Risk Factors Comparison 2025-03-27 to 2024-03-27 Form: 10-K

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Investing in our securities involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this ~~document~~ **Annual Report** , including our financial statements and the related notes and the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations " in this ~~document~~ **Annual Report** , before deciding whether to invest in our securities. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our securities could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations Summary of Risks Associated with Our Business Our business is subject to numerous risks and uncertainties that you should consider before investing in our Company. These risks include, but are not limited to, the following: • We are a clinical- stage drug development company with limited resources, a limited operating history and have no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability; • If we are unable to successfully raise additional capital, our future clinical trials and product development could be limited and our long- term viability may be threatened; • ~~There is substantial doubt regarding our ability to continue as a going concern and our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this Report. We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our clinical trials or other operations; • While the FDA lifted the clinical holds with respect to the Risvodetinib (IkT- 148009) programs relating to Parkinson' s disease and MSA, we may be subject to further clinical holds by the FDA in the future; •~~ Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have never generated any revenue from product sales, we may never generate any revenue from product sales, and we may fail to generate further revenue from grants or contracts or to be profitable ~~; • The wars between Russia and Ukraine and Israel and Hamas could materially adversely affect our business, results of operations, and financial condition; • Our results of operations have been adversely affected and, in the future, could be materially adversely impacted by the COVID- 19 virus~~ ; • Adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, including those we do business with, could adversely affect our operations and liquidity; • We have incurred significant net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future; • **If we fail to obtain additional financing, we may be unable to complete the development of and, if approved, commercialization of our product candidates; •** Due to the significant resources required for the development of our programs, and depending on our ability to access capital, we must prioritize development of certain product candidates; • Our business is highly dependent on the success of our initial product candidates targeting neurodegenerative **, cardiopulmonary and oncological** diseases **; • Our focus on IKT- 001 as a treatment for PAH may not prove successful** ; • We currently contract with various research institutions to perform the research and development activities needed to develop our products, and if we ever choose to or need to find alternative research institutions, we may not be able to do so at all or, if we are able to do so, it may be costly and may cause significant delays in the development and commercialization of our products; • Positive results from early preclinical or clinical studies of our product candidates are not necessarily predictive of the results of later preclinical studies and any current and future clinical trials of our product candidates; • We have ~~no history of completing~~ **limited experience with conducting** clinical trials for novel drug substances ~~or~~ **and no history of** commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability; • Our clinical trials may reveal significant adverse events, toxicities or other side effects not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates; • We have concentrated much of our research and development efforts on the treatment of neurodegenerative diseases, a field that has seen limited success in drug development; • We may encounter substantial delays in our current and planned clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all; • Our current and planned clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, which would prevent, delay or limit the scope of regulatory approval and commercialization; • Clinical development is a lengthy and expensive process with an uncertain outcome, and failure can occur at any stage of clinical development; • The manufacture of our product candidates is complex and difficulties may be encountered in production; • If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved; • Even if any product candidates we develop receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors, and others in the medical community necessary for commercial success ~~.~~ **;** • Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third- party reimbursement practices, or healthcare reform initiatives, which would harm our business ~~.~~ **;** • The regulatory approval processes of the FDA, EMA and comparable foreign regulatory authorities are lengthy, time consuming, and inherently unpredictable. Regulatory authorities have substantial discretion in the approval process and may refuse to accept an application, may disagree with our regulatory strategy or proposed pathway for approval or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies; • We expect to depend in whole or in part on collaborations with third parties for the research, development and commercialization of any product

candidates we may develop; • We contract with third parties for the manufacture of materials for our research programs, preclinical studies and current clinical trials and expect to continue to do so for any future clinical trials and for commercialization of any product candidates that we may develop; • We depend on a small number of third- party suppliers for key raw materials used in the manufacturing processes for our product candidates, and the loss of these third- party suppliers or their inability to supply us with adequate raw materials could harm our business; and • If we are unable to obtain and maintain patent protection for any product candidates we develop, our competitors could develop and commercialize products or technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected. Risks Related to Our Business, Financial Condition and Capital Requirements We are a clinical- stage drug development company with limited resources, a limited operating history and have no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability. We are a clinical stage drug development company that commenced operations in September 2008. We have limited facilities to conduct fundamental research and we have performed our research and development activities by collaboration with contract service providers, and contract manufacturers and by designing and developing research programs in collaboration with university- based experts who work with us to evaluate mechanism (s) of disease for which we have designed and developed product candidates. Our direct research capabilities are very limited. As of the date of this ~~document~~ **Annual Report** , we have not maintained a principal laboratory or primary research facility for the development of our product candidates. In addition, we have no products approved for commercial sale and therefore all of our revenue has been obtained solely through grants and contracts from private foundations and from state and federal grants from institutions such as the National Institutes of Health and the Department of Defense. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. As of the date of writing this **Annual** Report **,** we have not completed clinical trials for any of our product candidates, obtained marketing approval for any product candidates, manufactured a commercial scale product, or arranged for a third- party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Given the highly uncertain nature of drug development, we may never initiate or complete clinical trials for any of our product candidates, obtain marketing approval for any product candidates, 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. Our limited operating history as a company makes any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early- stage pharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business, operating results and financial condition will suffer. If we are unable to successfully raise additional capital, our future clinical trials and product development could be limited and our long- term viability may be threatened. We experienced negative operating cash flows since our inception and funded our operations prior to our initial public offering primarily through private, state and federal contracts and grants. In ~~December 2020, we completed an initial public offering of Common Stock, in June 2021 we completed a follow- on public offering, in January 2023 we completed a follow- on public offering and concurrent private placements (the" January 2023 Offering"), and in~~ February 2024, we entered into an At The Market Offering Agreement **(" ATM Agreement ")** with H. C. Wainwright & Co., LLC, as sales agent ~~(the " Agent ")~~ , ~~pursuant to~~ which ~~we may~~ **was subsequently terminated in December 2024. 315** , **338** ~~from time to time, issue and sell~~ shares of our Common Stock ~~, in~~ **were sold pursuant to the ATM Agreement for** an aggregate ~~offering~~ **gross sales** price of ~~up to~~ $ ~~5~~ **849** , ~~659~~ **188. In October 2024** , ~~255 through the Agent~~ **we completed a private placement of an approximately $ 110 million** (~~the~~ " ~~ATM~~ **October 2024 Offering** "). We anticipate we will need to seek additional funds in the future through equity or debt financings, or strategic alliances with third parties, either alone or in combination with equity financings to complete our product development initiatives. These financings could result in substantial dilution to the holders of our Common Stock or require contractual or other restrictions on our operations or on alternatives that may be available to us. If we raise additional funds by issuing debt securities, these debt securities could impose significant restrictions on our operations. Any such required financing may not be available in amounts or on terms acceptable to us, and the failure to procure such required financing could have a material and adverse effect on our business, financial condition and results of operations ~~, or threaten our ability to continue as a going concern~~ . Our present and future capital requirements will be significant and will depend on many factors, including: • the progress and results of our development efforts for our product candidates **; • the timing and results of the Phase 2b clinical objectives referenced under the October 2024 Offering and whether holders of Series A- 1 Warrants or Series B- 1 Warrants elect to exercise those warrants in accordance with their respective terms** ; • the costs, timing and outcome of regulatory review of our product candidates; • the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property- related claims; • the effect of competing technological and market developments; • market acceptance of our product candidates; • the rate of progress in establishing coverage and reimbursement arrangements with domestic and international commercial third- party payors and government payors; • the extent to which we acquire or in- license other products and technologies; and • legal, accounting, insurance and other professional and business- related costs. We may not be able to acquire additional funds on acceptable terms, or at all. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets or delay, reduce the scope of or eliminate some or all of our development programs. If we do not have, or are not able to obtain, sufficient funds, we may be required to delay development or commercialization of our product candidates. We also may have to reduce the resources devoted to our product candidates or cease operations. Any of these factors could harm our operating results ~~. There is substantial doubt regarding our ability to continue as a going concern and our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this Report. We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or~~

~~terminate our clinical trials or other operations. We have incurred net losses and used significant cash in operating activities since inception, and we expect to continue to generate operating losses for the foreseeable future. As of December 31, 2023, we had an accumulated deficit of $ 66, 900, 725. As of December 31, 2023, we had cash and cash equivalents of $ 9, 165, 179 and marketable securities of $ 4, 086, 873, which we believe that, together with the net proceeds of ATM, should be sufficient to fund our operating expenses into the first quarter of 2025. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Pursuant to the requirements of Accounting Standards Codification (ASC) 205- 40, Disclosure of Uncertainties about an Entity' s Ability to Continue as a Going Concern, and as a result of our financial condition and other factors described herein, there is substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern will depend on our ability to obtain additional funding, as to which no assurances can be given. Our future success depends on our ability to raise capital and / or execute our current operating plan. However, we cannot be certain that these initiatives or raising additional capital, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current shareholders may experience dilution. If we are unable to obtain funds when needed or on acceptable terms, we may be required to curtail our current clinical trials, cut operating costs, forego future development and other opportunities or even terminate our operations, which may involve seeking bankruptcy protection. We have identified conditions and events that raise doubt about our ability to continue as a going concern and our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements for the years ended December 31, 2023 and 2022 included in this Report~~ . Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have never generated any revenue from product sales, we may never generate any revenue from product sales, and we may fail to generate further revenue from grants or contracts or to be profitable. We have no products approved for commercial sale and have not generated any revenue from product sales. We anticipate generating additional revenue from private foundations and state and federal grants and contracts prior to generating revenue from product sales, but such grants and contracts are not guaranteed and will not make us profitable. Our ability to successfully commercialize our existing product candidates depends on our ability to successfully obtain regulatory approvals, among other factors. Thus, we may not generate meaningful revenue until after we have successfully begun and completed clinical development and received regulatory approval for the commercial sale of a product candidate. We may never begin clinical development or receive regulatory approval for the commercial sale of a product candidate and thus may never generate revenue from product sales. Our ability to generate revenue and achieve profitability depends significantly on many factors, including: • successfully completing research and preclinical and clinical development of our product candidates; • obtaining regulatory approvals and marketing authorizations for product candidates once we have successfully begun and completed clinical development and clinical trials; • identifying, assessing, acquiring and / or developing new product candidates; • successfully competing for grant revenue from private foundations and state and federal agencies; • negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter; • launching and successfully commercializing product candidates for which we obtain regulatory and marketing approval, either by collaborating with a partner or, if launched independently, by establishing a sales, marketing and distribution infrastructure; • obtaining and maintaining an adequate price for our product candidates, both in the United States and in foreign countries where our products are commercialized; • obtaining adequate reimbursement for our product candidates from payors; • obtaining market acceptance of our product candidates as viable treatment options; • addressing any competing technological and market developments; • maintaining, protecting, expanding and enforcing our portfolio of intellectual property rights, including patents, trade secrets and know- how; and • attracting, hiring and retaining qualified personnel. Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of our expenses, or when, if ever, we will be able to generate any meaningful revenue or achieve or maintain profitability. In addition, our expenses could increase beyond our current expectations if we are required by the FDA or foreign regulatory agencies to perform studies in addition to those that we currently anticipate, or if there are any delays in any of our or our future collaborators' preclinical or clinical trials or the development of any of our product candidates. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate and ongoing compliance efforts. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. Revenue from the sale of any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price and whether we own the commercial rights for that territory. If the number of addressable patients is not as significant as we anticipate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or continue our operations, and cause a decline in the value of our Common Stock, all or any of which may adversely affect our viability. Geopolitical instability and ongoing military conflicts,..... developments that are beyond our control. Adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, including those we do business with, could adversely affect our operations and liquidity. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market- wide liquidity problems. **Although we assess** ~~For example, on~~

~~March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or~~ **our** ~~the FDIC,~~ **banking and customer relationships** as ~~receiver. Our~~ **we believe necessary or appropriate, our** access to our cash and cash equivalents and our ability to access bank financing in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire or take down financing on acceptable terms or at all. Any material decline in available funding or our ability to access our cash and cash equivalents or our ability to access bank financing could adversely impact our ability to meet our operating expenses and result in breaches of our contractual obligations which could have material adverse impacts on our operations and liquidity. **Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. Currently, federal agencies in the U. S. are operating under a continuing resolution that is set to expire on September 30, 2025. Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the U. S. market could be impacted. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Our business is affected by macroeconomic conditions, including rising inflation, interest rates and supply chain constraints. Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and overall economic conditions and uncertainties such as those resulting from the current and future conditions in the global financial markets. Recent supply chain constraints have led to higher inflation, which if sustained could have a negative impact on our product development and operations. If inflation or other factors were to significantly increase our business costs, our ability to develop our current pipeline and new product candidates may be negatively affected. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the operation of our business and our ability to raise capital on favorable terms, or at all, in order to fund our operations. Similarly, these macroeconomic factors could affect the ability of our third- party suppliers and manufacturers to manufacture clinical trial materials for our product candidates.** We have incurred significant net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future. We have incurred net losses since our inception, including net losses of $ **27, 519, 886 and $** 19, 028, 883 ~~and $ 18, 054, 155~~ for the years ended December 31, **2024 and** 2023 ~~and 2022~~, respectively. As of December 31, ~~2023~~ **2024**, we had an accumulated deficit of $ ~~66~~ **94**, ~~900~~ **420**, ~~725~~ **611**. We have invested significant financial resources in research and development activities, including for our product candidates and our RAMPTM drug discovery program and prodrug technologies. We do not expect to generate revenue from product sales for several years, if at all. The amount of our future net losses will depend, in part, on the level of our future expenditures and our ability to generate revenue. Moreover, our net losses may fluctuate significantly from quarter to quarter and year to year, such that a period- to- period comparison of our results of operations may not be a good indication of our future performance. We expect to continue to incur significant expenses and increasingly higher operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we: • continue our research and discovery activities ~~; • continue dosing patients in our Phase II clinical trial of Risvodetinib (IkT- 148009)~~; • continue the development of our RAMPTM drug discovery platform and prodrug technologies; • advance our current and any future product candidates through preclinical and clinical development; • initiate and conduct additional preclinical, clinical or other studies for our product candidates; • work with our contract manufacturers to scale up the manufacturing processes for our product candidates or, in the future, establish and operate a manufacturing facility; • change or add additional contract manufacturers or suppliers; • seek regulatory approvals and marketing authorizations for our product candidates; • establish sales, marketing and distribution infrastructure to commercialize any products for which we obtain approval; • acquire or in- license product candidates, intellectual property and technologies; • make milestone, royalty or other payments due under any license or collaboration agreements; • obtain, maintain, protect and enforce our intellectual property portfolio, including intellectual property obtained through license agreements; • attract, hire and retain qualified personnel; • provide additional internal infrastructure to support our continued research and development operations and any planned commercialization efforts in the future; • experience any delays or encounter other issues related to our operations; • experience negative general market conditions or extraordinary external events, such as recessions **, interest rates, fuel prices, foreign currency fluctuations, international tariffs, social, political and economic risks, public health epidemics** or ~~the COVID- 19 pandemic~~ **pandemics and acts of war or terrorism** ; • **continue to** meet the requirements and demands of being a public company; and • defend against any product liability claims or other lawsuits related to our products.

Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' deficit and working capital. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline. If we fail to obtain additional financing, we may be unable to complete the development of and, if approved, commercialization of our product candidates. Our operations have required substantial amounts of cash since inception. Prior to our initial public offering, we financed our operations primarily through revenue generated by private, state and federal grants and contracts and subsequently through the issuance of securities in **various** ~~our December 2020 initial public offering~~ **offerings** ~~, our June 2021 follow- on public offering, our January 2023 Offering and through our At- The- Market (ATM) offering~~ . Developing our product candidates is expensive, and we expect to continue to spend substantial amounts as we fund our early- stage research projects, continue preclinical development of our early- stage programs and, in particular, advance **IKT- 001** ~~our lead program candidates~~ through preclinical development and clinical trials ~~, including our Phase 2 clinical trial of Risvodetinib (IkT- 148009)~~ . The successful development of our product candidates, obtaining regulatory approvals and launching and commercializing any product candidate will require substantial additional funding beyond the net proceeds of our securities offerings. **We** ~~The Company~~ had cash ~~and~~ **,** cash equivalents ~~of $ 9 , 165, 179~~ and marketable securities of $ ~~4~~ **97** , ~~086~~ **543** , ~~873~~ **528** as of December 31, ~~2023~~ **2024** . Our estimate as to how long we expect our working capital to be adequate to fund our operations is based on assumptions that may prove inaccurate, and we could use our available capital resources sooner than we currently expect. In addition, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control or if we choose to expand more rapidly than we presently anticipate. We will require additional capital for the further development and, if approved, commercialization of our product candidates. Additional capital may not be available when we need it, on terms acceptable to us, or at all. We have no committed source of additional capital. If adequate capital is not available to us on a timely basis, we may be required to significantly delay, scale back or discontinue our research and development programs or the commercialization of any product candidates, if approved, or be unable to continue or expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, prospects, financial condition and results of operations and cause the price of our common stock to decline. Market volatility resulting from **future epidemics,** ~~the COVID- 19 pandemic~~ **pandemics** or other factors could also adversely impact our ability to access capital as and when needed. Furthermore, debt financing, if available, may require payment of interest and potentially involve restrictive covenants that could impose limitations on our flexibility to operate. Any difficulty or failure to successfully obtain additional funding may jeopardize our ability to continue the business and our operations. Due to the significant resources required for the development of our programs, and depending on our ability to access capital, we must prioritize development of certain product candidates. We may expend our limited resources on programs that do not yield a successful product candidate and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. We seek to maintain a process of prioritization and resource allocation to maintain an optimal balance between aggressively advancing lead programs and ensuring replenishment of our portfolio. **For example,** ~~We have multiple programs~~ in ~~clinical~~ **January 2025, we announced that we were pausing further** development **of** ~~across two primary assets,~~ Risvodetinib (IkT- 148009) ~~and IkT~~ **in order focus our resources on advancing our lead program IKT** - ~~001Pro~~ **001** . Due to the significant resources required for the development of our programs, we must focus our programs on specific diseases and disease pathways and decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. We may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights. If we make incorrect determinations regarding the viability or market potential of any or all of our programs or product candidates or misread trends in the pharmaceutical industry, in particular, for neurodegenerative diseases, our business, prospects, financial condition and results of operations could be materially adversely affected. Our business is highly dependent on the success of our initial product candidates targeting neurodegenerative **, cardiopulmonary and oncological** diseases. All of our product candidates will require significant nonclinical and clinical development before we can seek regulatory approval for and launch a product commercially. Our business and future success depends on our ability to obtain regulatory approval of, and then successfully launch and commercialize our initial product candidates targeting neurodegenerative **, cancer and cardiopulmonary** diseases ~~, including Risvodetinib (IkT- 148009) and IkT- 001Pro~~ . Our product candidates ~~, including Risvodetinib (IkT- 148009),~~ may experience preliminary complications surrounding trial execution, such as complexities surrounding the submission and regulatory acceptance of INDs, trial protocols and design, patient recruitment and enrollment, quality and supply of clinical doses and safety issues. All of our product candidates are in the early stages of preclinical and / or clinical development and will require additional nonclinical and clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts, all of which will require additional capital, before we can generate any revenue from product sales ~~. In addition, if Risvodetinib (IkT- 148009) encounters safety, efficacy, supply or manufacturing problems, developmental delays, regulatory or commercialization issues or other problems, our development plans and business would be significantly harmed. While the FDA lifted the clinical holds with respect to the Risvodetinib (IkT- 148009) program relating to Parkinson's disease and Multiple System Atrophy, we may~~

~~be subject to further clinical holds by the FDA in the future. On November 7, 2022, the FDA informed the Company that it had reviewed the Company' s Investigational New Drug (" IND ") application for Risvodetinib (IkT- 148009) for the treatment of Multiple Systems Atrophy (" MSA ") and had issued a clinical hold on the Risvodetinib (IkT- 148009) 201 program in Parkinson' s disease (" PD ") and the use of Risvodetinib (IkT- 148009) in MSA. In January 2023, the FDA lifted its clinical hold on the Risvodetinib (IkT- 148009) program based on the Company' s complete response and amendment dated December 21, 2022, as well as further commitments on January 20, 2023 regarding ophthalmologic monitoring in the protocol of study Risvodetinib (IkT- 148009)- 201 and various modifications to the Investigator Brochure. In January 2023, the Company initiated its Phase 2 program, termed ' the 201 trial' (www. the201trial. com), for Risvodetinib (IkT- 148009) as a treatment for Parkinson' s disease and began the process of opening sites in the U. S. Although the clinical hold on the Risvodetinib (IkT- 148009) program has been lifted, we can provide no assurance that we will not be subject to a clinical hold. Further, the FDA or other regulatory agencies may continue to express safety concerns after the hold is lifted, and future preclinical or clinical studies involving Risvodetinib (IkT- 148009) may be more burdensome or include additional preclinical or clinical endpoints that are difficult to meet. In such instances, our progress in the development of this program may be significantly slowed and the associated costs may be significantly increased, which could adversely affect our business, prompt us to cease development of this program entirely and cause our stock price to decline~~ . Risks Related to the Discovery, Development and Commercialization of Our Product Candidates We currently contract with various research institutions to perform the research and development activities needed to develop our products, and if we ever choose to or need to find alternative research institutions, we may not be able to do so at all or, if we are able to do so, it may be costly and may cause significant delays in the development and commercialization of our products. We do not currently own, lease or operate a principal laboratory, research and development or manufacturing facility of our own. Currently, we collaborate with various research institutions to perform research and development for our products, including Johns Hopkins University, Arizona State University and Michigan State University. Establishing our own facilities would result in significant additional expense and may result in potential delays in testing and production. Building and operating our own production facilities would require substantial additional funds and other resources, of which there can be no assurance that we will be able to obtain. In addition, there can be no assurances that we would be able to enter into any arrangement with third parties to manufacture our product, if any, on acceptable terms or at all. The commercial success of products outside the United States will also be dependent on the successful completion of arrangements with future partners, licensees or distributors in each territory. There can be no assurance that we will be successful in continuing to contract with research institutions to perform research and development for our products, that we would be able to establish our own facilities should we choose to or find it necessary to do so, that we would be successful in establishing additional collaborative arrangements or that, if established, such future partners will be successful in commercializing our products. Research, development, and commercialization of pharmaceutical products is inherently risky. We are heavily dependent on the successful use of our ~~RAMPTM~~ -- **RAMP** drug discovery program and the product candidates that emerge from it and which are undergoing preclinical development. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized. We ~~are at an early~~ **have advanced into later-** stage ~~of~~ development **for certain** of ~~the~~ **our** product candidates currently in our programs and are further developing our RAMPTM drug discovery program and prodrug technologies to provide future additional product candidates. To date, we have invested substantially all of our efforts and financial resources to identify, develop intellectual property for, and advance our programs, including conducting preclinical studies for our lead programs, ~~commencing~~ **conducting** our clinical trials for **IKT- 001 and** Risvodetinib (IkT- 148009) and providing general and administrative support for these operations. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize our product candidates, and we may fail to do so for many reasons, including the following: • our product candidates may not successfully complete preclinical studies or begin or complete clinical trials; • our product candidates may fail to be delivered across the blood brain barrier ~~, or~~ **(“** BBB **”)** , and therefore may not be clinically viable for **central nervous system (“** CNS **”)** diseases such as PD; • a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; • our competitors may develop therapeutics that render our product candidates obsolete or less attractive; • our competitors may develop alternative technologies to deliver therapeutics across the BBB that outperform our product candidates; • the product candidates that we develop may not be sufficiently covered by intellectual property for which we hold exclusive rights; • the product candidates that we develop may be covered by third parties' patents or other intellectual property or exclusive rights; • the market for a product candidate may change so that the continued development of that product candidate is no longer reasonable or commercially attractive; **and** • a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; if a product candidate obtains regulatory approval, we may be unable to establish sales and marketing capabilities, or successfully market such approved product candidate, to gain market acceptance; and a product candidate may not be accepted as safe and effective by patients, the medical community or governmental third- party payors. We may not be successful in our efforts to further develop current or future product candidates. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Each of our product candidates will require significant clinical development, management of preclinical, clinical, and manufacturing activities, regulatory approval, adequate manufacturing supply, a commercial organization, and significant marketing efforts before we generate any revenue from product sales, if at all. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which could have a material adverse effect on our business and could potentially cause us to cease operations. Positive results from early clinical or preclinical studies of our product candidates are not necessarily predictive of the results of later preclinical studies and any current and future clinical trials of our product candidates. If we

cannot show positive results or replicate any positive results from our earlier clinical or preclinical studies of our product candidates in our later preclinical studies and current and future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates. Any positive results from clinical or preclinical studies of our product candidates may not necessarily be predictive of the results from later preclinical studies and current and future clinical trials. Similarly, even if we are able to complete our planned preclinical studies or any future clinical trials of our product candidates according to our current development timeline, the positive results from such clinical or preclinical studies and current and future clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results. Many companies in the pharmaceutical industry have suffered significant setbacks in late- stage clinical trials after achieving positive results in early- stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses **, including by regulatory authorities,** and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain regulatory approval. We **may seek approval of our product candidates into FDA' s Real- Time Oncology Review (" RTOR ") program. This program may not lead to a faster regulatory review or approval process and does not increase the likelihood that our product candidate (s) will receive marketing approval. While participation in FDA' s RTOR program is voluntary, we may decide to submit oncology marketing applications for our product candidates into FDA' s RTOR program. Our acceptance into RTOR does not guarantee or influence approval of our application, which is subject to the same statutory and regulatory requirements for approval as applications that are not included in RTOR. Although early approvals** have **occurred with applications selected for RTOR, this may not be the case for our application even if it is selected for RTOR. If at any time the FDA determines our participation in RTOR, if selected, is** no ~~history of completing~~ **longer appropriate, the FDA may rescind our acceptance and instruct us to follow routine submission procedures for marketing approval. We have limited experience with conducting** clinical trials for novel drug substances ~~or~~ **and no history of** commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability. Our operations to date have been limited to research, financing and staffing our company, developing our technology and developing our ~~lead product candidate, Risvodetinib (IkT- 148009), and other~~ product candidates and ~~commencing~~ **conducting** our Phase ~~I~~ **1** and Phase ~~II~~ **2** clinical trials for Risvodetinib (IkT- 148009). Our company has completed observational trials measuring biological parameters for specific indications in human patients from human fluids, but we have never completed a clinical development program for a new interventional drug, and we have not commercialized product candidates. Our product development strategy has included attempts to create molecules through RAMPTM that have predictable human safety margins for the target patient population, but we have never proved that our product candidates have this safety margin in clinical studies all the way through drug approval. We have not conducted pivotal clinical studies for any novel drug candidate and it may be years before any such trials is initiated, if at all. We cannot be certain that planned clinical trials will begin or be completed on time, if at all, that our planned development programs would be acceptable to the FDA or other regulatory authorities, or that, if approval is obtained, such product candidates can be successfully commercialized. Clinical trials and commercializing our product candidates will require significant additional financial and management resources, and reliance on third party clinical investigators, contract research organizations ~~or~~ **(" CROs ")** , consultants or collaborators. Relying on third party clinical investigators, CROs or collaborators may result in delays that are outside of our control. If our clinical development program, clinical trials or commercialization of our product candidates were to fail, it would have a material adverse effect on our business, prospects, financial condition and results of operations. Our clinical trials may reveal significant adverse events, toxicities or other side effects not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates. In order to obtain marketing approval for any of our product candidates, we must demonstrate the safety and efficacy of the product candidate for the relevant clinical indication or indications through clinical trials as well as additional supporting data. If our product candidates are associated with undesirable side effects in 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 sub populations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective. We cannot guarantee that any positive results in preclinical studies will successfully translate to human patients. Additionally, we cannot guarantee that additional preclinical studies will show positive results. It is not uncommon to observe results in human clinical trials that are unexpected based on preclinical testing, and many product candidates fail in clinical trials despite promising preclinical results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, **including by regulatory authorities,** and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products. Subjects in our planned clinical trials may suffer significant adverse events or other side effects not observed in our preclinical studies or earlier clinical trials. The observed potency and kinetics of our product candidates in preclinical studies may not be observed in human clinical trials. We have tested the dosing frequency and route of administration of our product candidates in preclinical studies, which will inform our dosing strategy for future clinical trials. However, such dose and route of administration may not result in sufficient exposure or pharmacological effect in humans, and may lead to unforeseen toxicity not previously observed in preclinical testing. Further, if our planned clinical trials of our product candidates fail to demonstrate efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. If significant adverse events or other side effects are observed in any of our current and future clinical trials, we may have difficulty recruiting patients to the related clinical trial, patients may drop out of the trial, or we may be required to

abandon the trial or our development efforts of that product candidate altogether. We, the FDA or other applicable regulatory authorities, or an institutional review board may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the pharmaceutical industry that initially showed therapeutic promise in early- stage studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies **or could require a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and / or other elements to assure safe use** . Any of these developments could materially harm our business, financial condition and prospects. Further, if any of our product candidates obtains marketing approval, toxicities associated with our product candidates may also develop after such approval and lead to a requirement to conduct additional clinical safety trials **or post- approval studies** , additional warnings **or contraindications** being added to the labeling, significant restrictions on the use of the product or the **suspension of marketing or** withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval **. Additionally, we could be sued or held liable for harm caused to patients and our reputation could suffer** . We may not be successful in our efforts to continue to create a pipeline of product candidates or to develop commercially successful products. If we fail to successfully identify and develop additional product candidates, our commercial opportunity may be limited. One of our strategies is to identify and pursue clinical development of additional product candidates. All of our programs are in the research, discovery, preclinical or clinical stages of development. Identifying, developing, obtaining regulatory approval and commercializing additional product candidates will require substantial additional funding beyond ~~the~~ **our** current financial resources ~~of the Company~~ and is prone to the risks of failure inherent in drug development. We may not be able to successfully identify or acquire additional product candidates, advance any of these additional product candidates through the development process, successfully commercialize any such additional product candidates, if approved. If we are unable to successfully identify, acquire, develop and commercialize additional product candidates, our commercial opportunity may be limited. If any of our product candidates successfully completes its planned clinical trials, we plan to seek regulatory approval to market such product candidates in the United States, the ~~European Union, or~~ EU, and in additional foreign countries where we believe there is a viable commercial opportunity. We have never commenced, compiled or submitted an application seeking regulatory approval to market any product candidate. We may never receive regulatory approval to market any product candidates even if such product candidates successfully complete clinical trials, which would adversely affect our viability. To obtain regulatory approval in countries outside the United States, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing, and distribution of our product candidates. We may also rely on collaborators or partners to conduct the required activities to support an application for regulatory approval, and to seek approval, for one or more of our product candidates. We cannot be sure that collaborators or partners will conduct these activities or do so within the time frame we desire. Even if we (or our collaborators or partners) are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue and results of operations could be negatively affected. Even if we receive regulatory approval to market any of our product candidates, whether for the treatment of neurodegenerative diseases or other diseases, we cannot assure you that any such product candidate will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. Investment in pharmaceutical product development involves significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide any assurance that we will be able to successfully advance any of our product candidates through the development process or, if approved, successfully commercialize any of our product candidates. We have concentrated much of our research and development efforts on the treatment of neurodegenerative diseases, a field that has seen limited success in drug development. We have focused much of our research and development efforts on addressing neurodegenerative diseases. Collectively, efforts by pharmaceutical companies in the field of neurodegenerative diseases have seen limited success in drug development. There are currently no marketed disease- modifying therapeutic options available for patients with PD and other neurodegenerative diseases. Disease- modifying therapies are therapies that would slow, stop or reverse neurodegenerative disease. While we believe our approach to therapy is disease- modifying, no markers to quantify disease progression have been identified. Our future success may be dependent on demonstrating disease- modification for neurodegenerative diseases using our product candidates. Developing and, if approved, commercializing our product candidates for treatment of neurodegenerative disease subjects us to a number of challenges, including engineering product candidates to cross the BBB to enable optimal concentration of the therapeutic in the brain and obtaining regulatory approval from the FDA and other regulatory authorities who have only a limited set of precedents to rely on. Our approach to the treatment of neurodegenerative diseases aims to identify and select targets with a biochemical link to neurodegenerative diseases, identify and develop biomarkers for the intended targets, which are biological molecules found in blood, other bodily fluids or tissues that are signs of a normal or abnormal process or of a condition or disease, to select the right patient population and demonstrate target engagement, pathway engagement and impact on disease progression of our molecules, identify and develop molecules that engage the intended target, and engineer our molecules to cross the BBB and act directly in the brain. This strategy may not prove to be successful. We cannot be sure that our approach will yield satisfactory therapeutic products that are safe and effective, scalable, profitable or able to obtain regulatory approval. Moreover, public perception of drug safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians to subscribe to novel treatments. We may encounter substantial delays in our

current and planned clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all. Our current and planned clinical trials are expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. We cannot be sure that submission of an IND, or, in the case of the EMA, a clinical trial application ~~, or~~ **(“** CTA **”)** , will result in the FDA or EMA allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely initiation or completion of clinical trials include: • inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials; • delays in confirming target engagement, patient selection or other relevant biomarkers to be utilized in preclinical and clinical product candidate development; • delays in reaching a consensus with regulatory agencies on study design; • delays in reaching agreement on acceptable terms with prospective ~~contract research organizations, or~~ CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; • delays in identifying, recruiting and training suitable clinical investigators; • delays in obtaining required IRB approval at each clinical trial site; • imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including, but not limited to, after review of an IND or amendment, CTA or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical trial operations or study sites; developments in trials conducted by competitors that raise FDA or EMA concerns about risk to patients broadly; or if the FDA or EMA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives; • delays or difficulties resulting from ~~the COVID- 19 pandemic or other~~ future **epidemics or** pandemics; • delays in identifying, recruiting and enrolling suitable patients to participate in our clinical trials, and delays caused by patients withdrawing from clinical trials or failing to return for post- treatment follow- up; • difficulty collaborating with patient groups and investigators; • failure by our CROs, other third parties, or us to adhere to clinical trial requirements; • failure to perform in accordance with the FDA’ s or any other regulatory authority’ s current good clinical practices, or cGCPs, requirements, or applicable EMA or other regulatory guidelines in other countries; • occurrence of adverse events associated with a product candidate that are viewed to outweigh its potential benefits; • changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; • changes in the standard of care on which a clinical development plan was based, which may require new or additional trials; • the cost of clinical trials of our product candidates being greater than we anticipate; • clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs; and • delays in manufacturing, testing, releasing, validating, or importing / exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing. Any inability to successfully initiate or complete current or future clinical trials could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our product shave patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such trial or by the FDA, EMA or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. **For example, in November 2002, the FDA issued a clinical hold on the Risvodetinib (IkT- 148009) 201 program in PD and the use of Risvodetinib (IkT- 148009) in MSA. Although the FDA lifted the clinical hold in January 2023, it still delayed our plans. We may be subject to clinical holds for other product candidates in the future and our progress in the development of this program could be significantly slowed and the associated costs may be significantly increased, which could adversely affect our business, prompt us to cease development of this program entirely and cause our stock price to decline.** We may encounter difficulties enrolling patients in our current and planned clinical trials, and our clinical development activities could thereby be delayed or otherwise adversely affected. The timely completion of our current and planned clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in such trials until their conclusion. We may experience difficulties in patient enrollment in our planned clinical trials for a variety of reasons, including: • the size and nature of the patient population; • the patient eligibility criteria defined in the protocol, and / or certain criteria related to stage of disease progression, which may limit the patient populations eligible for our clinical trials; • the size of the study population required for analysis of a trial’ s primary endpoints; • the proximity of patients to a trial site; • the **occurrence of** ~~COVID- 19 pandemic or other~~ future **epidemics or** pandemics; • the design of a trial; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • competing clinical trials for similar therapies or targeting patient populations meeting our patient eligibility criteria; • clinicians’ and patients’ perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies and product candidates; • our ability to obtain and maintain patient consents **; • pandemics or similar public health crises** ; and • the risk that patients enrolled in clinical trials will not complete such trials, for any reason. Our current and planned clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, which would prevent, delay or limit the scope of regulatory approval and

commercialization. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies of our product candidates may not be predictive of the results of early- stage or later- stage clinical trials, and results of early clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials. The results of our planned clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. This is particularly true in neurodegenerative diseases, where failure rates historically have been higher than in many other disease areas. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We cannot be certain that our current or planned clinical trials will be successful. Additionally, any safety concerns observed in any one of our current and planned clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, prospects, financial condition and results of operations. Even if our planned clinical trials were to be successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential. Clinical development is a lengthy and expensive process with an uncertain outcome, and failure can occur at any stage of clinical development. If we are unable to design, conduct and complete our current and planned clinical trials successfully, our product candidates will not be able to receive regulatory approval. In order to obtain FDA approval for any of our product candidates, we must submit to the FDA an NDA with substantial evidence that demonstrates that the product candidate is both safe and effective in humans for its intended use. This demonstration will require significant research, preclinical studies and clinical trials. Clinical trials are time- consuming, expensive, and difficult to design and implement, in part because they are subject to rigorous requirements and the outcomes are inherently uncertain. Clinical testing may take many years to complete, and failure can occur at any time during the clinical trial process, even with active ingredients that have previously been approved by the FDA as safe and effective. ~~If we~~ **While in November 2024, the Company** ~~receive~~ **received** authorization **for its Phase 2** ~~to conduct our planned clinical trials~~ **trial (702 trial) for IKT- 001 for PAH,** in addition to our already commenced Phase ~~I~~ **1** and Phase ~~II~~ **2** clinical trials and our two- part dose finding / dose equivalence study for ~~IkT~~ **IKT** - ~~001Pro~~ **001**, we could encounter problems that could halt our planned clinical trials or require us to repeat such clinical trials. If patients participating in our current and planned clinical trials suffer drug- related adverse actions during the course of such clinical trials, ~~or~~ if we or the FDA believe that patients are being exposed to unacceptable health risks, **or no meaningful benefits are observed from our product candidates,** such clinical trials may have to be suspended or terminated **. For example, in June 2024, Aerovate Therapeutics developing an inhaled imatinib product candidate for PAH announced topline Phase 2b clinical trial results indicating the trial did not meet its primary endpoint for improvement in pulmonary vascular resistance versus placebo** . Suspension, termination or the need to repeat a clinical trial can occur at any stage **and could materially harm the future of our business** . The clinical trial success of each of our product candidates depends on reaching statistically significant changes in patients' symptoms based on clinician- rated scales. There is a lack of consensus regarding standardized processes for assessing clinical outcomes based on clinician- rated scales. Accordingly, the scores from our clinical trials may not be reliable, useful or acceptable to the FDA or other regulatory agencies. Changes in standards related to clinical trial design could have a material adverse effect on our ability to design and conduct clinical trials as planned. For example, we expect to conduct clinical trials comparing our product candidates to both placebo and other approved drugs, but regulatory authorities may not allow us to compare our product candidates to a placebo in a particular clinical indication where approved products are available. In that case, both the cost and the amount of time required to conduct such a planned clinical trial could increase. The FDA may disagree with our trial design and our interpretation of data from our planned clinical trials or may change the requirements for approval even after it has reviewed and commented on the design for our planned clinical trials. The FDA may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post- approval clinical trials. In addition, the FDA may not approve the labeling claims or removal of certain warnings that we believe are necessary or desirable for the successful commercialization of our product candidates. Approval may be contingent on a ~~Risk Evaluation and Mitigation Strategy, or~~ REMS, which could have a material adverse effect on the labeling, distribution or promotion of a drug product. Any of these delays or additional requirements could cause our product candidates to not be approved, or if approved, significantly impact the timing and commercialization of our product candidates and significantly increase our overall costs of drug development. We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective

than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition. The development and commercialization of new drug products is highly competitive. Moreover, the neurodegenerative field is characterized by strong and increasing competition, and a strong emphasis on intellectual property. Our competitors may be able to develop other compounds, drugs, cellular or gene therapies that are able to achieve similar or better results. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major pharmaceutical companies and specialty pharmaceutical companies worldwide. 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. There are a number of pharmaceutical and biotech companies that are currently pursuing the development of products for the treatment of the neurodegenerative disease indications for which we have research programs or have commenced clinical development, including PD. Companies developing therapeutics in the neurodegenerative disease area include large companies with significant financial resources, such as Biogen, Inc., Neuropore Therapies, Inc., Bristol Meyers Squibb, Roche Holdings AG, Prothena Corporation plc, Sanofi S. A., Takeda Pharmaceutical Co. Ltd., UCB, S. A., Denali Therapeutics Inc., Sun SPARC, 1st Biotherapeutics and AbbVie Inc. In addition to competition from other companies targeting neurodegenerative indications, any products we may develop may also face competition from other types of therapies using distinct treatment modalities. Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and clinical development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. 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 trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunities 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. Furthermore, currently approved products could be discovered to have application for treatment of the same disease indications as our product candidates, which could give such products significant regulatory and market timing advantages over any of our product candidates. Our competitors also may obtain FDA, ~~EMA~~ **European Commission** or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA **or European Commission** for indications our product candidates are targeting, which could result in our competitors establishing a strong market **exclusivity** position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors. In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity and / or enforceability of our patents relating to our competitors' products and our competitors may allege that our products infringe, misappropriate or otherwise violate their intellectual property. See " —Risks Related to Our Intellectual Property. " The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize. The manufacture of our product candidates is complex and difficulties may be encountered in production. If such difficulties are encountered or failure to meet regulatory standards occurs, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure. The processes involved in manufacturing our drug product candidates are complex, expensive, highly- regulated and subject to multiple risks. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. Further, as product candidates are developed through preclinical studies to potential future clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our current and planned clinical trials or other future clinical trials. We expect to rely on third- party manufacturers for the manufacturing of our products. In order to conduct our current and planned or future clinical trials of our product candidates, or supply commercial products, if approved, we will need to have them manufactured in small and large quantities. Our manufacturing partners may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost- effective manner, or at all. **Furthermore, if any third- party manufacturers with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different third- party manufacturer, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original third- party manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back- up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third- party manufacturers for any reason, we will be required to verify that the new third- party manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new third- party manufacturer could negatively affect our ability to**

develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a third-party manufacturer may possess technology related to the manufacture of our product candidate that such third- party manufacturer owns independently. This would increase our reliance on such third- party manufacturer or require us to obtain a license from such third- party manufacturer in order to have another third- party manufacturer produce our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. In addition, quality issues may arise during scale- up activities. If our manufacturing partners are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. The same risks would apply to our internal manufacturing facilities, should we in the future decide to build internal manufacturing capacity. In addition, building internal manufacturing capacity would carry significant risks in terms of being able to plan, design and execute on a complex project to build manufacturing facilities in a timely and cost- efficient manner. In addition, the manufacturing process for any products that we may develop is subject to the FDA, EMA and foreign regulatory authority approval processes and continuous oversight, and we will need to contract with manufacturers who can meet all applicable FDA, EMA and foreign regulatory authority requirements, including complying with current good manufacturing processes, or on an ongoing basis. If we or our third- party manufacturers are unable to reliably produce products to specifications acceptable to the FDA, EMA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our ~~CMOs~~ **third- party manufacturers** will be able to manufacture the approved product to specifications acceptable to the FDA, EMA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, prospects, financial condition, results of operations and growth prospects **. Additionally, in 2024, there was Congressional activity related to interactions with Chinese biotech companies, including the introduction of the BIOSECURE Act. Although the BIOSECURE Act was not ultimately passed by Congress, had this bill become law, or if similar laws are passed in the future, they would have the potential to restrict the ability of U. S. biopharmaceutical companies that purchase services or products from, or otherwise collaborate with, certain Chinese biotechnology companies " of concern " without losing the ability to contract with, or otherwise receive funding from, the U. S. government. If we chose to do business with companies in China, including some named in these bills, it is possible some of our contractual counterparties could be impacted by the legislation described above. If the third parties that we currently engage, or engage in the future, to supply materials or manufacture products for our preclinical tests and clinical trials should cease to continue to do so for any reason, we would likely experience delays in advancing these tests and trials while we identify and qualify replacement suppliers or manufacturers, and we may be unable to obtain replacement supplies on terms that are favorable to us or at all. In addition, if we are not able to obtain adequate supplies of its product candidates or the substances used to manufacture them, it will be more difficult for us to develop its product candidates and compete effectively** . If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved. We do not have a sales or marketing infrastructure, nor have we sold, marketed, or distributed pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a sales, marketing, and commercial support infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved. There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel. Factors that may inhibit our efforts to commercialize any approved product on our own include: • our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel; • the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future approved products; • the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors; • the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability; • restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and • unforeseen costs and expenses associated with creating an independent commercialization organization. If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that

are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates if approved. **Even if any product candidates we develop receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors, and others in the medical community necessary for commercial success.** The commercial success of any of our product candidates will depend upon its degree of market acceptance by physicians, patients, third- party payors, and others in the medical community. Even if any product candidates we may develop receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors, and others in the medical community. The degree of market acceptance of any product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including: • the efficacy and safety of such product candidates as demonstrated in pivotal clinical trials and published in peer- reviewed journals; • the potential and perceived advantages compared to alternative treatments; • the ability to offer our products for sale at competitive prices; • the ability to offer appropriate patient access programs, such as co- pay assistance; • the extent to which physicians recommend our products to their patients; • convenience and ease of dosing and administration compared to alternative treatments; • the clinical indications for which the product candidate is approved by the FDA, ~~EMA~~ **European Commission** or other comparable foreign regulatory agencies; • product labeling or product insert requirements of the FDA, EMA or other comparable foreign regulatory authorities, including any limitations, contraindications or warnings contained in a product' s approved labeling; • restrictions on how the product is distributed; • the timing of market introduction of competitive products; • publicity concerning our products or competing products and treatments; • the effectiveness of marketing and distribution efforts by us and other licenses and distributors; • sufficient governmental third- party coverage or reimbursement; and • the prevalence and severity of any side effects. If any product candidates we develop do not achieve an adequate level of acceptance by physicians, healthcare payors, patients and the medical community, we will not be able to generate significant revenue, and we may not become or remain profitable. The failure of any of our product candidates to find market acceptance would harm our business prospects. **Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third- party reimbursement practices, or healthcare reform initiatives, which would harm our business.** The regulations that govern marketing approvals, pricing, and reimbursement for new drugs vary widely from country to country. In the United States, continual legislative changes may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval. Our ability to successfully commercialize any products that we may develop also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Government authorities currently impose mandatory discounts for certain patient groups, such as Medicare, Medicaid and Veterans Affairs ~~, or~~ **(“** VA **”)** , hospitals, and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our products, if they are approved for commercial sale. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, of the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to get reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower- priced generic versions of standard of care drugs. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. In the United States, no uniform policy of coverage and reimbursement for products exists among third- party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the medicine is approved by the FDA, ~~EMA~~ **European Commission** or other comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict

imports of drugs from countries where they may be sold at lower prices than in the United States. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government- funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition. If any of our product candidates obtain regulatory approval, additional competitors could enter the market with generic versions of such drugs, which may result in a material decline in sales of affected products. Under the Drug Price Competition and Patent Term Restoration Act of 1984 **(“** ~~, or the~~ Hatch- Waxman Act **”)** , a pharmaceutical manufacturer may file an ANDA, seeking approval of a generic copy of an approved, small molecule innovator product. Under the Hatch- Waxman Act, a manufacturer may also submit an NDA under section 505 (b) (2) that references the FDA’ s prior approval of the small molecule innovator product. A 505 (b) (2) NDA product may be for a new or improved version of the original innovator product. The Hatch- Waxman Act also provides for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and reviewing) of an ANDA or 505 (b) (2) NDA. These include, subject to certain exceptions, the period during which an FDA- approved drug is subject to orphan drug exclusivity. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, “ Approved Drug Products with Therapeutic Equivalence Evaluations, ” known as the “ Orange Book. ” If there are patents listed in the Orange Book, a generic or 505 (b) (2) applicant that seeks to market its product before expiration of the patents must include in the ANDA a “ Paragraph IV certification, ” challenging the validity or enforceability of, or claiming non- infringement of, the listed patent or patents. Notice of the certification must be given to the innovator, too, and if within 45 days of receiving notice the innovators use to protect its patents, approval of the ANDA is stayed for 30 months, or as lengthened or shortened by the court. Accordingly, if any of our product candidates are approved, competitors could file ANDAs for generic versions of our drug products or 505 (b) (2) NDAs that reference our drug products, respectively. If there are patents listed for our drug products in the Orange Book, those ANDAs and 505 (b) (2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit. We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any of our owned or in- licensed patents that are listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and its sales would likely decline rapidly and materially. Should sales decline, we may have to write off a portion or all of the intangible assets associated with the affected product and our results of operations and cash flows could be materially and adversely affected. See “ —Risks Related to Our Intellectual Property. ” Conducting any clinical trials of our product candidates and any future commercial sales of a product candidate may expose us to expensive product liability claims, and we may not be able to maintain product liability insurance on reasonable terms or at all and may be required to limit commercialization of our product candidates. We face an inherent risk of product liability as a result of the preclinical and clinical testing of our product candidates and will face an even greater risk when and if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during preclinical or clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit testing and commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: • decreased or interrupted demand for our products; • injury to our reputation; • withdrawal of clinical trial participants and inability to continue our clinical trials; • initiation of investigations by regulators; • costs to defend the related litigation; • a diversion of management’ s time and our resources; • substantial monetary awards to trial participants or patients; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • loss of revenue; • exhaustion of any available insurance and our capital resources; • the inability to commercialize any product candidate; and • a decline in the price of our Common Stock. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. Our insurance policies may have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. Risks Related to Regulatory Approval and Other Legal Compliance Matters The regulatory approval processes of the FDA, EMA and comparable foreign regulatory authorities are lengthy, time consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed. The time required to obtain approval by the FDA, ~~EMA~~ **European Commission** and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials, and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’ s clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse

to accept any application, may disagree with our regulatory strategy or proposed pathway for approval or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies **. The U. S. Supreme Court' s July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which FDA' s regulations, policies and decisions may become subject to increasing legal challenges, delays, and / or changes** . We have not submitted for, or obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Applications for our product candidates could fail to receive regulatory approval for many reasons, including, but not limited to the following: • the FDA, EMA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our preclinical or clinical trials; • the FDA, EMA or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use; • the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval; • we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate' s risk- benefit ratio when compared to the standard of care is acceptable; • the data collected from preclinical or clinical trials of our product candidates may not be sufficient to support the submission of an NDA, or other submission or to obtain regulatory approval in the United States or elsewhere; • we may be unable to demonstrate to the FDA, EMA or comparable foreign regulatory authorities that a product candidate' s risk- benefit ratio for its proposed indication is acceptable; • the FDA, EMA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third- party manufacturers with which we contract for preclinical, clinical and commercial supplies; and • the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our preclinical or clinical data insufficient for approval. This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505 (b) (2) regulatory approval pathway, or if the requirements for such product candidates under Section 505 (b) (2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful. We plan to seek FDA approval through the ~~Section505 ---~~ **Section 505** (b) (2) regulatory pathway for ~~IkT~~ **IKT** - ~~001Pro~~ **001** . The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch- Waxman Act, added Section 505 (b) (2) to ~~the~~ FDCA. ~~Section505 ---~~ **Section 505** (b) (2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505 (b) (2), if applicable to us under the FDCA, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA' s prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. On January 19, 2024, **our** members ~~of the Company~~ along with its medical oncology consultants met with the ~~FDA~~ Review Team ~~(the " Review Team ") from the Division of Hematologic Malignancies~~ in a Pre- NDA meeting to discuss our bioequivalence studies of ~~IkT~~ **IKT** - ~~001Pro~~ **001** and its path to approval. All questions were addressed and summarized in official meeting minutes issued by the FDA on February 12, 2024. During the meeting we inquired whether additional clinical studies may be needed to seek approval and discussed manufacturing and quality control requirements for approval. The Review Team acknowledged that the 505 (b) (2) pathway appears to be the appropriate pathway for approval of ~~IkT~~ **IKT** - ~~001Pro~~ **001** and indicated that, pending formal review of our clinical data, clinical studies completed to date indicate that 600 mg and 800 mg ~~IkT~~ **IKT** - ~~001Pro~~ **001** provides similar exposures to 400 mg and 600 mg imatinib mesylate, respectively, subject to review of the NDA upon filing. In addition, given that imatinib mesylate is approved for use between 300 mg and 800 mg once daily for a variety of blood and gastrointestinal cancers, the Review Team stated that if we intend to seek approval across all currently approved indications, we should evaluate additional dose (s) as needed to measure the safety, tolerability and bioequivalent dose of ~~IkT~~ **IKT** - ~~001Pro~~ **001** that would deliver up to 800 mg, the highest approved dose of imatinib mesylate **. We are considering the study of the 1200 mg dose of IKT- 001 that is expected to lead to exposures equivalent to 800 mg imatinib** . The Review Team also discussed the possible difference between ~~IkT~~ **IKT** - ~~001Pro~~ **001** and imatinib mesylate absorption in the gut and recommended that we evaluate whether ~~IkT~~ **IKT** - ~~001Pro~~ **001** and imatinib mesylate behave differently with respect to certain gut transporters that regulate absorption. We are in alignment with the FDA and are initiating the necessary pre- clinical test to evaluate this further to ensure that delivery of imatinib by ~~IkT~~ **IKT** - ~~001Pro~~ **001** mimics imatinib mesylate in all respects. Finally, a number of recommendations were discussed to prevent the potential mix- up between ~~001Pro~~ **IKT- 001** and imatinib mesylate either at the pharmacy or by patients for two drugs delivering the same active ingredient. We discussed alternate dosage forms for ~~IkT~~ **IKT** - ~~001Pro~~ **001** relative to imatinib mesylate as the primary mitigation strategy and will provide a justification of the dosage forms chosen and why they are unlikely to cause medication errors. **We** ~~To ensure that we meet the manufacturing requirements for approval, we~~ will request milestone- based meetings with the Review Team **to ensure the Company and the Review Team remain aligned** as we complete the ~~required~~ **necessary preclinical, clinical,** manufacturing and quality control ~~processes~~ **requirements for potential approval, but there is no guarantee that Review Team interactions will ultimately lead to the approval of IKT- 001 or any other product candidates we may develop** . If the FDA does not approve the NDA under the Section 505 (b) (2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain

FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We could need to obtain more additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505 (b) (2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505 (b) (2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization. In addition, notwithstanding the approval of a number of products by the FDA under ~~Section505~~ --- **Section 505** (b) (2) over the last few years, certain brand- name pharmaceutical companies and others have objected to the FDA' s interpretation of Section 505 (b) (2). If the FDA' s interpretation of Section 505 (b) (2) is successfully challenged, the FDA may change its ~~Section505~~ --- **Section 505** (b) (2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505 (b) (2). The pharmaceutical industry is highly competitive, and Section 505 (b) (2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a ~~Section505~~ --- **Section 505** (b) (2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505 (b) (2) regulatory pathway, there is no guarantee this would ultimately lead to faster product development or earlier approval. Moreover, even if our product candidates are approved under Section 505 (b) (2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post- marketing testing and surveillance to monitor the safety or efficacy of the products. If we file a Section 505 (b) (2) application that references a product marketed by another manufacturer, we may be subject to a patent infringement suit and the approval of our product may be delayed. If we file a ~~Section505~~ --- **Section 505** (b) (2) application that relies in whole or in part on studies conducted by a third- party, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA' s publication Approved Drug Products with Therapeutic Equivalence Evaluations **(“** ~~, which we refer to as the~~ Orange Book **”)** , with respect to the third- party NDA for the applicable approved drug candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our drug. A certification that our new drug will not infringe the Orange Book- listed patents for the applicable approved drug candidate, or that such patents are invalid, is called a paragraph IV certification. If we submit a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to the NDA holder once our ~~Section505~~ --- **Section 505** (b) (2) application is accepted for filing by the FDA. The third- party may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the Section 505 (b) (2) application until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of us. The third- party may file a patent infringement lawsuit outside the 45- day period, in which case, our Section 505 (b) (2) application will not be subject to the 30- month stay of FDA approval ~~. Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences. Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or other comparable foreign regulatory authorities. Drug- related side effects could affect patient recruitment, the ability of enrolled patients to complete the study, and / or result in potential product liability claims. We are required to maintain product liability insurance pursuant to our business practice. We may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations, prospects, and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical trial participants, costs due to related litigation, distraction of management' s attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates, and decreased demand for our product candidates, if approved for commercial sale. Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including, but not limited to: • regulatory authorities may withdraw approvals of such product or impose restrictions on distribution; • regulatory authorities may require additional warnings or contraindications on the label that could diminish the usage or otherwise limit the commercial success of the product; • we may be required to change the way the product is administered or conduct additional clinical trials or post- approval studies; • we may be forced to suspend marketing of the product; • we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and / or other elements to assure safe use; • we could be sued and held liable for harm caused to patients; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations, and prospects~~ . We may conduct future clinical trials for our product candidates outside

the United States, and the FDA, EMA and applicable foreign regulatory authorities may not accept data from such trials. We may in the future choose to conduct one or more clinical trials outside the United States, including in Europe. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA, EMA or applicable foreign regulatory authority may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to cGCP regulations. Additionally, the FDA' s clinical trial requirements, including sufficient size of patient populations and statistical significance, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time- consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction, and could significantly harm our business, prospects, financial condition, and results of operations. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA or ~~EMA~~ **European Commission** grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate for those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any partner we work with fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. Even if we obtain regulatory approval for a product candidate, our products will remain subject to extensive regulatory scrutiny. If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, conduct of post- marketing studies, and submission of safety, efficacy, and other post- market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. Manufacturers and manufacturers' facilities are required to comply with extensive requirements imposed by the FDA, EMA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, biologics license application to the FDA, or BLA or marketing authorization application ~~, or~~ **(“** MAA **”)** . Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Any regulatory approvals that we receive for our product candidates will be subject to limitations on the approved indicated uses for which the product may be marketed and promoted or to the conditions of approval (including the requirement to implement a REMS), or contain requirements for potentially costly post- marketing testing. We will be required to report certain adverse reactions and production problems, if any, to the FDA, EMA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product' s approved label. As such, we may not promote our products for indications or uses for which they do not have approval. The holder of an approved NDA, BLA, or MAA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post- marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post- marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post- marketing study or failure to complete such a study could result in the withdrawal of marketing approval. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things: • issue warning letters that would result in adverse publicity; • impose civil

or criminal penalties; • suspend or withdraw regulatory approvals; • suspend any of our ongoing clinical trials; • refuse to approve pending applications or supplements to approved applications submitted by us; • impose restrictions on our operations, including closing our contract manufacturers' facilities; • mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners; • refuse to allow us to enter into government contracts; • seize or detain products, refuse to permit the import or export of products; or • require a product recall. Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. In addition, the FDA' s regulations, policies or guidance may change and new or additional statutes or government regulations in the United States and other jurisdictions may be enacted that could further restrict or regulate post- approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products and / or product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability. Although we have received orphan drug designation for ~~IkT~~ **IKT** - ~~001Pro~~ **001 by the FDA** and may seek orphan drug designation for other product candidates, we may be unable to maintain the benefits associated with orphan drug designation, including market exclusivity, for ~~IkT~~ **IKT** - ~~001Pro~~ **001** , and may be unable to obtain such a designation for other product candidates. This may cause our revenue, if any, to be reduced. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200, 000 in the United States, or a patient population greater than 200, 000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA or BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user- fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other NDA or BLA applications to market the same drug or biologic for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan exclusivity or if the FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product. **Also, the FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.** If we lose orphan drug designation in the future for ~~IkT~~ **IKT** - ~~001Pro~~ **001** the development costs may outweigh the economic benefits from FDA approval, if any, and commercialization. ~~Although we~~ **Similarly, in the EU, the European Commission, upon the recommendation of the EMA' s Committee for Orphan Medicinal Products, grants an orphan designation in respect of a product if its sponsor can show that: (1) the product is** ~~intend~~ **intended for the diagnosis, prevention or treatment of a life- threatening or chronically debilitating condition; (2) either (i) such condition affects no more than 5 in 10, 000 persons in the EU when the application is made, or (ii) it is unlikely that, without the benefits derived from orphan status, sales of the product in the EU would generate sufficient return in the EU** to **justify the necessary investment in its development; and (3) there is no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or, if such a method exists, the product would be of a significant benefit to those affected by that condition. In the EU, orphan designation entitles a party to financial incentives such as reduction of fees or fee waivers. Generally, if a product with an orphan designation subsequently receives the first regulatory approval for the indication for which it has such designation in the EU, the product is entitled to a ten year period of marketing exclusivity, which precludes the EMA from approving another marketing authorization application for a similar medicinal product in the same indication for that time period, except in limited circumstances. The EU market exclusivity period can be reduced to six years if, at the end of the fifth year, a product no longer meets the criteria for orphan designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Proposed amendments to EU regulations regarding orphan medicines are under consideration that, if implemented, could reduce the current ten- year marketing exclusivity period in the EU for certain orphan medicines. Even if we obtain orphan exclusivity for any product candidate, that exclusivity may not effectively protect our product candidate from competition because different products can be approved for the same condition. If, in the future, we** seek a breakthrough therapy designation **by** ~~for Risvodetinib (IkT- 148009) and may seek a breakthrough therapy designation for other~~ -- **the FDA for our** product candidates ~~in the future~~ , we might not receive such designation, and even if we do, such designation may not lead to a faster development of any product candidate or approval process for any product candidate. ~~We intend to~~ **In the future, we may** seek a breakthrough therapy designation for ~~Risvodetinib (IkT- 148009) in one or~~ **our** ~~more indications or for other~~ product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a

serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the NDA is submitted to the FDA. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive breakthrough therapy designation, the receipt of such designation for a product candidate may not result in a faster development of any product candidate or approval process for product candidate. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In particular, the ~~Food and Drug Omnibus Reform Act, or "~~ FDORA ~~"~~ enacted in the Consolidated Appropriations Act on December 29, 2022, further directs FDA to specify conditions for post- approval studies for products approved under accelerated approval that may provide additional requirements and timelines for conducting such studies. FDORA also directs FDA to develop procedures for withdrawing a product' s accelerated approval on an expedited basis, which may also impact one or more of our products, if we are no longer able to continue to meet the requirements for accelerated **approval. In addition, in the EU, we may seek to participate in the PRIority MEdicines (" PRIME ") scheme for our potential product candidates. The PRIME scheme is intended to encourage development of products in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation, where the marketing authorization application will be made through the centralized procedure in the EU. Products from small- and medium- sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies on the basis of compelling non-clinical data and tolerability data from initial clinical trials. Eligible products must target conditions for which there is an unmet medical need (no treatment option exists in the EU or the product can offer a major therapeutic advantage over existing treatments). Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. There is no guarantee, however, that our potential product candidates would be deemed eligible for the PRIME scheme and, even if we do participate in the PRIME scheme, where during the course of development a product no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn. PRIME eligibility does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or** approval. Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that may affect our ability to profitably sell our product and product candidates, if approved. The United States government, state legislatures and foreign governments also 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. The Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. There have been significant ongoing judicial, administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act since its enactment. For example, the Tax Act enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate. The Affordable Care Act has also been subject to challenges in the courts. On December 14, 2018, a Texas U. S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. On December 18, 2019, the Fifth Circuit U. S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire Affordable Care Act. An appeal was taken to the U. S. Supreme Court which upheld the Affordable Care Act in June of 2021. There have been no significant judicial challenges since then. ~~The Biden Administration has~~ **Other legislative changes have** been **adopted since** ~~supportive of all aspects of~~ the Affordable Care Act ~~. Further changes~~ **was enacted, including aggregate reductions** to **Medicare payments to providers of up to 2 % per fiscal year, which went into effect in April 2013** and **will** ~~under the Affordable Care Act~~ remain ~~possible~~ **in effect through 2031** . ~~For example~~ **Under current legislation** , ~~the Biden Administration took additional steps to lower health care costs by requiring health insurance issuers, employer- based health plans, and other~~ -- **the** ~~group health plans~~ **actual reductions in Medicare payments may vary up** to **4 %** ~~report on prescription drug and health coverage costs~~ . The ~~rule is the fourth rule in a series that implement the No Surprises Act and transparency requirements of the~~ Consolidated Appropriations Act (CAA), **which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the CAA delays the 4 % Statutory Pay- As- You- Go Act of 2010, or " PAYGO " sequester for two years, through the end of calendar year 2024. Triggered by the enactment of the American Rescue Plan Act of** 2021 **, the 4 % cut to the Medicare program would have taken effect in January 2023** . ~~It~~ **The CAA' s health care offset title includes Section 4163, which extends the 2 % Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031. The American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the**

government to recover overpayments to providers from three to five years. Further, with passage of the Inflation Reduction Act (IRA) in August 2022, Congress authorized Medicare beginning in 2026 to negotiate lower prices for certain costly single- source drug and biologic products that do not have competing generics or biosimilars. This provision is ~~unknown precisely what form~~ **limited in terms of the number of pharmaceuticals whose prices can be negotiated in** any ~~such changes~~ **given year and it only applies to drug products that have been approved** ~~or~~ **for at least 9 years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition are categorically excluded from price negotiation. In addition, the new legislation provides that if pharmaceutical companies raise prices in Medicare faster than the rate of inflation, they must pay rebates back to the government for the difference. The IRA also caps Medicare out- of- pocket drug costs at an estimated $ 4, 000 a year in 2024 and, thereafter beginning in 2025, at $ 2, 000 a year. The IRA permits the U. S. Department of Health and Human Services or " HHS " to implement** ~~any~~ **many** ~~law would~~ **of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August 15, 2024, HHS announced the agreed- upon prices of the first ten drugs that were subject to price negotiations, which** take ~~, and how or whether it may affect~~ **effect** ~~our business~~ in **January 2026. HHS will select up to fifteen additional products covered under Part D for negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to** the ~~future~~ **Medicare Drug Price Negotiation Program. The Medicare Drug Price Negotiation Program is currently subject to legal challenges. The outcome of this litigation as well as the effects of the IRA on the pharmaceutical industry cannot yet be fully determined but is likely to be significant** . We expect that ~~changes or additions to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other~~ healthcare reform measures ~~, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry. We expect that the Affordable Care Act, as well as other healthcare reform measures such as the Transparency Act,~~ that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for our product and product candidates, if approved, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain and maintain profitability of our product and product candidates, if approved. Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: • comply with the laws of the FDA, EMA and other comparable foreign regulatory authorities; • provide true, complete and accurate information to the FDA, EMA and other comparable foreign regulatory authorities; • comply with manufacturing standards we have established; • comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or • report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. If we fail to comply with healthcare laws, we could face substantial penalties and our business, operations and financial conditions could be adversely affected. Healthcare providers, physicians and payors play a primary role in the recommendation and prescription of any product candidates for which we may obtain marketing approval. Our future arrangements with payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any product candidates for which we may obtain marketing approval. **Such laws include, without limitation, federal and state anti- kickback, fraud and abuse, false claims, data privacy and security and physician and other healthcare provider payment transparency laws and regulations.** Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third- party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal, state and foreign healthcare laws and regulations may affect our ability to operate and expose us to areas of risk, including: • federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which impose criminal and civil penalties, including through civil " qui tam " or " whistleblower " actions, against individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third- party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. A person or entity does not need to

have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation; • HIPAA, which created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ~~, or~~ **(“** HITECH **”)** , and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization; • **federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; •** the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’ s Health Insurance Program to report annually to the U. S. Department of Health and Human Services under the Open Payments Program, information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members, as well as other state and foreign laws regulating marketing activities; • federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and • analogous state and foreign laws and regulations, such as state and foreign anti- kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including, but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’ s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could, despite our efforts to comply, be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We and any contract manufacturers and suppliers we currently or may in the future engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third- party facilities. We also could incur significant costs associated with civil or criminal fines and penalties. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers’ compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our preclinical trials, future clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations, and prospects **. Data collection is governed by restrictive regulations governing the use, processing and cross- border transfer of personal information. Federal and state laws**

govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. By way of example, the California Consumer Privacy Act (CCPA) gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Similar laws have been passed in numerous other states. Although many of the existing state privacy laws exempt clinical trial information and health information governed by HIPAA, future privacy and data protection laws may be broader in scope. The existence of a variety of comprehensive privacy laws in different states would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. Moreover, a number of other states have passed or proposed more limited privacy laws that focus on specific privacy issues such as biometric data or the privacy of consumer health information, such as Washington state' s My Health My Data Act, which has a private right of action that further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data and a health privacy law is awaiting the governor' s signature in New York. At the federal level, the FTC has used its authority over " unfair or deceptive acts or practices " to impose stringent requirements on the collection and disclosure of sensitive categories of personal information, including health information. Moreover, the FTC' s expanded interpretation of a " breach " under its Health Breach Notification Rule could impose new disclosure obligations that would apply in the event of a qualifying breach. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products . Risks Related to Our Reliance on Third Parties We currently rely on and expect to continue to rely on third parties to conduct our clinical trials and preclinical testing, as well as future research and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, or testing. We currently rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our research, preclinical testing and clinical research and current clinical trial and will rely on such third parties to conduct any future clinical trials. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If we need to enter into alternative arrangements, it will delay our product development activities. Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that any current or future clinical trials would be conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with cGCPs for conducting, recording, and reporting the results of any current or future clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. We also are required to register any current or future clinical trials and post the results of completed clinical trials on a government- sponsored database within certain time frames. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions. Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical programs and any future clinical trials. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our preclinical or future clinical protocols, regulatory requirements or for other reasons, our preclinical and any future clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed. Switching or adding additional CROs involves additional cost and requires management time and focus. Identifying, qualifying and managing performance of third- party service providers can be difficult, time- consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. If any of our relationships with our CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, if these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our preclinical or any current or future clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines. We also expect to rely on other third parties to store and distribute drug supplies for any current or future clinical trials. Any performance failure on the part of our distributors could delay future clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, producing additional losses and depriving us of potential product revenue. We expect to depend in whole or in part on collaborations with third parties for the research, development and commercialization of any product candidates we may develop. If any such collaborations are not successful, we may not be able to realize the market potential of those product candidates. We expect to work with third- party collaborators in whole or in part for the development and commercialization of any product candidates we may develop. Our collaborators may include large and mid- size pharmaceutical companies, regional and national pharmaceutical companies and academic institutions and commercial research organizations. If we enter into any such arrangements with any third parties, we will likely have shared or limited control over the amount and timing of resources that our collaborators dedicate to the development or

potential commercialization of any product candidates we may seek to develop with them. Our ability to generate revenue from these arrangements with commercial entities will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into. Such collaborations pose the following risks to us: • collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations; • collaborators may not properly obtain, maintain, enforce, or defend intellectual property or proprietary rights relating to our product candidates or research programs or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property; • we may need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us; • disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of our product candidates or research programs or that result in costly litigation or arbitration that diverts management attention and resources; • collaborators may decide to not pursue development and commercialization of any product candidates we develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator' s strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates or research programs if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; • collaborators with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidates; • we may lose certain valuable rights under circumstances identified in our collaborations; collaborators may undergo a change of control and the new owners may decide to take the collaboration in a direction which is not in our best interest; • collaborators may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, know- how or intellectual property of the collaborator relating to our products, product candidates or research programs; • key personnel at our collaborators may leave, which could negatively impact our ability to productively work with our collaborators; collaborations may require us to incur short- and long- term expenditures or issue securities that dilute our stockholders or disrupt our management and business; collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and • collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our development or commercialization program under such collaboration could be delayed, diminished, or terminated. We may face significant competition in seeking appropriate collaborations. Recent business combinations among biotechnology and pharmaceutical companies have resulted in a reduction of potential collaborators. In addition, the negotiation process is time- consuming and complex, and we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue. If we enter into collaborations to develop and potentially commercialize any product candidates, we may not be able to realize the benefit of such transactions if we or our collaborator elect not to exercise the rights granted under the agreement or if we or our collaborator are unable to successfully integrate a product candidate into existing operations. In addition, if our agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator' s technology or intellectual property or require us to stop development of those product candidates completely. We may also find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. Many of the risks relating to product development, regulatory approval, and commercialization described in this " Risk Factors " section also apply to the activities of our collaborators and any negative impact on our collaborators may adversely affect us. We contract with third parties for the manufacture of materials for our research programs, preclinical studies and current clinical trial and expect to continue to do so for any future clinical trials and for commercialization of any product candidates that we may develop. This reliance on third parties carries and may increase the risk that we will not have sufficient quantities of such materials or product candidates that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts. We do not currently have any manufacturing facilities. We currently rely on third- party manufacturers for the manufacture of our materials for preclinical studies and current clinical trial and expect to continue to do so, including for any future clinical trials, unless we choose to establish our own manufacturing facilities for preclinical studies, any current and future clinical trials and for commercial supply of any product candidates that we may develop. We may be unable to establish any further 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: • the possible breach of the manufacturing agreement by the third- party; • the

possible termination or non- renewal of the agreement by the third- party at a time that is costly or inconvenient for us; • reliance on the third- party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting; and • the inability to produce required volume in a timely manner and to quality standards. Third- party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our third- party manufacturers may have little or no experience manufacturing materials that we require for our preclinical studies and current and future clinical trials. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in clinical holds on our trials, sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect our business, financial condition, results of operations, and prospects. Any product candidates 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. Any performance failure on the part of our existing or future manufacturers could delay any future clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for any of our product candidates. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer and may incur added costs and delays in identifying and qualifying any such replacement. Furthermore, securing and reserving production capacity with contract manufacturers may result in significant costs. Our current and anticipated future dependence upon others for the manufacture of any product candidates we may develop may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis. Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization. As we scale up manufacturing of our product candidates and conduct required stability testing, we may encounter product, packaging, equipment and process- related issues that may require refinement or resolution in order to proceed with any current or future clinical trials and obtain regulatory approval for commercial marketing. In the future, we may identify impurities, which could result in increased scrutiny by regulatory authorities, delays in our clinical programs and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for our product candidates. We depend on third- party suppliers for key raw materials used in the manufacturing processes for our product candidates, and the loss of these third- party suppliers or their inability to supply us with adequate raw materials could harm our business. We rely on third- party suppliers for the raw materials required for the production of our product candidates. Our dependence on these third- party suppliers and the challenges we may face in obtaining adequate supplies of raw materials involve several risks, including limited control over pricing, availability, quality and delivery schedules. As a small company, our negotiation leverage is limited and we are likely to get lower priority than our competitors who are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole source draw materials could materially harm the ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for future clinical trials and regulatory approvals, which would have a material adverse effect on our business. We currently rely on a small number of suppliers for manufacturing our product candidates. We currently rely on a small number of chemical manufacturers for our product candidates. If our suppliers were to have their businesses disrupted either inside or outside of the United States, we might be unable to find a replacement for such source in a timely manner, if at all. If a manufacturer were to be acquired by a competitor, the competitor may elect not to continue to manufacture for us at all. The loss of a supplier could cause manufacturing delays given the strict licensing requirements in this industry. If for any reason we were to change any one of our third- party contract manufacturers, we could face difficulties that might adversely affect our ability to maintain an adequate supply of our products, and we would incur costs and expend resources in the course of making the change. Moreover, we might not be able to obtain terms as favorable as those received from our current third- party contract manufacturers, which in turn would increase our costs. We are dependent on third- party manufacturers which are located in China, and any inability to obtain products from any such manufacturers could harm our business. Many of our current and future product candidates are expected to be manufactured in whole or in part by companies that are located in China. This concentration exposes us to risks associated with doing business globally. The political, legal and cultural environment in China is rapidly evolving, and any change that impairs our ability to obtain products from manufacturers in that region could have a material adverse effect on our business, operating results and financial condition. Political uncertainty in the United States may result in significant changes to U. S. trade policies, treaties and tariffs, potentially involving trade policies and tariffs regarding China, including the potential disallowance of tax deductions for imported merchandise or the imposition of unilateral tariffs on imported products. ~~These developments, or~~ **For** ~~the perception that any of~~ **example, on February 1, 2025,** ~~them~~ **the U. S. imposed a 10 % additional tariff on imports from China. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U. S. goods. Political tensions as a result of trade policies** could ~~occur~~ **reduce trade volume** , ~~may have~~ **investment, technological exchange and other economic activities between major international economies, resulting in** a material adverse effect on global economic conditions and the stability of global financial markets **. Any changes in political, trade, regulatory, and economic conditions, including U. S. trade policies, could have a material adverse effect on our financial condition or results of operations. Regulators and legislators in the U. S. are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Biden Administration' s executive order Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government- Related Data by Countries of Concern as implemented by Department of Justice regulations issued**

in December 2024, prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and / or civil sanctions, and may result in exclusion from participation in federal and state programs. These developments, or the perception that any of them could occur, may have a material adverse effect on global economic conditions and the stability of global financial markets , and may significantly reduce global trade and, in particular, trade between China and the United States. Any of these factors could depress economic activity, restrict our sourcing from suppliers and have a material adverse effect on our business, financial condition and results of operations and affect our strategy. We cannot predict whether any of the countries in which our product candidates or raw materials are currently manufactured or may be manufactured in the future will be subject to additional trade restrictions imposed by the United States and foreign governments, nor can we predict the likelihood, type or effect of any such restrictions. ~~Moreover, the recurrence of the COVID-19 pandemic~~ **If we are unable to obtain and maintain patent protection** ~~or~~ **for** ~~the rise of a new pandemic in China~~ **any product candidates we develop, our competitors** could ~~impair~~ **develop and commercialize products or technology similar or identical to ours, and** our ability to ~~obtain~~ **successfully commercialize any** product candidates **we may develop,** and ~~raw materials from manufacturers in that region or~~ **our technology** ~~to obtain products at marketable rates. Such events~~ may **be** ~~result in the need for us to consider and establish relationships with manufacturers in different countries from which to source our product candidates and raw materials and could have a material adverse~~ **adversely affected** ~~effect on our business, operating results and financial condition~~ . Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries for compositions of matter for each of our product candidates and any other technologies we may develop. We seek to protect our proprietary position by prosecuting intellectual property and filing patent applications in the United States and abroad relating to our product candidates, as well as other technologies that are important to our business. Given that the development of our technology and product candidates is at an early stage, our intellectual property portfolio with respect to certain aspects of our technology and product candidates is also at an early stage. We have filed patent applications on these aspects of our technology and core product candidates; however, there can be no assurance that any such patent applications will issue as granted patents. Furthermore, in some cases, we have only filed provisional patent applications on certain aspects of our technology and product candidates and each of these provisional patent applications is not eligible to become an issued patent until, among other things, we file a non- provisional patent application within 12 months of the filing date of the applicable provisional patent application. Any failure to file a non- provisional patent application within this timeline could cause us to lose the ability to obtain patent protection for the inventions disclosed in the associated provisional patent applications. Furthermore, in some cases, we may not be able to obtain issued claims covering compositions relating to our product candidates, as well as other technologies that are important to our business, and instead may need to rely on filing patent applications with claims covering a method of use and / or method of manufacture for protection of such product candidates and other technologies. There can be no assurance that any such patent applications will issue as granted patents, and even if they do issue, such patent claims may be insufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to our product candidates could have a material adverse effect on our business, financial condition, results of operations, and prospects. If any of our owned patent applications do not issue as patents in any jurisdiction, we may not be able to compete effectively. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. With respect to both in- licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties. The patent prosecution process is expensive, time- consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and product candidates would be adversely affected. The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our owned or in- licensed pending and future patent applications may not result in patents being issued which protect our product candidates or other technologies or which effectively prevent others from commercializing competitive technologies and product candidates. Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and

its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in- license may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether our product candidates or other technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, prospects, financial condition, results of operations and prospects. The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We or our licensors may be subject to a third- party pre- issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post- grant and inter partes review, or interference proceedings or other similar proceedings challenging our owned or licensed patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our owned or in- licensed patent rights, allow third parties to commercialize our product candidates or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. Moreover, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post- grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or our licensor' s priority of invention or other features of patentability with respect to our owned or in- licensed patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates and other technologies. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Some of our owned and in- licensed patents and patent applications are, and may in the future be, co- owned with third parties. For example, we co- own certain patents and patent applications relating to our pro drug technology to be applied to protein kinase inhibitors for oncology and non- oncology indications that was jointly developed with Sphaera. Our exclusive rights to certain of these patents and patent applications are dependent, in part, on operating agreements between the joint owners of such patents and patent applications. If our licensors or co- owners fail to sustain the grant of exclusive licenses to us or we are otherwise unable to maintain such exclusive rights, our licensors or co- owners may be able to license these rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of our licensors and co- owners in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business. We have entered into license agreements with third parties and may need to obtain additional licenses from others to advance our research or allow commercialization of product candidates. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third- party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties, which could be significant. In addition, each of our license agreements, and we expect our future agreements, will impose various development, diligence, commercialization, and other obligations on us. Certain of our license agreements also require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If these in- licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, prospects, financial conditions, results of operations, and prospects. Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • the sublicensing of patent and other rights under our collaborative development relationships; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; • the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors ~~rand~~ **and** us and our partners; and • the priority of invention of patented technology. In addition, the agreements under which we

currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, prospects, financial condition and results of operations. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, prospects, financial conditions and results of operations. We may not be able to protect our intellectual property and proprietary rights throughout the world. Filing, prosecuting, and defending patents on our product candidates and other technologies in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and this may have material adverse effects on our business, prospects, financial condition and results of operations. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U. S. and non- U. S. patent agencies. The USPTO and various non- U. S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, prospects, financial condition and results of operations. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy- Smith America Invents Act **(“** ~~, or the~~ America Invents Act **”)**, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third- party was the first to invent the claimed invention. A third- party that files a patent application in the USPTO after March 2013, but before us, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third- party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or other technologies or (ii) invent any of the inventions claimed in our or our licensor’ s patents or patent applications. The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post- grant proceedings, including post- grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary

standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third- party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third- party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third- party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in- licensed patent applications and the enforcement or defense of our owned or in- licensed issued patents, all of which could have a material adverse effect on our business, prospects, financial condition and results of operations. In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. Issued patents covering our product candidates and other technologies could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad. If we or one of our licensors initiated legal proceedings against a third- party to enforce a patent covering our product candidates or other technologies, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of our owned or in- licensed patents before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, post- grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover product candidates or other technologies. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution. If a third- party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates or other technologies. Such a loss of patent protection would have a material adverse impact on our business, prospects, financial condition and results of operations. If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed. Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our owned or in- licensed U. S. patents may be eligible for limited patent term extension under the Hatch- Waxman Act. The Hatch- Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. However, we may not be granted an extension in the United States and / or foreign countries and territories because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and could have a material adverse effect on our business, prospects, financial condition and results of operations. We may be subject to claims challenging the inventorship of our patents and other intellectual property. We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in- licensed patents, trade secrets, or other intellectual property as an inventor or co- inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates or other technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or our licensors' ownership of our owned or in- licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates and other technologies. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, prospects, financial condition and results of operations. Some intellectual property may have been discovered through government funded programs and thus may be subject to federal regulations such as " march- in " rights, certain reporting requirements and a preference for U. S.- based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non- U. S. manufacturers. All of our novel and in- licensed compounds were funded in whole or in part by the U. S. government, and are therefore subject to certain federal regulations. When new technologies are developed with U. S. government funding, the U. S. government generally obtains certain rights in any resulting patents, including a non- exclusive license authorizing the U. S. government to use the invention or to have others use

the invention on its behalf, commonly referred to as march- in rights. The U. S. government' s rights may also permit it to disclose the funded inventions and technology to third parties and to exercise march- in rights to use or allow third parties to use the technology we have licensed that was developed using U. S. government funding. The U. S. government may exercise its march- in rights if it determines that action is necessary because we fail to achieve practical application of the government- funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U. S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States in certain circumstances and if this requirement is not waived. Any exercise by the U. S. government of such rights or by any third- party of its reserved rights could have a material adverse effect on our business, prospects, financial condition, and results of operations. 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 our product candidates and other technologies, we also rely on trade secrets and confidentiality agreements to protect our unpatented know- how, technology, and other proprietary information and to maintain our competitive position. Trade secrets and know- how can be difficult to protect. We expect our trade secrets and know- how to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions. In addition, because we may collaborate with various collaborators on the development and commercialization of one or more of our product candidates and because we may rely on third parties to manufacture our product candidates, we may be required, at times, to share trade secrets with them prior to disclosing proprietary information. We seek to protect these trade secrets and other proprietary technology, in part, by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants as well as train our employees not to bring or use proprietary information or technology from former employers to us or in their work, and remind former employees when they leave their employment of their confidentiality obligations. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite our efforts, 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 or other third- party, we would have no right to prevent them from using that technology or information to compete with us. Given that our proprietary position is based, in part, on our know- how and trade secrets, if any of our trade secrets were to be disclosed to or independently developed by a competitor or other third- party, our competitive position would be materially and adversely harmed, and may have an adverse effect on our business. In addition, these agreements typically restrict the ability of our advisors, employees, third- party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with may be granted rights to publish data arising out of such collaboration, provided that we are notified in advance and given the opportunity to delay publication for a limited time period in order for us to secure patent protection of intellectual property rights arising from the collaboration, in addition to the opportunity to remove confidential or trade secret information from any such publication. Our existing collaborative research and development programs may require us to share trade secrets under the terms of our research and development collaborations or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third- party collaborators. A competitor' s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business. We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. Many of our employees, consultants, and advisors are currently or were previously employed at universities or other pharmaceutical companies, which may include competitors and potential competitors. Although we try to ensure that our employees, consultants, and advisors 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 individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual' s current or 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. In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self- executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, prospects, financial condition and results of operations. Third- party claims

of intellectual property infringement, misappropriation or other violation against us, our licensors or our collaborators may prevent or delay the development and commercialization of our product candidates and other technologies. The field of discovering treatments for our target indications is highly competitive and dynamic. Due to the research and development that is taking place in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, there may be significant intellectual property related litigation and proceedings relating to our owned and in- licensed, and other third-party, intellectual property and proprietary rights in the future. Our commercial success depends in part on our, our licensors' and our collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the pharmaceutical industry, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, recently, due to changes in U. S. law referred to as patent reform, new procedures including inter partes review and post- grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future. Numerous U. S. and foreign issued patents and pending patent applications owned by third parties exist relating to the fields in which we are developing our product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our product candidates and other technologies may give rise to claims of infringement of the patent rights of others. We cannot assure you that our product candidates and other technologies that we have developed, are developing or may develop in the future will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued and that a third- party, for example, a competitor in the fields in which we are developing our product candidates, and other technologies might assert are infringed by our current or future product candidates or other technologies, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover product candidates or other technologies. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates or other technologies, could be found to be infringed by our product candidates or other technologies. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates or other technologies may infringe. Third parties may have patents or obtain patents in the future and claim that the manufacture, use or sale of our product candidates or other technologies infringes upon these patents. In the event that any third- party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our product candidates or other technologies. In this case, the holders of such patents may be able to block our ability to commercialize the applicable product candidate or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third- party patent on commercially reasonable terms, we may be unable to commercialize our product candidates or other technologies, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing our infringing product candidates or other technologies. In addition, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and / or redesign our infringing product candidates or technologies, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidates or other technologies, which could harm our business significantly. Engaging in litigation to defend against third parties alleging that we have infringed, misappropriated or otherwise violated their patents or other intellectual property rights is very expensive, particularly for a company of our size, and time- consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, prospects, financial condition or results of operations. We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming, and unsuccessful. Competitors may infringe our patents or the patents of our licensing partners, or we may be required to defend against claims of infringement. In addition, our patents or the patents of our licensing partners also may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time consuming. In an infringement proceeding, a court may decide that a patent owned or in- licensed by us is invalid or unenforceable, the other party' s use of our patented technology falls under the safe harbor to patent infringement under 35 U. S. C. § 271 (e) (1), or may refuse to stop the other party from using the technology at issue on the grounds that our owned and in- licensed patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our owned or in- licensed patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of

hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. We use Inhibikase Therapeutics, the Inhibikase Therapeutics logo, and other marks to represent us in the United States and other countries. We have applied to federally register our primary trademarks in our primary market, the United States. Three of the four trademark applications that we filed for (INHIBIKASE, IKT (and Design) and RAMP) have issued to registration, and the fourth application (a second application for INHIBIKASE) is allowed and is currently awaiting registration by the United States Patent and Trademark Office. We have applied to register INHIBIKASE in Australia, Canada, the EU, Japan, Switzerland and the UK. Five of the six foreign trademark applications that we filed for have issued to registration, and the sixth application is currently awaiting registration by the Canada Patent and Trademark Office. In sum, other than the three U. S. federal registrations noted above and the registrations in the ex- US territories listed above, we have not secured trademark protection for any of our trademarks or trade names in any of our other geographic markets, and failure to secure those registrations could adversely affect our business. Our unregistered trademarks and trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other third- party marks. Indeed, it is unclear what enforceable rights, if any, we presently own in these marks or names outside of the United States. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks which are prior to our trademarks or trade names, and which are confusingly similar to our marks or names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, prospects, financial condition and results of operations. Intellectual property rights do not necessarily address all potential threats. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we license or may own; • we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed trade secret rights; • it is possible that our current or future pending owned or licensed patent applications will not lead to issued patents; • issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties; • our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets, provided those products do not infringe any patents we own or license in these markets; • we may not develop additional proprietary technologies that are patentable; • we might not be able to protect our trademarks and / or trade names; • the patents of others may harm our business; and • we may choose not to file a patent in order to maintain certain trade secrets or know- how, and a third- party may subsequently file a patent covering such intellectual property. Should any of these events occur, they could have a material adverse effect on our business, prospects, financial condition and results of operations. **The use of new and evolving technologies, such as artificial intelligence, in our offerings may result in spending material resources and presents risks and challenges that can impact our business including by posing security and other risks to our confidential information, proprietary information and personal information, and as a result we may be exposed to reputational harm and liability. We continue to build and integrate artificial intelligence into our offerings, and this innovation presents risks and challenges that could affect its adoption, and therefore our business. If we enable or offer solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability. The use of certain artificial intelligence technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. Additionally, we expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the EU' s Artificial Intelligence Act (AI Act) the world' s first comprehensive AI law is anticipated to enter into force in Spring 2024 and, with some exceptions, become effective 24 months thereafter. This legislation imposes significant obligations on providers and deployers of high risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. If we develop or use AI systems that are governed by the AI Act, it may necessitate ensuring higher standards of data quality, transparency, and human oversight, as well as adhering to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. The rapid evolution of artificial**

intelligence will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that artificial intelligence is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. Our vendors may in turn incorporate artificial intelligence tools into their own offerings, and the providers of these artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business. Risks Related to Our Operations We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth. As of the date of this **Annual** Report, we had ~~eight~~ **fifteen** full- time employees ~~,~~ **and** one part- time employee ~~and five contractors to oversee critical activities and perform services on our behalf~~ . Due to our limited employee headcount and dependence on contractors, we have operated with our employees and contractors conducting most of their activities outside of our offices ~~. In addition, historically we have limited our cash compensation expenses. After our initial public offering in December 2020, and again in March 2022, the cash compensation of our chief executive officer and our chief financial officer increased as described in the Section titled " Executive Compensation, " and our cash compensation expense for employees and consultants also increased~~ . As our development plans and strategies develop, and as we operate as a public company, we must add a significant number of additional managerial, operational, financial, and other personnel, as well as expand our facilities. Future growth will impose significant added responsibilities on members of management, including: • identifying, recruiting, integrating, retaining, and motivating additional employees and consultants; • identifying and leasing suitable corporate, development and / or research facilities; • managing our internal development efforts effectively, including the clinical and FDA review process for our current and future product candidates, while complying with our contractual obligations to contractors and other third parties; expanding our operational, financial and management controls, reporting systems, and procedures; and • managing increasing operational and managerial complexity. Our future financial performance and our ability to continue to develop and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day- to- day activities in order to manage these growth activities. Our ability to successfully manage our expected growth is uncertain given the fact that only one of our executive officers has been a full- time employee since our incorporation in June 2010. This lack of full- time experience working together as a company may adversely impact our senior management team' s ability to effectively manage our business and growth. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. These independent organizations, advisors and consultants may be employed by entities other than us, and may have commitments that limit their time, resources and availability to perform services for us. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements if necessary. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all. If we are not able to effectively expand our organization by hiring new employees and expanding our set of service providers, we may not be able to successfully implement the tasks necessary to further develop our product candidates and, accordingly, may not achieve our research, development, and commercialization goals. We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. Our ability to compete in the highly competitive pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our ~~management, particularly on our Chief Executive Officer, Dr. Werner, and our~~ scientific and medical contract employees and future personnel, including our board of directors and scientific advisory board, many of whom have significant experience in drug development and marketing, and who could prove hard to replace. The loss of the services provided by any of our executive officers, key employees and consultants, or other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in the development of our product candidates and harm our business ~~. As previously announced on January 16, 2024, on March 31, 2024, Mr. Frattaroli will step down from his role as Chief Financial Officer, and Garth Lees- Rolfe, our Vice President of Finance, is expected to take over this role. While we expect to engage in an orderly transition process if and when we integrate newly appointed officers and managers, we face a variety of risks and uncertainties relating to management transition, including diversion of management attention from business concerns, failure to retain other key personnel, or loss of institutional knowledge~~ . We conduct our operations in Atlanta, Georgia and Lexington, Massachusetts, both regions that are headquarters to many other pharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Our consultants and advisors may be engaged or employed by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. We expect that we may need to recruit talent from outside of our regions, and doing so may be costly and difficult. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided and will continue to provide stock option grants that vest over time and performance stock if performance conditions are met. In the future we may grant restricted stock units. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our

control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, these employment agreements ~~, other than for Dr. Werner,~~ provide for at- will employment, which means that any of our employees could leave our employment at any time, with or without notice ~~. We maintain a " key man " insurance policy on the life of Dr. Werner~~ . If we are unable to attract and incentivize quality personnel on acceptable terms, or at all, it may cause our business and operating results to suffer. Cybersecurity breaches could expose us to liability, damage our reputation, compromise our confidential information or otherwise adversely affect our business. We maintain sensitive company data on our computer networks, including our intellectual property and proprietary business information, as well as certain information regarding our product candidates and clinical trials. We face a number of threats to our networks from unauthorized access, security breaches and other system disruptions. Despite our security measures, our infrastructure may be vulnerable to attacks by hackers or other disruptive problems. Any such security breach may compromise information stored on our networks and may result in significant data losses or theft of our intellectual property, proprietary business information or our customers' personally identifiable information. A cybersecurity breach could hurt our reputation by adversely affecting the perception of customers and potential customers of the security of their orders and personal information. In addition, a cybersecurity attack could result in other negative consequences, including disruption of our internal operations, increased cybersecurity protection costs, lost revenues or litigation. Our computer systems, or those used by our third- party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches. Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors and consultants may be vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on our third- party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed. Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations, and those of our third- party research institution collaborators, CROs, CMOs, suppliers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical pandemics ~~such as COVID- 19~~ , and other natural or man- made disasters or business interruptions, for which we may not be insured. In addition, we rely on our third- party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third- party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man- made or natural disaster or other business interruption. Damage or extended periods of interruption to our facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Our ability to use our net operating loss carry forwards and certain other tax attributes may be limited. As of December 31, ~~2023~~ **2024** , **we had** federal net operating loss carryforwards of approximately $ 1. 6 million **,** which will begin to expire in varying amounts annually beginning in 2030 **,** and $ ~~33~~ **46** . ~~1~~ **5** million of federal net operating losses with no expiration. At December 31, ~~2023~~ **2024** , **we** ~~the Company~~ had state net operating loss carryforwards of approximately $ ~~30~~ **36** . ~~2~~ **1** million which will begin to expire in varying amounts annually beginning in 2030. These net operating loss carry forwards could expire unused and be unavailable to offset future income tax liabilities. Additionally, under current federal income tax law, federal net operating loss incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal net operating loss generally is limited to 80 % of U. S. federal taxable income. The Tax Cuts and Jobs Act (**"** TCJA **"**) resulted in significant changes to the treatment of research and developmental (**"** R & D **"**) expenditures under Section 174. For tax years beginning after **December** ~~Dec.~~ 31, 2021, taxpayers are required to capitalize and amortize all R & D expenditures that are paid or incurred in connection with their trade or business. Specifically, costs for U. S.- based R & D activities must be amortized over five years and costs for foreign R & D activities must be amortized over 15 years ~~—~~ **-** both using a midyear convention. During the year ended December 31, ~~2023~~ **2024** , **we** ~~the Company~~ capitalized for tax purposes $ ~~12~~ **11** . ~~6~~ **3** million and $ 0. 7 million of domestic and foreign R & D expenses, respectively. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any. We may be limited in the portion of net operating loss carry forwards and other tax attributes, such as research tax credits, that we can use in the future to offset taxable income for U. S. federal and state income tax purposes. Under Sections 382 and 383 of the United States Internal Revenue Code of 1986, as amended **("** ~~, or the~~ Code **")** , and corresponding provisions of state law, if a corporation undergoes an " ownership change " (generally defined as a greater than 50- percentage- point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three- year period), the corporation' s ability to use its pre- change net operating loss carry forwards and other pre-change tax attributes, such as research tax credits, to offset its post- change taxable income or taxes may be limited. We **preliminarily determined that we** experienced ownership changes in connection with our ~~December 2020 initial public offering and~~ June 2021 ~~and January 2023 follow on offerings~~ - **Offering , and October 2024 Offering** and may do so in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control **including, without**

limitation, the exercise of the Series A- 1 Warrants or the Series B Warrants under the October 2024 Offering . Our net operating loss carry forwards may also be subject to limitation under state laws. Further, our ability to utilize net operating loss carry forwards of companies that we may acquire in the future may also be subject to limitations. As a result, even if we attain profitability, we may be unable to use a material portion of our net operating loss and other tax attributes, such as research tax credits, which could adversely affect our future cash flows. Geopolitical instability and ongoing military conflicts,including the conflict between Russia and Ukraine and the conflict between Israel and Hamas could materially adversely affect our business,results of operations,and financial condition.In February 2022,Russian military forces invaded Ukraine,and in October 2023,Israel launched a military response against Hamas in Gaza.Although the length,impact,and outcome of these ongoing conflicts is highly unpredictable,they have led,and could continue to lead,to significant market and other disruptions,including instability in financial markets,supply chain interruptions,political and social instability,and increases in cyberattacks,intellectual property theft,and espionage.We are actively monitoring the situations in Ukraine and Gaza and assessing their impact on our business.We have no way to predict the progress or outcome of these conflicts,as they,and any resulting government reactions,are rapidly developing and beyond our control.The extent and duration of the conflicts,sanctions,and resulting market disruptions could be significant and could potentially have a substantial impact on the global economy and our business for an unknown period of time.Any of the above- mentioned factors could materially adversely affect our business,financial condition,and results of operations.Any such disruptions may also magnify the impact of other risks described in this " Risk Factors " section and elsewhere in this Annual Report on Form 10- K.Our results of operations have been adversely affected and,in the future,could be materially adversely impacted by ~~future epidemics and pandemics~~ **the COVID- 19 virus** .Our business and results of operations could be adversely impacted by ~~future~~ epidemics or pandemics,such as ~~we observed with~~ COVID- 19,particularly if there are closures or other restrictions in the places where we or our manufacturers and suppliers operate.For example,we have in the past and may in the future experience impacts to certain of our suppliers as a result of ~~epidemics or~~ **the COVID- 19** ~~pandemics~~ - **pandemic** or other health **epidemics or** outbreaks occurring in one or more of locations,which may materially and adversely affect our business,financial condition and results of operations.Further,our operation has in the past and may in the future experience disruptions,including in connection with temporary office closures and suspension of services by our suppliers,which may result in us having to procure the components for our product candidates from alternate suppliers,which may materially and adversely affect our development timelines,and our business,financial condition and results of operations. ~~Future epidemics and pandemics~~ **Pandemics** may also have adverse consequences for clinical trials,including the drop- out of subjects or inability to attract subjects. **While we believe we have generally recovered** ~~Inadequate funding for the NIH,FDA,the SEC and other government agencies,including~~ from ~~government shutdowns,policy or administrative changes or other~~ -- **the** ~~disruptions to~~ **adverse impact that** ~~these~~ -- **the COVID- 19 pandemic had** ~~agencies' operations,could hinder their ability to hire and retain key leadership and other personnel,prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions~~ on ~~which~~ **our business during 2020,we believe that** the **COVID- 19 virus could continue to adversely impact our results of** ~~operation~~ **operations ,cash flows and financial condition in the future,and it is likely that we will still need to make adjustments to our operating plans in reaction to developments that are beyond our control.** Risks Related to Ownership of Our Common Stock The market price of our common stock may be volatile. Some of the factors that may cause the market price of our common stock to fluctuate include: • results of our preclinical studies and clinical trials, or regulatory status of our product candidates; • results of preclinical studies, clinical trials, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors; • delays in filing our INDs, commencing trials, or objections by the FDA as to the content of our INDs; • failure or discontinuation of any of our product development and research programs; • any delay of the FDA in approving, or failure to approve, the design of our planned clinical trials for our current product candidates or for any future product candidates that we may develop; • the results of our efforts to develop additional product candidates or products; • commencement or termination of collaborations for our product development and research programs; • the success of existing or new competitive products or technologies; • the level of expenses related to any of our research programs, clinical development programs, or product candidates that we may develop; • regulatory or legal developments in the United States and other countries; • developments or disputes concerning patent applications, issued patents, or other proprietary rights; • actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts; • announcement or expectation of additional financing efforts; • sales of our common stock by us, our insiders, or other stockholders; • expiration of lock- up agreements; • variations in our financial results or those of companies that are perceived to be similar to us; • changes in estimates or recommendations by securities analysts, if any, that cover our stock; • changes in the structure of healthcare payment systems; • market conditions in the pharmaceutical sector; and • general economic, industry, and market conditions. In recent years, the stock market in general, and the market for pharmaceutical companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company' s securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management' s attention and resources from our business. **Commencing December 31** ~~A substantial amount of our total outstanding shares are restricted from immediate resale and may be sold only under the limitations of Rule 144 under the Securities Act of 1933 or pursuant to a future registration statement. The sale of such shares could cause the market price of our common stock to decline significantly~~ , **2025** ~~even if our business is doing well. A substantial number of shares held by our directors~~ , **we** ~~executive officers and other affiliates~~ will **no longer**

qualify ~~continue to be subject to certain limitations of Rule 144 under the Securities Act of 1933,~~ as ~~amended, or the Securities Act. However, such limitations may be reduced or removed in the future, if for example such shares are subsequently registered pursuant to the Securities Act. Sales of a substantial number of shares of our common stock in the public market could occur at any time. If such sales occur, or if there is a perception that such sales will occur, the market price of our common stock could fall significantly, even if our business is doing well. We will require additional capital in the future and raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. We will require additional capital in the future and we may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. We, and indirectly, our stockholders, will bear the cost of issuing and servicing such securities. Because our decision to issue debt or equity securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any future offerings. To the extent that we raise additional capital through the sale of equity or debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us. Insiders control a significant number of shares of our common stock, which could limit your ability to affect the outcome of key transactions, including a change of control. Our directors, executive officers, holders of more than 5 % of our outstanding stock and their respective affiliates beneficially own shares representing approximately 16. 8 % of our outstanding common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. As of March 1, 2024, Dr. Werner alone beneficially owned shares representing approximately 14. 6 % of our outstanding common stock. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock. We are~~ an " emerging growth company " ~~and a " smaller reporting company "~~ **as defined in the JOBS Act,** and the reduced disclosure requirements applicable to emerging growth companies **will no longer apply** ~~may make our common stock less attractive~~ to ~~investors~~ **us** . ~~We are~~ **As of December 31, 2025, we will no longer qualify as** an " emerging growth company, " as defined in the Jumpstart Our Business Startups Act of 2012 **(**~~"~~**")** ~~, as amended, or the~~ JOBS Act **")** . **As such,** ~~For so long as~~ we ~~remain~~ **will incur significant additional expenses that we did not previously incur in complying with the Sarbanes- Oxley Act of 2002** ~~an~~ **and** ~~emerging growth company, we are permitted and plan~~ **rules implemented by the SEC. We will become subject** to ~~rely on exemptions from~~ certain disclosure requirements that are applicable to other public companies that ~~are~~ **were** not **applicable to us as an** emerging growth ~~companies~~ **company** ~~. These exemptions include~~ , **for example,** ~~but are not limited to: (i) exemption from compliance with the auditor attestation requirements pursuant to Section 404 (b) of the Sarbanes- Oxley Act of 2002 (" SOX "); (ii) exemption from~~ compliance with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor' s report providing additional information about the audit and the **consolidated** financial statements ~~; (iii) reduced disclosure about our executive compensation arrangements;~~ and **compliance with** ~~(iv) exemptions from~~ the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. ~~We~~ **However, we** will continue to **qualify as** ~~remain an emerging growth company until the earliest of the following: (i) the last day of the fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (ii) the last day of the fiscal year in which our total annual gross revenue is equal to or more than $ 1. 07 billion; (iii) the date on which we have issued more than $ 1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. In addition, we are currently~~ a " smaller reporting company, " as defined in the Securities Exchange Act of 1934, as amended, or Exchange Act, and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies. To the extent that we continue to qualify as a " smaller reporting company " as such term is defined in Rule 12b- 2 under the Exchange Act, after we cease to qualify as an emerging growth company, certain of the exemptions available to us as an " emerging growth company " may continue to be available to us as a " smaller reporting company, " including exemption from compliance with the auditor attestation requirements pursuant to SOX and reduced disclosure about our executive compensation arrangements. We will continue to be a " smaller reporting company " until we have $ 250 million or more in public float (based on our Common Stock) measured as of the last business day of our most recently completed second fiscal quarter or, in the event we have no public float (based on our Common Stock) or a public float (based on our Common Stock) that is less than $ 700 million, annual revenues of $ 100 million or more during the most recently completed fiscal year. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. At the time of writing this, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company, nor have we included all of the quantitative and qualitative disclosures about market risk that would be required if we were not a smaller reporting company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile. **Additionally** ~~In addition~~ , **we expect** ~~the JOBS Act provides~~ that ~~an~~ **our loss of "** emerging growth company ~~can take advantage of~~ **" status will require additional attention from management** ~~an~~ **and** ~~extended transition period for complying~~ **will result in increased costs to us, which could include higher legal fees,**

accounting fees and fees associated with **investor relations activities, among** ~~new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise~~ --- **others** ~~apply to private companies. We have opted to take advantage of this extended transition period for the adoption of certain accounting standards~~ . We will **continue to** incur increased costs as a result of operating as a public company, and our management **is** ~~will be~~ required to devote substantial time to new compliance initiatives and corporate governance practices. As a public company, **we will continue to incur significant legal, accounting,** and ~~particularly~~ **other expenses that we did not incur as a private company, and these expenses may increase even more** after we are no longer an emerging growth company ~~, we will incur significant legal, accounting, and other expenses that we did not incur as a private company~~ . Section 404 of SOX, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to **continue to** hire additional accounting, finance, and other personnel in connection with our efforts to comply with the requirements of being a public company, and our management and other personnel will need **to continue** to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements ~~will~~ increase our legal and financial compliance costs and ~~will~~ make some activities more time- consuming and costly. Pursuant to Section 404 of SOX, we **are** ~~will be~~ required to furnish a report by our management on our internal control over financial reporting ~~beginning with our second filing of an Annual Report on Form 10- K with the SEC~~ . However, while we remain an emerging growth company or smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 of SOX ~~within the prescribed period~~ , we **are** ~~will be~~ engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. ~~Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed time frame or at all, that our internal control over financial reporting is effective as required by SOX. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.~~ We do not expect to pay any dividends for the foreseeable future. Investors in our common stock may never obtain a return on their investment. You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future credit facility we enter into, or debt instrument that we issue, may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock. Delaware law and provisions in our amended and restated certificate of incorporation and bylaws might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock. Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might **otherwise** ~~other wise~~ receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our charter documents: • establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three- year terms; • provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; • provide that our directors may only be removed for cause; • eliminate cumulative voting; • authorize our board of directors to issues shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, **without** ~~with out~~ stockholder approval; • provide our board of directors with the exclusive right to elect a director to fill a vacancy or newly created directorship; • permit stockholders to only take actions at a duly called annual or special meeting and not by written consent; • prohibit stockholders from calling a special meeting of stockholders; • require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings; • authorize our board of directors, by a majority vote, to amend the bylaws; and • require the affirmative vote of at least 66 2 / 3 % or more of the outstanding shares of common stock to amend many of the provisions described above. In addition, Section 203 of the General Corporation Law of the State of Delaware ~~, or~~ **(“** DGCL **”)** , prohibits a publicly- held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15 % of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Any provision of our amended and restated certificate of incorporation, amended and restated bylaws, or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for: • any action asserting a claim of breach of fiduciary duty; • any action asserting

a claim against us arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; and • any action asserting a claim against us that is governed by the internal- affairs doctrine. The choice of the Court of Chancery of the State of Delaware as the sole and exclusive forum for any derivative action or proceeding brought on behalf of **us** ~~the Company~~ shall not apply to suits seeking to enforce a duty or liability created by the Securities Act or the Exchange Act. In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. There is uncertainty as to whether a court would enforce such provisions. Some companies that adopted a similar federal district court forum selection provision are currently subject to a suit in the Chancery Court of Delaware by stockholders who assert that this provision is not enforceable. If a court were to find either choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act are accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well- conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected. General Risk Factors If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline. The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. We currently are being covered by a limited number of financial analysts. If no additional analysts commence coverage of us or existing analysts cease coverage, the trading price of our stock could decrease. Even if we do obtain additional analyst coverage, if one or more of the analysts covering our business down grade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline. Changes in U. S. tax law could adversely affect our business and financial condition. The laws, rules and regulations dealing with U. S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future. ~~For example, the Tax Cuts and Jobs Act, or the TCJA, was enacted in 2017 and made significant changes to corporate taxation, including the reduction of the corporate tax rate from a top marginal rate of 35 % to a flat rate of 21 %, the limitation of the tax deduction for net interest expense to 30 % of adjusted taxable income (except for certain small businesses), the limitation of the deduction for net operating losses from taxable years beginning after December 31, 2017 to 80 % of current year taxable income and the elimination of net operating loss carry backs generated in taxable years ending after December 31, 2017 (though any such net operating losses may be carried forward indefinitely), and the modification or repeal of many business deductions and credits. The TCJA resulted in significant changes to the treatment of research and developmental (R & D) expenditures under Section 174. For tax years beginning after Dec. 31, 2021, taxpayers are required to capitalize and amortize all R & D expenditures that are paid or incurred in connection with their trade or business. Specifically, costs for U. S.- based R & D activities must be amortized over five years and costs for foreign R & D activities must be amortized over 15 years — both using a midyear convention.~~ It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock. If we engage in acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks. We may engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses **. For example, in February 2025 we acquired CorHepta and issued shares of our common stock as consideration, which diluted our stockholders** . Any acquisition or strategic partnership may entail numerous risks, including: • increased operating expenses and cash requirements; • the potential issuance of our equity securities which would result in dilution to our stockholders; • assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel; • the diversion of our management' s attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership; • retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships; • risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and • our inability to generate revenue from acquired intellectual property, technology and / or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs. In addition, if we undertake such a transaction, we may issue dilutive securities, assume or incur debt obligations, incur large one- time expenses and acquire intangible assets that could result in significant future amortization expense. Our business activities may be subject

to the Foreign Corrupt Practices Act ~~, or~~ **(“** FCPA **”)** , and similar anti- bribery and anti- corruption laws. Our business activities may be subject to the FCPA and similar anti- bribery or anti- corruption laws, regulations or rules of other countries in which we operate, including the U. K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non- U. S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non- U. S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminals actions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition. Our business is subject to economic, political, regulatory and other risks associated with conducting business internationally. Our business is subject to risks associated with conducting business internationally because some of our suppliers and collaborative relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including: • economic weakness, including inflation, or political instability in particular non- U. S. economies and markets; • differing and changing regulatory requirements in non- U. S. countries; • challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; • difficulties in compliance with non- U. S. laws and regulations; • changes in non- U. S. regulations and customs, tariffs and trade barriers; • changes in non- U. S. currency exchange rates and currency controls; • changes in a specific country’ s or region’ s political or economic environment; • trade protection measures, import or export licensing requirements or other restrictive actions by U. S. or non- U. S. governments; • negative consequences from changes in tax laws; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • workforce uncertainty in countries where labor unrest is more common than in the United States; • difficulties associated with staffing and managing international operations, including differing labor relations; • potential liability under the FCPA or comparable foreign laws; and • business interruptions resulting from geo- political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods, fire **, epidemics** and pandemics **. Significant political, trade, or regulatory developments,** such as ~~the~~ **those** ~~ongoing~~ **stemming from the change in U. S. federal administration, are difficult to predict and may have a material adverse effect on us. Similarly, changes in U. S. federal policy that affect the geopolitical landscape could give rise to circumstances outside our control that could have negative impacts on our business operations. For example, on February 1, 2025, the U. S. imposed a 25 % tariff on imports from Canada and Mexico, which were subsequently suspended for a period of one month, and a 10 % additional tariff on imports from China. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U. S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on** global ~~COVID- 19 pandemic~~ **economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U. S. trade policies, could have a material adverse effect on our financial condition or results of operations** . These and other risks associated with conducting business internationally may materially adversely affect our ability to attain profitable operations.