " for further information about the Company' s intellectual property. **Competition The biotechnology and pharmaceutical industries are characterized by continuing technological advancement and significant competition. While we believe that our product candidates, technology, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. The availability of reimbursement from government and other third- party payors will also significantly affect the pricing and competitiveness of our products. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Many of the companies against which we may compete have significantly greater financial resources and expertise in**

research and development, manufacturing, preclinical testing, conducting clinical studies, obtaining regulatory approvals and marketing approved products than we do. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. The competitive conditions faced by the Company are also described in greater detail in Part I, Item 1A. Risk Factors in this Annual Report on Form 10- K under the caption " We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do. " Manufacturing We do not own or operate manufacturing facilities for the production of tegoprubart or any future product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on third parties for raw materials and the manufacturing of drug substance and drug product for nonclinical and clinical activities. As of the date of this Annual Report, we have not experienced any difficulty in obtaining raw materials required with respect to the manufacturing of tegoprubart. We believe we have enough drug substance and drug product on hand and manufacturing capacity with our third- party manufacturing providers to meet forecasted clinical trial demand. We also rely on third parties to label, store and distribute drug product for our nonclinical and clinical trials. Government Regulation Government authorities in the United States, including federal, state, and local authorities, and in other countries, extensively regulate, among other things, the manufacturing, research and clinical development, marketing, labeling, and packaging, storage, distribution, post- approval monitoring and reporting, advertising and promotion, and export and import of pharmaceutical and biological products, such as those we are developing. Pricing of such products is also subject to regulation in many countries. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. U. S. Government Regulation The FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (" FDCA ") and its implementing regulations, and biologics under the FDCA and the Public Health Service Act (" PHSA ") and its implementing regulations. FDA approval is required before any new unapproved drug or biologic or dosage form, including a new use of a previously approved drug, can be marketed in the U. S. Drugs and biologics are also subject to other federal, state, and local statutes and regulations. If we fail to comply with applicable FDA or other requirements at any time during the product development process, clinical testing, approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA' s refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any FDA enforcement action could have a material adverse effect on us. The process required by the FDA before product candidates may be marketed in the United States generally involves the following: • completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the Good Laboratory Practices (" GLP ") regulations; • submission to the FDA of an IND which must become effective before human clinical trials may begin and must be updated annually; • approval by an independent institutional review board (" IRB ") or ethics committee representing each clinical site before each clinical trial may be initiated; • performance of adequate and well- controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication; • completion of manufacturing scale up and stability studies, all performed in accordance with the Good Manufacturing Practices " GMP " regulations; • preparation of and submission to the FDA of a biologics license application (" BLA ") or a new drug application, or NDA, after completion of all pivotal clinical trials; • potential review of the product application by an FDA advisory committee, where appropriate and if applicable; • a determination by the FDA within 60 days of its receipt of a BLA or NDA to file the application for review; • satisfactory completion of an FDA pre- approval inspection of the manufacturing facilities where the proposed product is produced to assess compliance with current Good Manufacturing Practices (" cGMP ") regulations; • potential FDA audit of the clinical trial sites that generated the data in support of the BLA or NDA; and • FDA review and approval of a BLA or NDA prior to any commercial marketing or sale of the product. The preclinical and clinical testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans in clinical trials. The central focus of an IND submission is on the general investigational plan and the protocol (s) for human trials. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational new drug. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical trials can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence. The FDA may impose a clinical hold at any time during clinical trials and may impose a partial clinical hold that would limit trials, for example, to certain doses or for a certain length of time. Clinical Trials Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with Good Clinical Practices (" GCPs ") which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site' s IRB before the trials may be initiated, and the IRB must monitor the trial until completed. There are also requirements governing the

reporting of ongoing clinical trials and clinical trial results to public registries. The clinical investigation of a drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. • Phase 1. The drug is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational new drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. • Phase 2. The drug is administered to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks, and preliminarily evaluate efficacy. • Phase 3. The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites to generate enough data to evaluate dosage, clinical effectiveness and safety, to establish the overall benefit- risk relationship of the investigational new drug product, and to provide an adequate basis for physician labeling. In some cases, the FDA may condition approval of a BLA or NDA for a product candidate on the sponsor' s agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the drug. Such post- approval studies are typically referred to as Phase 4 clinical trials. Sponsors must also report to the FDA, within certain timeframes, serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator' s brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the product candidate. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives or competitive climate. The clinical trial process can take three to ten years or more to complete, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Results from one trial are not necessarily predictive of results from later trials. A drug being studied in clinical trials may be made available to individual patients in certain circumstances. Pursuant to the 21st Century Cures Act (" Cures Act ") which was signed into law in December 2016, the manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug (compassionate use). This requirement applies on the later of 60 calendar days after the date of enactment of the Cures Act or the first initiation of a Phase 2 or Phase 3 trial of the investigational drug. At this time, Eledon does not have a program for the compassionate use of an investigational product outside of a clinical trial as it is not applicable to our investigational products. Submission of a BLA or NDA to the FDA Assuming successful completion of all required testing (e. g., completion of pivotal clinical trials) in accordance with all applicable regulatory requirements, detailed investigational new drug product information is submitted to the FDA in the form of a BLA or NDA requesting approval to market the product for one or more indications. Under federal law, the submission of most BLAs and NDAs is subject to an application user fee and these fees are typically increased on an annual basis. Applications for orphan drug products are exempted from the BLA and NDA user fees and may be exempted from product and establishment user fees, unless the application includes an indication for other than a rare disease or condition. No application user fees were paid for tegoprubart in calendar ~~2022~~ **2023** . A BLA or NDA for a new molecular entity must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product' s chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company- sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from several alternative sources, including investigator- initiated trials that are not sponsored by Eledon. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational new drug product to the satisfaction of the FDA. Once a BLA or NDA for a new molecular entity has been submitted, the FDA' s goal is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life- threatening indication, six months after the FDA accepts the application for filing. The review process is often significantly extended by the FDA' s requests for additional information or clarification. Before approving a BLA or NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA or NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA' s Decision on a BLA or NDA The FDA evaluates a BLA to determine whether the data demonstrate that the biologic is safe, pure, and potent, or effective, and an NDA to determine whether the drug is safe and effective. After the FDA evaluates the BLA or NDA and conducts inspections of manufacturing facilities where the product will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application is not ready for approval. A Complete Response Letter may require additional clinical data or an additional pivotal Phase 3 clinical trial (s), or other significant, expensive and time- consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the BLA or NDA does not satisfy the criteria for approval and issue a denial. The FDA could also

approve the BLA or NDA with a Risk Evaluation and Mitigation Strategy (“ REMS ”) plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post- market studies or clinical trials. Such post- market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product’ s safety and effectiveness after commercialization. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA’ s policies may change, which could delay or prevent regulatory approval of our products under development. Pediatric Trials and Exclusivity Under the Pediatric Research Equity Act of 2003 (“ PREA ”) as amended, BLAs and NDAs must contain data to assess the safety and effectiveness of an investigational new drug product for the claimed indications in all relevant pediatric populations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. A sponsor who is planning to submit a marketing application for a drug product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan (“ PSP ”) within sixty days of an end- of- phase 2 meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers if certain criteria are met. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed- upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials, and / or other clinical development programs. The requirements for pediatric data do not apply to any drug for an indication for which orphan designation has been granted. In the future we may seek pediatric approval for tegoprubart applications in connection with renal and islet cell transplantations, which may require the submission of a PSP. Pediatric exclusivity is another type of non- patent exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the five- year and three- year non- patent and orphan exclusivity. This six- month exclusivity may be granted if a BLA or NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA’ s request, the additional protection is granted. If reports of FDA- requested pediatric trials are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection covering the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot accept or approve another application relying on the BLA or NDA sponsor’ s data. Post- Approval Requirements Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data. Drug manufacturers are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third- party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. We rely, and expect to continue to rely, on third parties for the production of clinical quantities of our product candidates and expect to rely in the future on third parties for the production of commercial quantities. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production, distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved BLA or NDA, including withdrawal or recall of the product from the market or other voluntary, FDA- initiated or judicial action that could delay or prohibit further marketing. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA’ s policies may change, which could delay or prevent regulatory approval of our products under development. The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post- market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things: • restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls; • fines, untitled or warning letters or holds on post- approval clinical trials; • refusal of the FDA to approve pending BLAs or NDAs or supplements to approved BLAs or NDAs, or suspension or revocation of licenses or withdrawal of approvals; • product seizure or detention, or refusal to permit the import or export of products; or • injunctions or the imposition of civil or criminal penalties. The FDA strictly regulates marketing, labeling, advertising, and promotion of

products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses, and a company that is found to have improperly promoted off- label uses may be subject to significant liability. Orphan Designation and Exclusivity The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200, 000 individuals in the United States, or if it affects more than 200, 000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales 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. In addition, if a product is the first to receive FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. The Company received orphan drug designations for tegoprubart for the treatment of ALS and prevention of allograft rejection in pancreatic islet cell transplantation. Patent Term Restoration Depending upon the timing, duration, and specifics of the FDA approval of the use of our product candidates, some of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product' s approval date. The patent term restoration period is generally one- half the time between the effective date of an IND and the submission date of a BLA or NDA, plus the time between the submission date and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within 60 days of the product' s approval. The U. S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of the patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA or NDA. Abbreviated New Drug Applications for Generic Drugs In 1984, with passage of the Hatch- Waxman Amendments, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application (" ANDA ") to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug (" RLD "). Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is " bioequivalent " to the innovator drug. Under the statute, a generic drug is bioequivalent to an RLD if " the rate and extent of absorption of the generic drug do not show a significant difference from the rate and extent of absorption of the listed drug. " Upon approval of an ANDA, the FDA indicates that the generic product is " therapeutically equivalent " to the RLD and it assigns a therapeutic equivalence rating to the approved generic drug in its publication " Approved Drug Products with Therapeutic Equivalence Evaluations, " also referred to as the " Orange Book. " Physicians and pharmacists consider an " AB " therapeutic equivalence rating to mean that a generic drug is fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA' s designation of an " AB " rating often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient. The FDCA provides a period of five years of non- patent exclusivity for a new drug containing a new chemical entity. In cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three- year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. Hatch- Waxman Patent Certification and the 30- Month Stay Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant' s product or a method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. Specifically, the applicant must certify with respect to each patent that: • the required patent information has not been filed; • the listed patent has expired; • the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or • the listed patent is invalid, unenforceable or will not be infringed by the new product. A certification that the new product will not infringe the already approved product' s listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the

FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant. European Union / Rest of World Government Regulation In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. The cost of establishing a regulatory compliance system for numerous varying jurisdictions can be very significant. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union (" EU ") and in other jurisdictions, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others. Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, a clinical trial authorization application (" CTA ") must be submitted for each clinical protocol to each country' s national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is accepted in accordance with a country' s requirements, the clinical trial may proceed. The requirements and process governing the conduct of clinical trials vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP the applicable regulatory requirements, and the ethical principles that have their origin in the Declaration of Helsinki. To obtain regulatory approval of an investigational medicinal product under EU regulatory systems, we must submit a marketing authorization application. The content of the BLA or NDA filed in the United States is like that required in the EU, except, among other things, country- specific document requirements. For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing product licensing, pricing, and reimbursement vary from country to country. Countries that are part of the EU, as well as countries outside of the European Union, have their own governing bodies, requirements, and processes with respect to the approval of pharmaceutical and biologic products. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Authorization Procedures in the EU Medicines can be authorized in the EU by using either the centralized authorization procedure or national authorization procedures. • Centralized procedure. The EMA implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the European Economic Area (" EEA "). This procedure results in a single marketing authorization issued by the EMA that is valid across the EEA. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV / AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines. • For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the European Commission following a favorable opinion by the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health. • National authorization procedures. There are also two other possible routes to authorize medicinal products in several EU countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure: • Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure. • Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization. In some cases, a Pediatric Investigation Plan (" PIP ") or a request for waiver or deferral, is required for submission prior to submitting a marketing authorization application. A PIP describes, among other things, proposed pediatric trials and their timing relative to clinical trials in adults. A PIP will be submitted to EMA and other EU countries, as required. The PIP will need to be submitted early during product development before marketing authorization applications are submitted. The timing of PIP submission cannot be after initiation of pivotal trials or confirmatory (phase 3) trials. In the future we may seek pediatric approval for tegoprubart applications in connection with renal and islet cell transplantations, which may require the submission of a PIP. Exclusivity of New Chemical Entities and New Fixed Dose Combinations In the EU, new chemical entities, sometimes referred to as new active substances as well as new fixed dose combinations, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator' s data to assess a generic (abbreviated) application for eight years, after which a generic application can be submitted, and the innovator' s data may be referenced, but not approved for two years. The overall ten- year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Exceptional Circumstances / Conditional Approval Orphan drugs or drugs with unmet medical needs may be eligible for EU approval under exceptional circumstances or with conditional approval. Approval under exceptional circumstances may be applicable to orphan products and is used when an applicant is unable to provide comprehensive data on the efficacy and safety under normal conditions of use because the indication for which the product is intended is encountered so rarely that the applicant cannot reasonably be expected to provide

comprehensive evidence, when the present state of scientific knowledge does not allow comprehensive information to be provided, or when it is medically unethical to collect such information. Conditional marketing authorization may be applicable to orphan medicinal products, medicinal products for seriously debilitating or life- threatening diseases, or medicinal products to be used in emergency situations in response to recognized public threats. Conditional marketing authorization can be granted on the basis of less complete data than is normally required in order to meet unmet medical needs and in the interest of public health, provided the risk- benefit balance is positive, it is likely that the applicant will be able to provide the comprehensive clinical data, and unmet medical needs will be fulfilled. Conditional marketing authorization is subject to certain specific obligations to be reviewed annually. Accelerated Review Under the centralized procedure in the EU, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the EMA' s Committee for Medicinal Products for Human Use, or CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days, excluding clock stops. Pharmaceutical Coverage, Pricing and Reimbursement Significant uncertainty exists as to the coverage and reimbursement status of any products for which we obtain regulatory approval. In the United States and in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third- party payors. Third- party payors include government authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Third- party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA- approved products for a particular indication. Moreover, a payor' s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third- party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Third- party payors are increasingly challenging the price and examining the medical necessity and cost- effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost- effectiveness of our products, in addition to the costs required to obtain regulatory approvals. Our product candidates may not be considered medically necessary or cost- effective. If third- party payors do not consider a product to be cost- effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. The U. S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government- paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. By way of example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the Affordable Care Act, contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. Some of the provisions of the Affordable Care Act have yet to be fully implemented, while certain provisions have been subject to judicial and congressional challenges. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, that while not a law, is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the Affordable Care Act. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the Affordable Care Act that are repealed. Thus, the full impact of the Affordable Care Act, any law replacing elements of it, or the political uncertainty surrounding its repeal or replacement on our business remains unclear. Adoption of government controls, measures and tightening of restrictive policies in jurisdictions with existing controls and measures could limit payments for pharmaceuticals. In European countries, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost- effectiveness of a product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross- border imports from low- priced markets exert a commercial pressure on pricing within a country. The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third- party payors fail to provide adequate coverage and reimbursement. In addition, the emphasis on cost containment measures in the United States and other countries has increased, and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third- party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Other Healthcare Laws and Compliance Requirements If we obtain regulatory approval for any of

our product candidates, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include: • the federal Anti- Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; • federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third- party payors that are false or fraudulent; • the federal Health Insurance Portability and Accountability Act of 1996, (" HIPAA "), which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters; • the federal transparency laws, including the provision of the Affordable Care Act referred to as the federal Physician Payment Sunshine Act, that requires drug and biologics manufacturers to disclose payments and other transfers of value provided to physicians and teaching hospitals and ownership interests of physicians and their immediate family members; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (" HITECH ") and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and • state law equivalents of each of the above federal laws, such as anti- kickback and false claims laws that may apply to items or services reimbursed by any third- party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. The Affordable Care Act broadened the reach of the fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti- Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U. S. C. § 1320a- 7b. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute. Many states have adopted laws similar to the federal Anti- Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs. We are also subject to the U. S. Foreign Corrupt Practices Act (" FCPA ") which prohibits improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business. Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, and others may be ineffective, and violations of the FCPA and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, financial condition and result of operations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, exclusion from participation in government healthcare programs, such as Medicare and Medicaid and imprisonment, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Employees As of March ~~29~~ **25** , ~~2023~~ **2024** , Eledon had ~~seventeen~~ **twenty** employees, all of whom are full time. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good. Corporate Information **Otic Pharma, Ltd. (" Otic ") was founded in the State of Israel in 2008. In 2015, Otic established U. S. operations and moved its corporate headquarters to Irvine, California. In 2017, Otic consummated a reverse merger with Tokai Pharmaceuticals, Inc. (" Tokai "), a Delaware corporation that was incorporated on March 26, 2004, pursuant to which, among other things, Tokai purchased from Otic and its stockholders all of the common and preferred shares of Otic in exchange for the issuance of a certain number of shares of common stock of Tokai (the " Reverse Merger "). Following the Reverse Merger, Tokai changed its name to Novus Therapeutics, Inc.** On September 14, 2020, the Company acquired Anelixis Therapeutics, Inc. (" Anelixis "), a Delaware Corporation, after which Anelixis became a wholly owned subsidiary of the Company. On January 4, 2021, the Company changed its name from Novus Therapeutics, Inc. to Eledon Pharmaceuticals, Inc. Our executive offices are located at 19900 MacArthur Boulevard, Suite 550, Irvine, California 92612. The Company also has a research and development office in Burlington, Massachusetts. Our telephone number is (949) 238- 8090 and our website is www. eledon. com. You are advised to read this Annual Report on Form 10- K in conjunction with other reports and documents that we file from time to time with the Securities and Exchange Commission (" SEC "). In particular, please read our definitive proxy statement, which will be filed with the SEC in connection with our ~~2022~~ **2023** annual meeting of stockholders, our quarterly reports on Form 10- Q and any current reports on Form 8- K that we may file from time to time. You may obtain copies of these reports after the date of this annual report directly from us or from the SEC at its website at www. sec. gov. We make our periodic and current reports available on our internet website, free of charge, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. Item 1A. Risk Factors. An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this Annual Report on Form 10- K ~~,~~ and in our other public filings. The occurrence of any of these risks could harm our business, financial condition, results of operations and / or growth prospects or cause our actual results to differ materially from those contained in forward- looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described in our public filings when evaluating our business. Risks Related to Our ~~Limited Operating~~ **Operations** ~~History, Financial Condition, and Capital Requirements. Our short operating history and the Anelixis acquisition may make it difficult to evaluate the success of our business to date and to assess our future viability.~~ We are a clinical stage biopharmaceutical

company. Our ongoing operations to date have been limited to organizing and staffing the Company, business planning, raising capital, acquiring and developing technology, identifying potential product candidates and pursuing nonclinical and clinical trials. We have not yet demonstrated our ability to successfully manufacture drug product in large enough quantities and with stability to support additional clinical trials, execute pivotal clinical trials, obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. It can take many years to develop a new medicine from the time it is discovered to when it is available for treating patients. Consequently, any predictions made about our future success or viability based on our short operating history to date may not be as accurate as they could be if we had a longer operating history. In addition, as a result of the acquisition of Anelixis and our ~~recent~~ decision to discontinue our **Company funding of the** islet cell transplantation program and ~~deprioritize~~ the IgAN program, our future business, prospects, financial position and operating results could be significantly different than those in historical periods or previously projected by our management. In addition, as an early- stage business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. To successfully market any of our current or future product candidates, we will need to transition from a company with a clinical development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. Our consolidated financial statements have been prepared assuming that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. ~~Based on our current operating plans~~ **As a result of the Private Placement described in Part I, Item 2, Management' s Discussion and Analysis of Financial Condition and Results of Operations** , we ~~expect our existing capital resources will fund our planned operating expenses into~~ **may receive up to an additional $ 105. 0 million in tranche financing in a second and a third closing of the Private Placement, subject to achieving specified clinical development milestones and volume weighted average share price levels and trading volume conditions, and an additional $ 45. 5 million assuming the exercise of all Common Warrants issued in the initial closing of the Private Placement. Due to the contingent nature of the Common Warrants and the second and third closings of the Private Placement, the Company has excluded** ~~the~~ **them** ~~first quarter of 2024~~ **from its going concern analysis** . Accordingly, based on recurring losses from operations incurred since inception, the expectation of continued operating losses, and the need to raise additional capital to finance our future operations, we determined that there is substantial doubt about our ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. Additionally, our independent registered public accounting firm has included in its audit opinion for the year ended December 31, ~~2022~~ **2023** , an explanatory paragraph that there is substantial doubt as to our ability to continue as a going concern. There is no assurance that **the milestones required to complete the second and third closings of the Private Placement will be satisfied, that the Common Warrants will be exercised or that other** funding will be available to us, will be obtained on terms favorable to us or will provide us with sufficient funds to meet our objectives. The reaction of investors to the inclusion of a going concern statement by our auditors and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or enter into partnerships. If we become unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our **consolidated** financial statements. We have incurred significant annual net operating losses in every year since our inception. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other general and administrative expenses related to our ongoing operations. If tegoprubart or any future product candidates we develop are not successfully developed and approved, we may never generate any revenue from sales of products. The Company has experienced recurring net losses and negative cash flows from operating activities since its inception. The Company' s net loss for the year ended December 31, ~~2022~~ **2023** is $ ~~88~~ **40** . ~~0~~ **3** million. As of December 31, ~~2022~~ **2023** , the Company had cash and cash equivalents **and short- term investments** of $ ~~56~~ **51** . ~~4~~ **1** million, working capital of $ ~~53~~ **52** . ~~0~~ **2** million and an accumulated deficit of $ ~~202~~ **243** . ~~9~~ **2** million. We have not generated any revenues from product sales, have not completed the development of any product candidate and may never have a product candidate approved for commercialization. We expect it will be several years, if ever, before we have a product candidate ready for commercialization. We have financed our operations to date primarily through **the** ~~sales~~ **sale** of **preferred** ~~equity, including approximately $ 108. 1 million in total gross offering proceeds raised from our September~~ and **common stock** ~~December 2020 financings~~ , and ~~we anticipate that we will require additional financing in~~ the **sale of warrants and** ~~next twelve months. We~~ have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and our clinical trials. Our net losses may fluctuate significantly from quarter to quarter and year to year and will depend, in part, on the rate at which we incur expenses and our ability to generate revenue. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We anticipate that we will continue to incur significant expenses as we: • conduct nonclinical and clinical development of our product candidates or any future product candidate; • seek to identify and acquire additional product candidates; • acquire or in- license other products and technologies; • enter into collaboration arrangements with regards to product discovery or development; • develop manufacturing processes; • seek marketing approvals for any of our product candidates that successfully complete clinical trials; • establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval; • maintain, expand, and protect our intellectual property portfolio; • hire additional personnel; • add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and • operate as a public company. To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including completing clinical trials of our product candidates, obtaining marketing approval for these product candidates and manufacturing, marketing and selling those products for which we obtain marketing approval. We may never succeed in these activities,

including if we do not have available financial resources to allow us to pursue clinical trials and other clinical development activities, and, even if we are successful, we may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the Company, could impair our ability to raise capital, maintain our nonclinical and clinical development efforts, and expand our business or continue our operations and may require us to raise additional capital that may dilute the ownership interest of common stockholders. A decline in the value of the Company could also cause stockholders to lose all or part of their investment. We will require additional funding to be able to complete the development of our lead drug candidate. If we are unable to raise capital, we will be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether. **Our consolidated** ~~Based on our current operating plans, we expect our existing resources will fund our planned operating expenses into the first quarter of 2024, which is less than twelve months from the date of this Annual Report. Accordingly, our~~ financial statements have been prepared on a going concern basis, which contemplates the continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. **As a result of the Private Placement described in Part I, Item 2, Management' s Discussion and Analysis of Financial Condition and Results of Operations, we may also receive up to an additional $ 105. 0 million in tranche financing in a second and a third closing of the Private Placement, subject to achieving specified clinical development milestones and volume weighted average share price levels and trading volume conditions, and an additional $ 45. 5 million assuming the exercise of all Common Warrants issued in the initial closing of the Private Placement. There is no assurance that the milestones required to complete the second and third closings of the Private Placement will be satisfied or that the Common Warrants will be exercised.** We **can also provide no assurance that other funding** will **be available** ~~need substantial additional capital~~ to ~~operate~~ **us, will be obtained on terms favorable to us** ~~our~~ **or** ~~business and continue~~ **will provide us with sufficient funds to meet** our **objectives** ~~development activities~~. If we are unable to raise such capital, or if we are unable to do so on acceptable terms, we will be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether. For example, we are currently unable to continue our clinical development of tegoprubart for people with ALS without additional financing, and we can provide no assurances that we will be able to obtain financing on acceptable terms or at all. Our funding needs may fluctuate significantly based on a number of factors, such as: • the scope, progress, results and costs of formulation development and manufacture of drug product to support nonclinical and clinical development of our product candidates; • the extent to which we enter into additional collaboration arrangements regarding product discovery or development, or acquire or in- license products or technologies; • our ability to establish additional collaborations with favorable terms, if at all; • the costs, timing, and outcome of regulatory review of our product candidates; • the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval; • revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and • the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property- related claims. Identifying potential product candidates and conducting formulation development, nonclinical testing and clinical trials is a time- consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Even if we generate positive clinical data or are able to successfully commercialize one or more of our product candidates, additional financing may not be available to us on acceptable terms, or at all **. In addition to the dilution of our current stockholders' ownership as a result of the Private Placement, we currently have a significant number of securities outstanding that are exercisable for our common stock, which could result in significant additional dilution and downward pressure on our stock price. Future issuances of our common stock, including common stock that may be issuable pursuant to outstanding warrants or other convertible securities, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. As of December 31, 2023, there were 24, 213, 130 shares of our common stock outstanding. As a result of the first closing of the of Private Placement on May 5, 2023, we issued 8, 730, 168 shares of our common stock, Pre- Funded Warrants to purchase 6, 421, 350 shares of common stock and Common Warrants to purchase 15, 151, 518 shares of our common stock to the Purchasers therein. Additionally, up to 20, 202, 024 and 25, 252, 530 shares of common stock or Pre- Funded Warrants may be issued in a second and third closing of the Private Placement, respectively, subject to our achievement of certain milestones and conditions (which may be waived). The issuance of the common stock in the first closing of the Private Placement diluted the ownership interests of our existing stockholders, and the issuance of shares of common stock upon exercise of the Pre- Funded Warrants or the Common Warrants issued in the initial closing of the Private Placement or any additional shares of common stock that may be issued, including pursuant to the exercise of additional Pre- Funded Warrants, in the second or third closings of the Private Placement, would result in significant additional dilution to our current stockholders, which could adversely affect the price of our common stock and the terms on which we could raise additional capital. If we sell additional shares of common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock** . We currently do not have any products that have gained regulatory approval. We have invested substantially all **of** our efforts and financial resources in the development of our lead drug candidate tegoprubart, including funding nonclinical studies, clinical trials, drug formulation and the manufacturing of clinical trial materials. Our ability to generate product

revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of one or more drug candidates. As a result, our business is substantially ~~dependent~~ **depending** on our ability to successfully complete the development of and obtain ~~regulatory~~ approval for one of our potential future additional product candidates. We have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical area. For example, to execute our business plan, we will need to successfully: • obtain additional financing in order to advance our drug product through clinical development, and to manufacture, obtain regulatory approval for and commercialize our product candidates; • execute formulation, manufacturing, clinical, and nonclinical development activities; • manufacture drug product at commercial scale; • establish and confirm commercially acceptable stability (shelf- life) of our drug products; • in- license or acquire other product candidates and advance them through clinical development; • obtain required regulatory approvals for the development and commercialization of tegoprubart or other product candidates; • maintain, leverage, and expand our intellectual property portfolio; • build and maintain robust sales, distribution and marketing capabilities, either on our own or in collaboration with strategic partners; • gain market acceptance for any approved and marketed drug products; • obtain and maintain adequate product pricing and reimbursement; • develop and maintain any strategic relationships we elect to enter; and • manage our spending as costs and expenses increase due to product manufacturing, nonclinical development, clinical trials, regulatory approvals, post- marketing commitments, and commercialization. If we are unsuccessful in accomplishing these objectives, we may not be able to successfully develop and commercialize our or other product candidates, and our business will suffer. **Public health crises, including pandemics or epidemics could adversely affect our business.** Our business and operations, including but not limited to ongoing or planned research and development activities ~~, have been and~~ may ~~continue to~~ be **impacted by public health crises. For example, our business was** adversely affected by the COVID- 19 pandemic, which ~~has~~ also caused significant disruption in the operations of third parties upon whom we rely. Other future public health crises, **including any future** pandemics or epidemics could have a similar impact on our business. We have experienced, and may in the future experience disruptions as a result of the COVID- 19 pandemic or from another public health crisis, **including any future** pandemic or epidemic **,** that could severely impact our operations and development activities, including, but not limited to: • delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; • delays in manufacturing of our drug candidates due to increased competition for manufacturing capacity as a result of the pandemic; • limitations in employee resources that would otherwise be focused on the conduct of our development activities, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; • refusal of the FDA to accept data from clinical trials in affected geographies; • delays in procuring drug substance and / or in manufacturing drug product due to limitations in employee resources or forced furloughs at our contract manufacturing organizations; • delays in initiation of future clinical trials, including delays in receiving authorization from local regulatory authorities to initiate such clinical trials; and • delays or disturbances in enrollment and trial execution, for example, because clinical trial sites may be unable to operate normally, or patients may elect to forego visits to medical facilities or undertake voluntary medical procedures. Any of the foregoing factors, or other effects of **any** ~~the COVID- 19 pandemic or another~~ public health crisis, **including any future** pandemic or epidemic, could materially affect our business, possibly to a significant degree. The severity and duration of any such impacts cannot be predicted. Unfavorable global economic conditions could adversely affect our business, financial condition and results of operations ~~.~~ The global economy, including the financial and credit markets, ~~has recently~~ **continues to** ~~experienced~~ **experience** extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates, rising interest rates and uncertainty about economic stability. Likewise, the current ~~conflict~~ **conflicts** ~~between~~ **in** Ukraine and ~~Russia has~~ **the Middle East have** created extreme volatility in the global capital markets and global economic consequences, including disruptions of the global supply chain and energy markets. A severe or prolonged economic downturn or continued volatility in the financial and credit markets could negatively impact our ability to obtain necessary debt or equity financing in a timely manner or on favorable terms, if at all. The severity and duration of any such impacts cannot be predicted. Any such failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies or cause us to delay our clinical development plans, research and development programs or commercialization efforts, out- license intellectual property rights to our product candidates or sell unsecured assets, or a combination of the above. Any of these actions could materially harm our business. For example, we do not currently have sufficient liquidity to fund the continued clinical development of tegoprubart for people with ALS without additional financing, notwithstanding the positive topline results of our Phase 2a study of tegoprubart for adult subjects with ALS. In addition, ~~our existing capital resources will fund our planned operating expenses only into the first quarter of 2024 and~~ if we are unable to raise capital, we will be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether. In addition, inflation has recently increased throughout the U. S. economy. As a result of inflation, we have experienced and may continue to experience cost increases, including costs of clinical trials and research and development of our product candidates, production costs, the price of labor, administration and other costs of doing business. Although we may continue to take measures to mitigate the impact of this inflation, if these measures are not effective, our business, financial condition, results of operations and liquidity could be materially adversely affected. Further, in an inflationary environment, cost increases may outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise more capital to fund our operations than expected, and such capital may not be available in sufficient amounts or on reasonable terms, if at all. We ~~regularly~~ **currently** maintain domestic cash deposits **, for short term operating requirements,** in Federal Deposit Insurance Corporation (" FDIC ") insured banks, which exceed the FDIC insurance limits. **Our additional cash and cash equivalents are held in accounts managed by third - party financial**

institutions and consist of primarily of cash invested in money market funds and government bonds. Bank failures, events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, or concerns or rumors about such events, may lead to widespread demands for customer withdrawals and liquidity constraints that may result in market- wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank failed and was taken into receivership by the FDIC. At ~~this~~ **that** time, we maintained deposits amounting to approximately 78 % of our total cash at Silicon Valley Bank. On March ~~13~~ **26** , 2023, the assets **, deposits** and ~~operations~~ **loans** of Silicon Valley Bank were acquired by ~~Silicon Valley Bridge~~ **First- Citizens** Bank **& Trust Company** ~~, which is guaranteeing full access to deposits, including ours~~ . In response to the failure of Silicon Valley Bank, we ~~are in the process of diversifying~~ **diversified** our cash deposits **into money market funds** , ~~although we expect that~~ **U. S. treasuries and U. S. government agency securities and, as of the date of this report,** our **total** cash **maintained in** ~~deposits will continue to exceed~~ FDIC ~~limits~~ **insured banking accounts is less than 3 % of our total cash and cash equivalents and short- term investments** . The failure of a bank, or other adverse conditions in the financial or credit markets impacting financial institutions at which we maintain balances, could adversely impact our liquidity and financial performance. There can be no assurance that our deposits in excess of the FDIC or other comparable insurance limits will be backstopped by the U. S. or any applicable foreign government in the future or that any bank or financial institution with which we do business will be able to obtain needed liquidity from other banks, government institutions or by acquisition in the event of a future failure or liquidity crisis **. Additionally, our cash investments outside of FDIC insured bank accounts are subject to general credit, liquidity, market, and interest rate risks. If the carrying value of an investment exceeds the fair value, and the decline in fair value is deemed to be other- than- temporary, we are required to write down the value of the investment, which could materially harm our results of operations and financial condition and could limit our access to liquidity** . Drug development involves a lengthy and expensive process with an uncertain outcome, including failure to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the formulation and commercialization of our product candidates. Given the early stage of development for our product candidates, the risk of failure is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must conduct nonclinical trials, and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Formulation and device development, nonclinical and clinical testing are all expensive activities, difficult to design and implement, and can take years to complete. Failure can occur at any time during the development program, including during the clinical trial process. Further, the results of nonclinical studies and early clinical trials of our product candidates, as well as earlier generation formulations may not be predictive of the results of later- stage clinical trials. Interim results of a clinical trial do not necessarily predict final results. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical and clinical trials have nonetheless failed to obtain marketing approval of their products. There is a risk that additional nonclinical and / or clinical safety studies will be required by the FDA or similar regulatory authorities outside the United States and / or that subsequent studies will not match results seen in prior studies. It is impossible to predict when or if any of our product candidates will prove effective, safe and well- tolerated in humans or will receive regulatory approval. We may experience delays in our clinical trials, and we do not know whether planned clinical trials will begin or enroll subjects on time, need to be redesigned or be completed on schedule, if at all. There can be no assurance that the FDA or equivalent foreign regulatory bodies will approve investigational new drug applications and allow us to start clinical trials for any of our product candidates in the future, including for islet cell transplant. Once a clinical trial has commenced, there is also no assurance that the FDA or equivalent foreign regulatory body will not put any of our product candidates on clinical hold. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as: • delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that we want to execute; • delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial; • delays in reaching, or failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites; • delays in completing formulation development and manufacturing as a prerequisite to commencing clinical work; • inability, delay, or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in other clinical programs; • delay or failure in recruiting and enrolling suitable subjects to participate in a trial; • delay or failure in having subjects complete a trial or return for post- treatment follow- up; • clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial; • lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials and increased expenses associated with the services of our contract research organizations (“ CROs ”) and other third parties; • clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; • the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate; • we may experience delays or difficulties in the enrollment of patients that our product candidates are designed to target; • our third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • we may have difficulty partnering with experienced CROs and study sites that can identify patients that our product candidates are designed to target and run our clinical trials effectively; • regulators or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; •

the cost of clinical trials of our product candidates may be greater than we anticipate; • the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; or • there may be changes in governmental regulations or administrative actions. In addition, our development and commercialization activities could be harmed or delayed by a shutdown of the U. S. government, including the FDA. For example, a prolonged shutdown may significantly delay the FDA' s ability to timely review and process any submissions we may file or cause other regulatory delays, which could materially and adversely affect our business. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive, or if there are safety concerns, we may: • be delayed in obtaining marketing approval for our product candidates; • not obtain marketing approval at all; • obtain approval for indications or patient populations that are not as broad as intended or desired; • obtain approval with labeling that includes significant use or distribution restrictions or safety warnings that would reduce the potential market for our products or inhibit our ability to successfully commercialize our products; • be subject to additional post- marketing restrictions and / or testing requirements; or • have the product removed from the market after obtaining marketing approval. Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our nonclinical studies or clinical trials will need to be restructured or will be completed on schedule, or at all. Significant nonclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or may allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented and expenses for the development of our product candidates could increase. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to demonstrate safety and efficacy. We do not know whether the ongoing or planned clinical trials will enroll subjects in a timely fashion, require redesign of essential trial elements or be completed on its projected schedule. In addition, competitors may have ongoing clinical trials for product candidates that treat related or the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Patient enrollment is affected by other factors including: • the eligibility criteria for the study in question; • the perceived risks and benefits of the product candidate under study; • the efforts to facilitate timely enrollment in clinical trials; • the inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same disease indication; • the patient referral practices of physicians; • the proximity and availability of clinical trial sites for prospective patients; • ambiguous or negative interim results of our clinical trials, or results that are inconsistent with earlier results; • feedback from regulatory authorities, IRBs, ethics committees (" ECs "), or data safety monitoring boards, or results from earlier stage or concurrent nonclinical and clinical trials, that might require modifications to the protocol; • decisions by regulatory authorities, IRBs, ECs, or the Company, or recommendations by data safety monitoring boards, to suspend or terminate clinical trials at any time for safety issues or for any other reason; and • unacceptable risk- benefit profile or unforeseen safety issues or adverse effects. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of the Company to decline and limit our ability to obtain additional financing. Our ability to conduct clinical trials in some jurisdictions outside of the United States may be adversely affected. We currently have clinical trial sites in regions outside the United States, including Asia, the European Union and the United Kingdom, and we will continue to conduct future clinical trials in these markets. Our ability to conduct clinical trials at sites located outside the United States is subject to numerous risks unique to conducting business in jurisdictions outside the United States, including: • difficulty in establishing or managing relationships with qualified CROs, physicians and clinical trial sites; • different local standards for the conduct of clinical trials; • difficulty in complying with various and complex import laws and regulations when shipping drugs to certain countries; • the potential burden of complying with a variety of laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments; • lack of consistency in standard of care from country to country; • diminished protection of intellectual property in some countries; • instability in economic or political conditions, including inflation, recession and actual or anticipated military conflicts, social upheaval or political uncertainty; • foreign exchange fluctuations; • cultural differences in medical practice and clinical research; and • changes in country or regional regulatory requirements. **The ongoing conflict in** ~~Additionally, Russia' s February 2022 invasion of~~ Ukraine and the resulting imposition of economic and other sanctions by the United States, European Union and many other nations on Russia, individuals in Russia, Russian businesses and the Russian central bank, or any escalation of tensions in the region, could have a broader impact that expands into other countries. **The ongoing conflict in the Middle East could have similar impacts.** Although the length and impact of any military action and expansion of the conflict into other countries are highly unpredictable, if ~~the~~ **either** conflict spreads or has effects on **additional** countries ~~outside Ukraine and Russia~~, we may experience disruptions or delays in our plans to conduct clinical trial activities in affected regions outside the United States. If our product candidates are associated with undesirable effects in nonclinical or clinical trials or have characteristics that are unexpected, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective. Any occurrences of clinically significant adverse events with our product candidates may harm our business, financial condition and prospects significantly. Tegoprubart is an early - product candidate, and the side effect profile in humans has not been fully established. Currently unknown, drug- related side effects may be identified through ongoing and future clinical trials and, as such, these

possible drug- related side effects could affect patient recruitment, the ability of enrolled subjects to complete the trial, or result in potential product liability claims. We are highly dependent on the product development, clinical and business development expertise of the principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executives and key employees, each of them may terminate their employment with us at any time. We do not maintain " key person " insurance for any of our executives or other employees. Our recent decision to discontinue the islet cell transplantation program and ~~deprioritize the~~ IgAN program and uncertainties regarding our financial condition may increase the likelihood that employees depart in the foreseeable future. Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel is critical to our success. Due to the small size of the Company and the limited number of employees, each of our executives and key employees serves in a critical role. The loss of the services of our executive officers or other key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of, and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating drug product, nonclinical development, clinical development, regulatory strategy, and commercial strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to provide services to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited. Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters Our product candidates must be approved by the FDA pursuant to a new drug application in the United States and by other regulatory authorities outside the United States prior to commercialization in the respective regions. The process of obtaining marketing approvals, both in the United States and outside the United States, is expensive and takes several years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any country. We have no experience in filing and supporting the applications necessary to gain marketing approvals for our products and may engage third- party consultants to assist in this process. Securing marketing approval requires the submission of extensive nonclinical and clinical data, and other supporting information to regulatory authorities for each therapeutic indication to establish the product candidate' s safety and efficacy. Securing marketing approval also requires the submission of information about the product formulation and manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical, clinical or other data. In addition, varying interpretations of the data obtained from nonclinical and clinical trials could delay, limit or prevent marketing approval of a product candidate. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may also cause delays in or prevent the approval of an application. Any marketing approval we ultimately obtain may be for fewer or more limited indications than requested or subject to restrictions or post- approval commitments that render the approved product not commercially viable or its market potential significantly impaired. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. In order to market and sell our products in the EU and other international jurisdictions outside of the United States, we or our third- party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may require additional nonclinical, clinical or health outcome data. In addition, the time required to obtain approval may differ substantially amongst international jurisdictions. The regulatory approval process outside the United States generally includes all the risks associated with obtaining FDA approval. In addition to regulatory approval, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired. Any product candidate for which we obtain marketing approval will be subject to extensive post- marketing regulatory requirements and could be subject to post- marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved. Our product candidates and the activities associated with their development and commercialization, including their testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation that are specific to those defined by regulatory authorities in the countries where the product is approved. In the United States and other countries that follow the International Conference on Harmonization, these requirements include submissions of safety and other post- marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by the FDA and other regulatory authorities, requirements regarding the distribution of samples to physicians and recordkeeping. The FDA, or other regulatory authorities,

may also impose requirements for costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post- approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products and if we promote our products beyond their approved indications, we may be subject to enforcement action for off- label promotion. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including: • restrictions on such products, manufacturers, or manufacturing processes; • restrictions on the labeling or marketing of a product; • restrictions on product distribution or use; • requirements to conduct post- marketing studies or clinical trials; • warning or untitled letters; • withdrawal of the products from the market; • refusal to approve pending applications or supplements to approved applications that we submit; • recall of products; • fines, restitution or disgorgement of profits or revenues; • suspension or withdrawal of marketing approvals; • refusal to permit the import or export of our products; • product seizure; or Non- compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the EU' s requirements regarding the protection of personal information can also lead to significant penalties and sanctions. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes intended to contain healthcare costs and modify the regulation of drug and biologic products. These and other regulatory changes could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. For example, on August 16, 2022, the U. S. government enacted the Inflation Reduction Act of 2022, which, among other things, includes policies that are designed to have a direct impact on drug prices and reduce drug spending by the federal government, which shall take effect in 2023. The Inflation Reduction Act requires drug manufacturers to pay rebates to Medicare if they increase prices faster than inflation for certain drugs used by Medicare beneficiaries. The mechanics of the rebate calculation would mimic those of the Medicaid rebate, but the expansion of inflation- based rebates may further complicate pricing strategies. The Inflation Reduction Act of 2022 or other similar legislation could have the effect of reducing the prices we can charge and reimbursement we receive for our products, thereby reducing our profitability. We expect that additional state and federal healthcare reform measures and regulations will be adopted in the future. Any of these measures and regulations could limit the amounts that federal and state governments will pay for healthcare products and services, result in reduced demand for our product candidates or additional pricing pressures and affect our product development, testing, marketing approvals and post- market activities. Laws, restrictions, and other regulatory measures are also imposed by healthcare laws and regulations in international jurisdictions and in those jurisdictions we face the same issues as in the United States regarding difficulty and cost for us to obtain marketing approval and commercialization of our product candidates and which may affect the prices we may obtain. In some countries, particularly the countries of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially. Our business operations and relationships with healthcare providers, physicians, third- party payers, and customers will be subject to applicable anti- kickback, fraud and abuse and other broadly applicable healthcare laws, which could expose us to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm and diminished profits and future earnings. Healthcare providers, physicians and third- party payers will play a primary role in the recommendation and prescription of any product candidates for which we receive marketing approval. Our current and future arrangements may expose us to broadly applicable fraud and abuse and other healthcare laws that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute the products for which we receive marketing approval. Even though we will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third- party payers, federal and state healthcare laws are and will be applicable to our business. Such laws include, but are not limited to federal false claims, false statements and civil monetary penalties laws, including the federal civil False Claims Act (" FCA "), the federal Anti- Kickback Statute, the federal Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), patient data privacy and security regulation, including, in the United States, HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009 (" HITECH "), the federal transparency requirements under the Physician Payments Sunshine Act, and analogous state, local or foreign law. Pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off- label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, disgorgement, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting obligations, contractual damages,

reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Laws, restrictions, and other regulatory measures are also imposed by anti- kickback, fraud and abuse, and other healthcare laws and regulations in international jurisdictions, and in those jurisdictions we face the same issues as in the United State regarding exposure to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm, and diminished profits and future earnings. We depend on our information ~~technology~~ systems and those of our third- party collaborators, service providers, contractors or consultants. Our **information** ~~internal computer~~ systems, or those of our third- party collaborators, service providers, contractors or consultants, may fail or suffer ~~security~~ **cybersecurity** ~~breaches, disruptions, or~~ incidents, which could result in a material disruption of our development programs or loss of data or compromise the privacy, security, integrity or confidentiality of sensitive information related to our business and have a material adverse effect on our reputation, business, financial condition or results of operations. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. Our **information** ~~internal technology~~ systems and infrastructure, and those of our current or future third- party collaborators, service providers, contractors and consultants are vulnerable to damage from **cybersecurity incidents, including** computer viruses **, denial- of- service attacks, hacking, phishing and other social engineering attacks** , unauthorized access or use resulting from malware, **as well as disruptions due to** natural disasters, terrorism, war and telecommunication and electrical failures **. We may also experience cybersecurity incidents stemming from** ~~, denial- of- service attacks, cyber- attacks or cyber- intrusions over the Internet, hacking, phishing and other social engineering attacks,~~ persons inside our organizations (including employees or contractors), ~~loss~~ or **other** ~~theft, or~~ persons with access to **information** systems inside our organization. Attacks on information ~~technology~~ systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized foreign governments, groups and individuals with a wide range of motives and expertise. In addition to extracting or accessing sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial- of- service attacks, social engineering and other means to affect service reliability and threaten the security, confidentiality, integrity and availability of information. The prevalent use of mobile devices that access sensitive information also increases the risk of data security incidents which could lead to the loss of confidential information or other intellectual property. While to our knowledge we have not experienced any material **information** system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or the operations of third- party collaborators, service providers, contractors and consultants, it could result in a material disruption of our development programs and significant reputational, financial, legal, regulatory, business or operational harm. The costs to us to mitigate, investigate and respond to potential security incidents, breaches, disruptions, network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information ~~technology~~ systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any real or perceived security breach affects our **information** systems (or those of our third- party collaborators, service providers, contractors or consultants), or results in the loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could ~~incur~~ **be found to have violated applicable U. S. and international privacy, data protection and other laws, which could subject us to litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the U. S. and by international regulatory entities, resulting in exposure to material civil and / or criminal** ~~liabilities~~ **liability .** and the further development of our product candidates could be delayed. Such a breach may require notification to governmental agencies, the media or individuals pursuant to various foreign, domestic (federal and state) privacy and security laws, if applicable, including HIPAA, as amended by HITECH, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to ~~security~~ **cybersecurity** ~~breaches, cyberattacks and other related~~ incidents. Any failure or perceived failure by us or any third- party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations, or any data security incidents or other security breaches that result in the accidental, unlawful or unauthorized access to, use of, release of, processing of, or transfer of sensitive information, including personally identifiable information, may result in negative publicity, harm to our reputation, governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or could result in claims by third parties, including those that assert that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. To the extent we maintain individually identifiable health information, we could be subject to fines and penalties (including civil and criminal) under HIPAA for any failure by us or our business associates to comply with HIPAA' s requirements. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm. While we have implemented data security measures intended to protect our information, data, information ~~technology~~ systems, applications and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or ~~data security~~ **cybersecurity** incidents. European data collection is governed by restrictive regulations governing the collection, use, processing and cross- border transfer of

personal information. We may collect, process, use or transfer personal information from individuals located in the European Economic Area in connection with our business, including in connection with conducting clinical trials in the EEA. Additionally, if any of our product candidates are approved, we may seek to commercialize those products in the European Economic Area. The collection and use of personal health data in the European Economic Area is governed by the provisions of the General Data Protection Regulation ((EU) 2016 / 679) (the " GDPR "), along with other European Union and country-specific laws and regulations. The United Kingdom and Switzerland have also adopted data protection laws and regulations. These legislative acts (together with regulations and guidelines) impose requirements relating to having legal bases for processing personal data relating to identifiable individuals and transferring such data outside of the European Economic Area, including to the United States, providing details to those individuals regarding the processing of their personal data, keeping personal data secure, having data processing agreements with third parties who process personal data, responding to individuals' requests to exercise their rights in respect of their personal data, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers or corporate representatives, conducting data protection impact assessments and record- keeping. The GDPR imposes additional responsibilities and liabilities in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. Failure to comply with the requirements of the GDPR and related national data protection laws of the member states of the European Economic Area and other states in the European Economic Area may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, financial condition and results of operations. European data protection authorities may interpret the GDPR and national laws differently and may impose additional requirements, which adds to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices are often updated or otherwise revised. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our nonclinical or clinical development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Risks Related to the Commercialization of Our Product Candidates If any of our product candidates receives marketing approval, we may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payers and others in the medical community. In addition, physicians, patients and third- party payers may prefer other novel products to ours. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including: • the efficacy and safety and potential advantages and disadvantages compared to alternative treatments; • the ability to offer our products for sale at competitive prices; • the convenience and ease of administration compared to alternative treatments; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • the strength of our marketing and distribution support; • the availability of third- party coverage and adequate reimbursement, including patient cost- sharing programs such as copays and deductibles; • the ability to develop or partner with third- party collaborators to develop companion diagnostics; • the prevalence and severity of any side effects; and • any restrictions on the use of our products together with other medications. Clinical trials are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent beneficial effect of a product candidate that is greater than the actual positive effect in a broader patient population or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following events could occur: • regulatory authorities may withdraw their approval of the product or seize the product; • the product may be required to be recalled or changes may be required to the way the product is administered; • additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the product; • regulatory authorities may require the addition of labeling statements, such as a " black box " warning or a contraindication; • the creation of a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients; • additional restrictions may be imposed on the distribution or use of the product via a Risk Evaluation and Mitigation Strategy; • we could be sued and held liable for harm caused to patients; • the product may become less competitive; and • our reputation may suffer. Any of these events could have a material and adverse effect on our operations and business. The commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired. We currently have no marketing and sales force. If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell our product candidates, if approved, or generate product revenues. We currently do not have a marketing or sales team for the marketing, sales and distribution of any of our product candidates that are able to obtain regulatory approval. In order to commercialize any product candidates, we must build on a territory- by-territory basis marketing, sales, distribution, managerial and other non- technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we intend to establish an internal sales and marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time- consuming, will require significant attention of our executive officers to manage and may nonetheless fail to effectively market and sell our product candidates. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our products that we obtain approval to market. With respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory- by- territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution

systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses. The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are several large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Specifically, there are a number of companies developing competing anti- CD40 and anti- CD40L therapeutics in clinical trials for transplant, autoimmune or central nervous system indications, including: Novartis, Sanofi, UCB, Amgen (post - acquisition of Horizon Therapeutics), Bristol Myers Squibb, and Kiniksa. All of these companies are larger than Eledon and have significantly greater resources to develop their drug candidates. If approved, we expect that tegoprubart will face competition from numerous FDA- approved therapeutics for the prevention of transplant rejection, including PROGRAF ®, ASTAGRAF XL ®, ENVARSUS XR ®, NULOJIX ®, CELLCEPT ®, MYFORTIC ®, and numerous other branded and generic immunosuppressive agents. Multiple companies are working on islet cell and kidney transplant solutions that may ultimately potentially negate the need for immunosuppressive agents in these indications altogether. ~~If approved, we expect tegoprubart will face competition from other FDA- approved therapeutics for the treatment of LN, FSGS or IgAN, including TARPEYO ™, LUPKYNIS ™ and BENLYSTA ®, SPARSENTAN, and numerous other branded and generic medicines are already being used " off- label " to treat them.~~ We expect that tegoprubart will face competition from FDA- approved therapeutics for the treatment of ALS including RADICAVA ®, RELYVRIO ™, RILUZOLE, and numerous other branded and generic immunosuppressive agents. Multiple pharmaceutical and biotechnology companies, including but not limited to Biogen, Ionis Pharmaceuticals, Alexion Pharmaceuticals, Orion Pharma, Orphazyme, AZTherapies, Voyager Therapeutics, Apic Bio, Brainstorm Cell Therapeutics, and Cytokinetics, are also working on competing ALS pharmaceutical, gene therapy and cell therapy approaches. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. In addition, our ability to compete may be affected in many cases by insurers or other third- party payers seeking to encourage the use of generic products. Generic products are currently available, with additional generic products expected to become available over the coming years, potentially creating pricing pressure. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic products. Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, conducting nonclinical studies, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. The availability and extent of reimbursement by governmental and private payers is essential for most patients to be able to afford expensive treatments. Sales of our product candidates will depend substantially, both domestically and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third- party payers. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. There is significant uncertainty related to the insurance coverage and reimbursement of newly - approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payers tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost- containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable

revenues and profits. Moreover, increasing efforts by governmental and third- party payers, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. Increased expense is incurred to cover costs of health outcome focused research used to generate data necessary to justify the value of our products in order to secure reimbursement. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market. In addition, many private payers contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our products. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in decreased demand for any product candidates or products that we may develop; injury to our reputation and significant negative media attention; withdrawal of clinical trial participants; significant costs to defend the related litigation; substantial monetary awards to trial participants or patients; loss of revenue; reduced resources of our management to pursue our business strategy; and the inability to commercialize any products that we may develop. We currently hold $ 10. 0 million in product liability insurance coverage in the aggregate, with a per incident limit of $ 10. 0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Risks Related to Our Dependence on Third Parties We contract with third parties for the manufacture of our product candidates for nonclinical and clinical trials and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products at an acceptable cost and quality, which could delay, prevent or impair our development or commercialization efforts. We have utilized, and intend to continue utilizing, third parties to formulate, manufacture, package, and distribute clinical supplies of our drug candidates. We have no experience in manufacturing and do not have any manufacturing facilities. Currently, we rely on third parties for the manufacturing of drug substance and drug product for nonclinical and clinical activities. Our manufacturing vendors utilize proprietary cell culture media, cell lines, buffers, manufacturing equipment, manufacturing supplies, and storage buffers for the manufacturing of tegoprubart and other product candidates. These materials are custom- made and available from only a limited number of sources. Although we believe that our third- party suppliers maintain a significant supply of these materials and equipment on hand, any sustained disruption in this supply, could adversely affect our operations. We do not have any long- term agreements in place with our current suppliers. If we are required to change manufacturers, we may experience delays associated with finding an alternate manufacturer that is properly qualified to produce supplies of our products and product candidates in accordance with regulatory requirements and our specifications. Any delays or difficulties in obtaining or in manufacturing, packaging or distributing approved product candidates could negatively impact our clinical trials. We expect to rely on third- party manufacturers or third- party collaborators for the manufacture of commercial supply of any other product candidates for which our collaborators or we obtain marketing approval. Despite drug substance and product risk management, this reliance on third parties presents a risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. For example, these third parties experienced disruptions in their operations in conjunction with the COVID- 19 pandemic. Any delay or performance failure on the part of our existing or future manufacturers of drug substance or drug products could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply. If suppliers cannot supply us with our requirements, we may be required to identify alternative manufacturers, which would lead us to incur added costs and delays in identifying and qualifying any such replacement. Formulations and devices used in early studies are not final formulations and devices for commercialization. Additional changes may be required by the FDA or other regulatory authorities on specifications and storage conditions. These may require additional studies and may result in a delay in our clinical trials and commercialization activities. We also expect to rely on other third parties to label, store, and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue. We may be unable to establish any agreements with third- party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third- party manufacturers, reliance on third- party manufacturers entails additional risks, including: • reliance on the third party for regulatory compliance and quality assurance; • the possible breach of the manufacturing agreement by the third party; • the possible misappropriation of our proprietary information, including our trade secrets and know- how; and • the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. The third parties we rely on for manufacturing and packaging are also subject to regulatory review, and any regulatory compliance problems with these third parties could significantly delay or disrupt our clinical or commercialization activities. Third- party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays,

suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Additionally, macro- economic conditions may adversely affect these third parties, causing them to suffer liquidity or operational problems. If a key third- party vendor becomes insolvent or is forced to lay off workers assisting with our projects, our results and development timing could suffer. Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. We depend on CROs and other contracted third parties to perform nonclinical and clinical testing and certain other research and development activities. As a result, the outcomes of the activities performed by these organizations will be, to a certain extent, beyond our control. The nature of outsourcing a substantial portion of our business will require that we rely on CROs and other contractors to assist us with research and development, clinical testing activities, patient enrollment, data collection, and regulatory submissions to the FDA or other regulatory bodies. As a result, our success will depend partially on the success of these third parties in performing their responsibilities. Although we intend to pre- qualify our CROs and other contractors and we believe that the contractors selected will be fully capable of performing their contractual obligations, we cannot directly control the adequacy and timeliness of the resources and expertise that they apply to these activities. Additionally, macro-economic conditions may affect our development partners and vendors, which could adversely affect their ability to timely perform their tasks. If our contractors do not perform their obligations in an adequate and timely manner, the pace of clinical development, regulatory approval and commercialization of our drug candidates could be significantly delayed, and our prospects could be adversely affected. Risks Related to Our Intellectual Property Our success depends in large part on our ability to obtain and maintain patent protection in relevant countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States and internationally that are related to our novel technologies and product candidates. This patent portfolio includes issued patents and pending patent applications covering pharmaceutical compositions and methods of use. 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. We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our discovery and nonclinical development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, India and China do not allow patents for methods of treating the human body. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot 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, 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 EU, the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The risks described pertaining to our patents and other intellectual property rights also apply to the intellectual property rights that we license, and any failure to obtain, maintain and enforce these rights could have a material adverse effect on our business. In some cases, we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain and enforce the licensed patents. Any inability on our part to protect adequately our intellectual property may have a material adverse effect on our business, operating results and financial position. The USPTO and various non- U. S. governmental patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In certain situations, non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business. In addition, we have acquired rights to tegoprubart and other product candidates through a license agreement with The ALS Therapy Development Institute, and may in the future enter into other license agreements with third parties for other intellectual property rights or assets. These license agreements may impose various diligence, milestone payment, royalty, and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our drug candidates than if we had developed the licensed technology internally. In some cases, patent prosecution of our licensed technology may be controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could

lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we may control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time- consuming and unsuccessful. Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party' s intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Because competition in our industry is intense, competitors may infringe or otherwise violate our issued patents, patents of our licensors or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent' s claims narrowly, or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could be significant. 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. We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. If we were not able to obtain a license or are not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. Any NDAs or similar agreements entered into by the Company may not be with all relevant parties, or adequately protect the confidentiality of our trade secrets. Moreover, to the extent we enter into such agreements, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate them, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. We may be subject to claims of misappropriation of trade secrets from former employers of Company personnel. Many of our employees and certain of our directors were previously employed at or affiliated with research foundations or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees and directors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these employees or directors have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee' s or director' s former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. Risks Related to Our Common Stock We expect our stock price to be volatile, and the market price of our common stock may drop unexpectedly. The market price of our common stock could be subject to significant fluctuations. Market prices for securities of early- stage pharmaceutical, biopharmaceutical, and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include: • uncertainties regarding our financial condition and our ability to raise sufficient capital to fund our ongoing operations; • our ability to obtain regulatory approvals for our product candidates or other product candidates, and delays or

failures to obtain such approvals; • failure of any of our product candidates, if approved, to achieve commercial success; • issues in manufacturing our approved products, if any, or product candidates; • the results of our current and any future clinical trials of our product candidates; • the entry into, or termination of, key agreements, including key commercial partner agreements; • the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others; • announcements by commercial partners or competitors of new commercial products, clinical progress, or the lack thereof, significant contracts, commercial relationships, or capital commitments; • the introduction of technological innovations or new therapies that compete with our potential products; • the loss of key employees; • changes in estimates or recommendations by securities analysts, if any, who cover our common stock; • general and industry- specific economic conditions that may affect our research and development expenditures; • changes in the structure of healthcare payment systems; ~~and~~ • period- to- period fluctuations in our financial results **; and • future issuances of shares of common stock** . Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In the past, following periods of volatility in the market price of a company' s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation. Ensuring that we will have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time- consuming effort that needs to be re- evaluated frequently. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with ~~accounting principles generally accepted in the United States (" GAAP ")~~. If we are unable to successfully maintain internal controls over financial reporting, the accuracy and timing of our financial reporting, and our stock price, may be adversely affected and we may be unable to maintain compliance with the applicable stock exchange listing requirements. Additionally, as we become a larger company, we will become subject to Section 404 (b) of the Sarbanes- Oxley Act, which requires our independent auditors to document and test our internal controls. These additional requirements are costly, and our auditors may identify control deficiencies. Implementing any appropriate changes to our internal controls may distract the officers and employees of the Company, entail substantial costs to modify its existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of the internal controls of the Company, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase operating costs and harm the business. In addition, investors' perceptions that the internal controls of the Company are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm the stock price of the Company. Provisions in our corporate charter documents and under Delaware law could make an acquisition of the Company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our corporate charter and bylaws may discourage, delay or prevent a merger, acquisition or other change in control of the Company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our Board is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by stockholders to replace or remove the current management by making it more difficult for stockholders to replace members of our Board. Among other things, these provisions: • establish a classified Board such that not all members of the Board are elected at one time; • allow the authorized number of our directors to be changed only by resolution of our Board; • limit the manner in which stockholders can remove directors from our Board; • establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board; • require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent; • limit who may call stockholder meetings; • authorize our Board to issue preferred stock without stockholder approval, which could be used to institute a " poison pill " that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board; and • require the approval of the holders of at least 75 % of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of the Company' s charter or bylaws. We do not expect to pay any cash dividends in the foreseeable future. We expect to retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain, if any, for any stockholders for the foreseeable future.