Risk Factors Comparison 2025-04-15 to 2024-04-16 Form: 10-K

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

You should carefully consider the following risks and uncertainties when reading this Annual Report on Form 10- K. If any of the following risks actually occurs, our business, financial condition and results of operations could be materially and adversely affected. In that event, the trading price of our common stock could decline. Although we believe that we have identified and discussed below the key risk factors affecting our business, there may be additional risks and uncertainties that are not presently known or that are not currently believed to be significant that may adversely affect our performance or financial condition. Information concerning the shares of our common stock and related share prices in these risk factors has been adjusted to reflect the 1- for- **18 reverse split of our common stock that was made effective on April 19, 2024 and the 1- for-** 50 reverse split of our common stock that was made effective on February ~~24~~ **20** , ~~2023~~ **2025** . Risks Related to Our ~~Financial Condition~~ **Finances and Capital Requirements** Our current cash position, losses, negative cash flows from operations, and accumulated deficit raise substantial doubt about our ability to continue as a going concern absent obtaining adequate new debt or equity financings. **Our ability to continue as a going concern requires that we obtain sufficient funding to finance our operations in the near term.** The auditor' s opinion on our audited financial statements for the year ended December 31, ~~2023~~ **2024** includes an explanatory paragraph stating that we have incurred recurring losses from operations that raise substantial doubt about our ability to continue as a going concern. **Subsequent** ~~Management has also concluded that substantial doubt exists about our ability~~ to ~~continue as a going concern. As of~~ December 31, ~~2023~~ **2024 and through April 15** , **2025, (i)** we **sold** ~~had cash and~~ - **an** ~~cash equivalents~~ **additional 0. 2 million shares of common stock under the ELOC Purchase Agreement for net proceeds** of $ ~~4~~ **1. 5 million following mandatory redemption payments on our Series C Preferred Stock; (ii) 47, 799 July 2024 Warrants were converted into 47, 799 shares of common stock for gross and net proceeds of $ 0** . 3 million **; (iii) on March 18, 2025, we agreed to issue and sell to two institutional investors** ~~and~~ - **an** ~~current liabilities~~ **aggregate principal amount** of $ **312, 500, at an original issue discount of 20 %, in senior secured notes due in 2026 for net proceeds of $ 250, 000; and (iv) on April** 4 **,** ~~. 0 million. In April 2024~~ **2025** , ~~we entered into a Securities Purchase Agreement, or the Purchase Agreement, with the buyers named therein, pursuant to which~~ we agreed to **issue and** sell **to two institutional investors** senior ~~convertible~~ **secured promissory** notes **in an aggregate principal amount of $ 312** , ~~or the Notes~~ **500, at an original issue discount of 20 %** , for **net proceeds of** $ **250, 000** ~~1. 5 million of gross proceeds~~ . As a result, we believe that we have sufficient resources available to fund our business operations through April ~~2024~~ **2025 , but will need additional capital to continue** ~~. We do not have sufficient cash and cash equivalents as of the date of this Annual Report on Form 10- K~~ to support our operations for **more than** ~~at least the~~ 12 months following the date ~~that the~~ **of issuance of our consolidated** financial statements ~~are issued~~ **as of and for the year ended December 31, 2024** . ~~These conditions~~ **As of December 31, 2024, we had cash and cash equivalents of $ 1. 8 million and current liabilities of $ 5. 7 million, and management has concluded that this circumstance** ~~raise~~ **raises** substantial doubt about our ability to continue as a going concern. To alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, management plans to secure additional capital, potentially through a combination of public or private securities offerings; convertible debt financings; ~~and / or~~ strategic transactions, including potential licensing arrangements, alliances and drug product collaborations focused on specified geographic markets **; and / or potential revenues from any future acquisitions of small companies with FDA- approved products as a result of our new corporate strategy announced in January 2025** ; however, none of these alternatives are committed at this time. There can be no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all, or identify and enter into any strategic transactions that will provide the capital that we will require. If none of these alternatives is available, or if available ~~,~~ **and** we are unable to raise sufficient capital through such transactions, we will not have sufficient cash resources and **will experience difficulty in** ~~liquidity to fund our business operations~~ - **operating as** ~~for at least the next 12 months following the date that the financial statements are issued. In addition, we may be unable to pay our vendors and other service partners on time, or at all. If any of our key vendors and service providers were to cease working with us or subject the delivery of products or services to timing or payment preconditions, our development activities may be adversely affected, which could have~~ a **going concern as a result** ~~material adverse effect on our business and operations~~ . ~~Additionally~~ **Moreover** , if **such** ~~we are unable to regain compliance with the listing standards of Nasdaq, our common stock may become delisted, which could have a material adverse effect on the liquidity of our common stock and our ability to raise funding. If~~ additional financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be ~~require~~ required to delay, limit ~~,~~ or eliminate the development of business opportunities and our ability to achieve our business objectives and our competitiveness, and our business, financial condition, and results of operations will be materially adversely affected. **The** ~~In addition, market instability, including as a result of geopolitical instability, may reduce our ability to access capital, which could negatively affect our liquidity and ability to continue as a going concern. Further, the~~ perception that we may not be able to continue as a going concern may ~~cause others~~ **impede our ability** to ~~choose not to deal with us~~ **pursue strategic opportunities or operate our business** due to concerns about our ability to meet our contractual obligations. ~~Our forecast of~~ **Further, under** the ~~period~~ **terms** of ~~time through which our~~ **certain securities purchase agreements that we entered into in July 2024 (the " PIPE Purchase Agreements "), we are subject to certain restrictive covenants that may make it difficult to procure additional** ~~financial~~ **financing** ~~resources will~~ **. For additional information, see the risk factor captioned " Under the terms of the PIPE Purchase Agreements, we are subject to certain restrictive covenants that may make it difficult to procure additional financing. " As a result of these covenants, our**

ability to respond to changes in business and economic conditions may be **limited** ~~adequate to support our operating requirements is a forward- looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors~~ , including ~~the factors discussed elsewhere in this " Risk Factors " section. We have based this estimate on a number of assumptions that may prove to be wrong and changing circumstances beyond~~ our ~~control may cause us to consume capital more rapidly than we currently anticipate. Our inability~~ -- **ability** to obtain additional ~~funding when we~~ **debt or equity financing as** ~~need~~ **needed** ~~it~~ **in the future, on favorable terms, if at all, which** could ~~seriously harm~~ **adversely affect** our business **, financial condition, and results of operations. If we fail to raise sufficient capital, we potentially could be forced to limit or cease our development activities, as well as modify or cease our operations, either of which would have a material adverse effect on our business, financial condition, and results of operations. In addition, sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, including pursuant to our existing ELOC, could depress the market price of our common stock and could further impair our ability to raise capital through the sale of additional equity securities. These conditions are indicators that further impact our ability to continue as a going concern** . We have incurred significant operating losses since inception, we expect to incur operating losses in the future, and we may not be able to achieve or sustain profitability. We have incurred operating losses since our incorporation on November 6, 1992. For the years ended December 31, **2024 and** 2023 ~~and 2022~~ , we had operating losses of $ **26. 1 million and $** 20. 6 million ~~and $ 41. 3 million~~ , respectively. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~844~~ **846** . ~~8~~ **6** million. To date, we have financed our operations primarily through private placements and public offerings of our common and preferred stock and borrowings from investors and financial institutions. As of December 31, ~~2023~~ **2024** , we had cash and cash equivalents of $ ~~4~~ **1** . ~~3~~ **8** million and current liabilities of $ ~~4~~ **5** . ~~0~~ **7** million ~~. In April 2024, we entered into the Purchase Agreement pursuant to which we agreed to sell the Notes for $ 1. 5 million of gross proceeds. As a result, we believe that we have sufficient resources available to fund our business operations through April 2024~~ . We expect to continue to incur significant research and clinical development, regulatory and other expenses as we (i) develop product candidates; (ii) seek regulatory clearances or approvals for our planned or future product candidates; (iii) conduct clinical trials on our planned or future product candidates; and (iv) manufacture, market, and sell any product candidates for which we may obtain regulatory approval. As a result, we expect to continue to incur operating losses for the foreseeable future and may never achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. If we do not achieve or sustain profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives, either of which would have a material adverse effect on our business, financial condition and results of operations and may cause the market price of our common stock to decline. We have incurred indebtedness, which could adversely affect our operating flexibility and financial condition. We have, and may from time to time in the future have, third- party debt service obligations pursuant to our outstanding indebtedness ~~, which currently includes $ 1. 5 million in aggregate principal amount, or the Notes~~ . The degree to which we are leveraged could have important consequences. For example, it could: ● make it more difficult for us to satisfy our obligations with respect to our existing indebtedness; ● increase our vulnerability to general adverse economic and industry conditions; ● require us to dedicate a substantial portion of our cash flows from operations to payments on our indebtedness, thereby reducing the availability of our cash flows to fund working capital and capital expenditures, and for other general corporate purposes; ● limit our flexibility in planning for, or reacting to, changes in our business and industry, which may place us at a competitive disadvantage compared to our competitors that have less debt; ● restrict us from making strategic acquisitions or other investments or cause us to make non- strategic divestitures; and ● limit, along with the financial and other restrictive covenants in the documents governing our indebtedness, among other things, our ability to obtain additional financing for working capital and capital expenditures, and for other general corporate purposes. If we cannot maintain an adequate cash balance to service our debt, we may be unable to pay amounts due under our outstanding indebtedness or to fund other liquidity needs and it may be required to refinance all or part of our then existing indebtedness, sell assets, reduce or delay capital expenditures or seek to raise additional capital, any of which could have a material adverse effect on our business, results of operations and financial condition. We cannot assure you that our business will generate sufficient cash flows from operations in an amount sufficient to enable us to pay our indebtedness or to fund our other liquidity needs. Further, we cannot assure you that we will be able to refinance any of our indebtedness on commercially reasonable terms, or at all. In addition, in some cases, ~~the Notes~~ **our debt instruments may** allow for the interest to be paid in a combination of cash and shares of our common stock, and **may** ~~allows~~ **allow** for the interest to be convertible into shares of our common stock, which may dilute our existing stockholders. Such conversion ~~is~~ **may** also subject to adjustment, which may cause further dilution to our existing stockholders. ~~The Notes are~~ **Our debt instruments may also be** subject to restrictive and other covenants that may limit our discretion and the discretion of our subsidiaries with respect to certain business matters. A breach of any of these covenants could result in a default under our outstanding indebtedness, which would have a material adverse effect on our business, results of operations and financial condition. We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, or other operations. The development of biopharmaceutical product candidates is capital- intensive. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our planned clinical trials under our key clinical development programs, continue research and development and potentially initiate clinical trials under our other development programs and seek regulatory approval for any product candidates we may develop. In addition, as our product candidates progress through development and toward commercialization, we may need to make milestone payments to licensors and other third parties from whom we have in- licensed or acquired our product candidates. Furthermore, if and to the extent we seek to acquire or in- license additional product candidates in the future, we may be required to make significant upfront payments, milestone payments, and / or licensing payments. If we obtain regulatory approval for any of our product candidates, we also expect to incur significant

commercialization expenses related to product manufacturing, marketing, sales and distribution. Because the outcome of any clinical trial or preclinical study is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Moreover, a small group of investors that hold a significant portion of our issued and outstanding common stock may be in a position to influence the terms of a funding transaction, potentially making it more difficult to reach agreement on terms that are acceptable to investors participating in the financing, in a timely manner, if at all. If we are unable to raise sufficient capital to fund our activities when needed and on acceptable terms, we could be forced to delay, reduce or eliminate our research and development programs or, if our product candidates are approved, any future commercialization efforts. We have based estimates included in our operating plan on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day- to- day activities, which may adversely affect our ability to develop our product candidates. Our future capital requirements will depend on many factors, including: ● the type, number, scope, progress, expansions, results, costs and timing of our clinical trials and preclinical studies of our product candidates, which we are pursuing or may choose to pursue in the future; ● the costs and timing of manufacturing for our product candidates, including commercial manufacturing if any product candidate is approved; ● the costs, timing and outcome of regulatory review of our product candidates; ● the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights; ● the timing and amount of the milestone or other payments we must make to the licensors and other third parties from whom we have in- licensed or acquired our product candidates; ● the costs and timing of establishing or securing sales and marketing capabilities if any product candidate is approved; ● the costs, terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; ● costs associated with any product candidates or technologies that we may in- license or acquire; and ● our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from payors and adequate market share and revenue for any approved products. Conducting clinical trials and preclinical studies is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us at any time on acceptable terms, or at all. **As a result of our failure to timely file our Quarterly Report on Form 10- Q for the quarterly period ended September 30, 2024 with the SEC, we are currently ineligible to file new registration statements on Form S- 3, which may impair our ability to raise capital in a timely manner or at all. Because we were unable to file our Quarterly Report on Form 10- Q for the quarterly period ended September 30, 2024 with the SEC on a timely basis, we will not be eligible to register the offer and sale of our securities using a registration statement on Form S- 3 until no earlier than December 1, 2025. Should we wish to register the offer and sale of our securities to the public prior to the time we are eligible to use Form S- 3, including for purposes of raising capital or permitting the resale of privately placed securities, we will be required to file a registration statement on Form S- 1 which may be reviewed and will need to be declared effective by the SEC. Doing so would likely take longer than filing a registration statement on Form S- 3 and increase our transaction costs, making it more difficult to execute any such transaction successfully and potentially harming our liquidity and financial condition.** Our strategy to expand our pipeline on our own, through acquisitions of early- stage product candidates, or through research partnerships, may not be successful. Our business is focused on advancing early and late- stage innovative therapies for critical conditions and diseases. In this regard, we continue to pursue internal discovery efforts or partnerships with pharmaceutical and biotech companies, with the goal of identifying new product candidates to advance into clinical trials. Our efforts to identify new product candidates will require substantial technical, financial and human resources. These discovery efforts may initially show promise in identifying potential product candidates, yet ultimately fail to yield product candidates for clinical development for a number of reasons. For example, potential product candidates may, on later stage clinical trial, be shown to have inadequate efficacy, harmful side effects, suboptimal pharmaceutical profiles or other characteristics suggesting that they are unlikely to be commercially viable products. Apart from our internal efforts, we may continue to seek to broaden and diversify our product portfolio through acquisitions. This strategy is dependent on our ability to successfully identify and acquire relevant product candidates. For example, in April 2024, we entered into an Asset Purchase Agreement, or the Asset Purchase Agreement, with Varian Biopharmaceuticals, Inc., or Varian, to acquire certain of Varian' s assets, including a proprietary aPKCi inhibitor. The acquisition of a product is a highly competitive area, and many other companies are pursuing the same or similar product candidates to those that we may consider attractive. In particular, larger companies with more well- established and diverse revenue streams may have a competitive advantage over us due to their size, financial resources and more extensive clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign rights to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising product candidates. The process of proposing, negotiating and implementing an acquisition of a product candidate is lengthy and complex, and we may be unable to acquire the rights to any such products or product candidates from third parties for several reasons. We may also be unable to acquire additional relevant product candidates on acceptable terms. Further, even if we identify acquisition targets, we may not be able to complete the transactions or we may determine after due diligence investigation not to pursue identified targets. Even if we succeed in our efforts to obtain rights to suitable product candidates, the success of our investments in these areas ~~, our~~

~~investment strategy~~ will remain subject to the inherent risks associated with the development and commercialization of the product ~~,~~ and with the competitive business environment in which we operate **.** In addition, acquisitions may entail numerous operational, financial and legal risks, including: ● potential failure of the due diligence process to identify significant problems, liabilities or other shortcomings or challenges of an acquired product candidate or technology, including problems, liabilities or other shortcomings or challenges with respect to intellectual property, product quality, partner disputes or issues and other legal and financial contingencies and known and unknown liabilities; ● assumption of unknown or contingent liabilities or incurrence of unanticipated expenses; ● exposure to known and unknown liabilities, including possible intellectual property infringement claims, violations of laws, tax liabilities and commercial disputes; ● incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions; ● incurrence of large one- time expenses and acquiring intangible assets that could result in significant future amortization expense and significant write- offs; ● higher than expected acquisition and integration costs; and ● inability to maintain uniform standards, controls, procedures and policies. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Until we can generate substantial product revenues to support our operations, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other strategic transactions. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect their rights as common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and / or that may reduce the value of our common stock. Unstable market and economic conditions may have serious adverse consequences on our business, financial condition, and stock price. Global financial markets have recently, and may continue to, experience extreme volatility and disruptions, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability as a result of geopolitical unrest, liquidity constraints, failures and instability in U. S. and international financial banking systems, inflation, and other factors beyond control. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy and ability to raise capital may be adversely affected by any such economic downturn, volatile business environment, or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers, and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies, including in connection with the COVID- 19 pandemic, which resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. For additional information regarding the impact of **any** ~~the COVID- 19~~ pandemic, please see **the risk factor captioned** " ~~Risk Factors — The COVID- 19~~ **Our business may be adversely affected by a** pandemic ~~has negatively impacted~~ , **epidemic** ~~and may continue to negatively impact~~ , ~~our~~ **or outbreak of an infectious disease** ~~ability to develop our product candidates~~ . " Further, the impacts of political unrest, including as a result geopolitical tension, such as a deterioration in the relationship between the U. S. and China or continued conflict between Russia and Ukraine, including any additional sanctions, export controls or other restrictive actions that may be imposed by the U. S. and / or other countries against governmental or other entities in, for example, China or Russia, also could lead to disruption, instability, and volatility in the global markets, which may have an adverse impact on our business or ability to access the capital markets. Broad market and industry factors, including potentially worsening economic conditions, inflationary pressures, and other adverse effects, political, regulatory, and other market conditions, may negatively affect the market price of shares of our common stock, regardless of our actual operating performance **. Our business could be adversely affected by economic downturns, changes in inflation and interest rates, changes in trade policy, political crises, geopolitical events, such as the ongoing war between Russia and Ukraine and the war involving Israel, or other macroeconomic conditions, which may in the future negatively impact our business and financial performance. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, changes in inflation and interest rates, and uncertainty about economic stability. For example, during 2022 and 2023, the Federal Reserve raised interest rates multiple times in response to concerns about inflation. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. Trade policies and geopolitical disputes and conflicts can result in tariffs, sanctions and other measures that restrict international trade, and may adversely affect our costs of doing business, particularly if these measures occur in regions where our suppliers source components or raw materials, such as China. Similarly, the ongoing war between Russia and Ukraine and the war involving Israel have created volatility in the global capital markets and are expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Additionally, a general slowdown in the global economy, including a recession, or in a particular region or industry, an increase in trade tensions between the U. S. and its trading**

partners, imposition of higher tariffs and sanctions, particularly if such measures occur in regions where drug products are manufactured or raw materials are sourced, inflation or a tightening of the credit markets could negatively impact our business, financial condition and liquidity. Adverse global economic conditions have from time to time caused or exacerbated significant slowdowns in the industries and markets in which we operate, which could adversely affect our ability to commercialize our products and continue development of our product candidates, finance our operations in a timely manner or on favorable terms, and materially harm our business, operations and financial condition. Natural disasters, including those resulting from significant climate change, could adversely affect our business and our third-party partners' businesses. Natural disasters, such as hurricanes, tornadoes, floods, wildfire, and drought may impact our operations or our partners' businesses. Climate change is increasing the frequency, intensity, and duration of these weather events. These natural disasters, including those resulting from significant climate change, could destroy or damage facilities or other properties, disrupt business, increase the probability of power or other outages, or otherwise cause significant economic dislocation in the affected regions. Any of these situations may adversely affect our financial condition and results of operations . Adverse developments affecting the financial services industry, including events or concerns involving liquidity, defaults or non- performance by financial institutions or transactional counterparties, could adversely affect our business, financial condition or results of operations. Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems ~~. Most recently, 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 as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership~~ . Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. 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 financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our business, financial condition or results of operations. Due to the significant resources required to develop our product candidates, we must prioritize development of certain product candidates and / or certain disease indications. We may ~~be delayed in advancing a product candidate or potential indication if our plan does not include sufficient funding to execute a clinical program. If we~~ expend our limited resources on candidates or indications that do not yield a successful product and fail to capitalize on other product candidates or indications that may be more profitable or for which there is a greater likelihood of success ~~, such failure could have a material adverse effect on our business, financial condition, results of operations, and prospects~~ . We are currently focused on developing product candidates to address unmet medical needs in acute cardiovascular diseases. We seek to allocate our limited capital among our programs in an efficient manner and to advance our cardiovascular product candidate. However, due to the significant resources required to advance the development of our product candidates, we also must focus on specific indications and disease pathways and decide which product candidates and indications to pursue and the amount of resources to allocate to each such product candidate. Our ability to advance a product candidate depends on our ability to secure the additional capital required to execute each phase of product development. In developing our plan, we were aware of the size and projected costs of our planned late stage development of istaroxime to improve cardiac function and clinical outcomes in patients with AHF. We have allocated our limited resources initially toward cardiogenic shock as we believe this may be a less resource intensive and faster development program. Such decisions concerning the allocation of research and development funds towards, or away from, 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, any decision to delay, terminate or engage with third parties in respect of certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. In that event, our business, financial condition and results of operations could be materially adversely affected. As a result, 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 development and commercialization rights. We have a significant amount of intangible assets recorded on our consolidated balance sheets which may lead to potentially significant impairment charges. As a result of the acquisition of CVie Therapeutics in December 2018, we have recorded significant intangible assets on our consolidated balance sheets, which could become impaired and lead to material charges in the future. The identifiable intangible assets resulting from the CVie Therapeutics acquisition relate to IPR & D of istaroxime and rostafuroxin, which, as of December 31, ~~2023~~ **2024** , were $ 22. 3 million and $ ~~2~~ **1** . ~~9~~ **8** million, respectively, recorded in aggregate on our consolidated balance sheet as intangible

assets of $ ~~25~~ **24** . ~~3~~ **1** million ~~. As of December 31, 2023, goodwill was zero on our consolidated balance sheet~~ . Throughout the year, we consider whether any events or changes in the business environment have occurred which indicate that intangible assets ~~or goodwill~~ may be impaired. If an impairment exists, we would be required to take an impairment charge with respect to the impaired asset. Events giving rise to impairment are difficult to predict, including the uncertainties associated with the development of product candidates and the success of business development activities, and are an inherent risk in the pharmaceutical industry. ~~Based on~~ **As part of** our annual quantitative impairment assessment of ~~our~~ indefinite- lived IPR & D intangible assets as of December 1, ~~2023~~ **2024 , we reassessed certain assumptions related to our rostafuroxin drug candidate due to the continued difficulties in current macroeconomic conditions which have continued to make it more challenging to secure the funding needed to conduct the additional Phase 2 clinical trial and have therefore further delayed our intended development of rostafuroxin. As a result** , we concluded that the ~~assets were not impaired. Since early 2022, we have experienced a declining trend in the closing share price of our common stock, on a split- adjusted basis. During each of the first and second quarters of 2023, the continued declining trend in the closing share price of our common stock, on a split- adjusted basis, suggested that the~~ fair value of **the IPR & D related to** our ~~reporting unit~~ **rostafuroxin drug candidate** was ~~more likely than not~~ less than its carrying value. **We estimated** ~~As a result, in each quarter, we performed~~ the **fair value of** ~~interim goodwill impairment test consistent with~~ the ~~methodology that we use when performing~~ **asset using multi- period excess earnings method,** ~~our~~ **or MPEEM,** ~~annual goodwill impairment assessment~~ and determined that the fair value **as** of ~~our reporting unit~~ **December 1, 2024** was ~~more likely~~ **approximately $ 1. 8 million. We** ~~than~~ **then** ~~not less than its~~ **compared this fair value to the** carrying value **of approximately $ 2** . ~~We~~ **9 million, and** recorded a loss on impairment of ~~goodwill~~ **intangible assets** of $ **1** ~~0. 5 million in the first quarter of 2023 and an additional loss of $ 2. 6 million, representing the remaining balance of goodwill, in the second quarter of 2023. For the year ended December 31, 2023, the aggregate loss on impairment of goodwill is $ 3~~ . 1 million **related to the IPR & D of our rostafuroxin drug candidate. We also reassessed the assumptions related to the fair value of the IPR & D related to our istaroxime drug candidate. The estimated fair value exceeded the carrying value of that asset. As a result** , **no impairment charge was** recognized **related to the IPR & D** ~~within operating expenses in our consolidated statement~~ of ~~operations. As of December 31, 2023, goodwill was zero on~~ our ~~consolidated balance sheet~~ **istaroxime drug candidate** . If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline. Pursuant to Section 404 of the Sarbanes- Oxley Act of 2002, as amended, we are required to furnish a report by our management on our internal control over financial reporting. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If our financial statements are not accurate, investors may not have a complete understanding of our operations. If we do not file our financial statements on a timely basis as required by the SEC, we could face severe consequences. **For example, as a result of our failure to timely file our Quarterly Report on Form 10- Q for the quarterly period ended September 30, 2024 with the SEC, we are currently ineligible to file new registration statements on Form S- 3, which may impair our ability to raise capital in a timely manner or at all. However, such failure to timely file such Quarterly Report was determined not to be a result of any material weakness or significant deficiency in our internal control over financial reporting.** If we are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by ~~the~~ **The** Nasdaq Stock Market LLC, or Nasdaq, the SEC or other regulatory authorities. Moreover, responding to such investigations, are likely to consume a significant amount of our management resources and cause us to incur significant legal and accounting expense. Failure to remedy any material weakness in our internal control over financial reporting, or to maintain effective control systems, could also restrict our future access to the capital markets. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. Risks Related to our Development Activities and Regulatory Approval of our Product Candidates We are substantially dependent on the success of our lead product candidate istaroxime. To the extent that our clinical development of istaroxime is not successful, our business, financial condition, and results of operations may be materially adversely affected and the price of our common stock may decline. We currently have no product candidates approved for sale, and we may never be able to develop marketable products. We are focusing a significant portion of our activities and resources on our lead product candidate, istaroxime, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully obtain regulatory approval for istaroxime. We currently do not have sufficient capital to fully execute clinical trials with respect to istaroxime. Furthermore, the clinical development and regulatory approval of istaroxime is subject to many risks, including the risks discussed in other risk factors, and istaroxime may not receive marketing approval from any regulatory agency. If we are unable to continue to advance istaroxime through clinical development, or if the results or timing of regulatory filings, the regulatory process, regulatory developments, clinical trials or preclinical studies, or other activities, actions or decisions related to istaroxime do not meet our or others' expectations, the market price of our common stock could decline significantly. Should the results of our clinical development program be insufficient to support regulatory approval, we may be forced to rely on our other product candidates, which will require additional time and resources to potentially obtain regulatory approval. There can be no assurance that we will be able to successfully develop istaroxime. Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of preclinical studies and early clinical trials are not necessarily predictive of future results. In addition, our assumptions about why certain of our product candidates are worthy of future development and potential approval are based on data primarily collected by other companies. Our product candidates may not have favorable results in later clinical trials, if any, or receive regulatory approval on a timely basis, if at all. Clinical drug development is

expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process as a result of inadequate study design, inadequate performance of a drug, inadequate adherence by patients or investigators to clinical trial protocols, or other factors. For example, conducting a toxicology study as part of a preclinical program, to be included in a required regulatory submission, could result in unanticipated findings that could potentially negatively impact the clinical program. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high. Product candidates in later stages of clinical trials may fail to achieve the desired safety and efficacy outcomes despite having progressed through earlier clinical trials. As a result, data we obtain from our ~~phase~~ **Phase** 2 clinical trials may not accurately predict ~~phase~~ **Phase** 3 trial results, whether due to differences in sample size, study arms, duration, endpoints, or other factors. If any of our product candidates should fail to perform as designed in their respective ~~phase~~ **Phase** 3 clinical programs, such failures could adversely affect the results of our clinical development program despite promising results in earlier trials. If clinical trials for any of our product candidates fail to demonstrate safety or efficacy to the satisfaction of the U. S. Food and Drug Administration, or FDA, or the equivalent regulatory authorities in other countries, the FDA or the equivalent regulatory authorities in other countries will not approve that drug and we would not be able to commercialize it, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if we are required to cease development activities on any of our recently acquired product candidates due to adverse clinical results or otherwise, it could result in impairment of related intangible assets and goodwill on our consolidated balance sheets. Even if later stage clinical trials are successful, regulatory authorities may question the trial design or sufficiency for approval of the endpoints we select for our clinical trials or add new requirements, such as the completion of additional studies, as conditions for obtaining approval or obtaining an indication. For the foregoing reasons, we cannot be certain that our planned clinical trials and preclinical studies will be successful. Any safety concerns observed in any one of our 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, financial condition and results of operations, and result in significant additional costs and expenses, require additional time and have an adverse effect on our business, including our financial condition and results of operations. Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to continue development activities, including our ability to obtain trial results, regulatory approval and commence product sales or allow for competition to emerge. We may experience delays in clinical trials of our product candidates, or the time required to complete clinical trials for our product candidates may be longer than anticipated. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including, but not limited to: ● our inability to raise funding necessary to initiate or continue a trial; ● delays in obtaining regulatory approval to commence a trial or reaching a consensus with regulatory authorities on trial design or product standards; ● delays in reaching an agreement with the FDA or the equivalent foreign regulatory authorities in other countries on final trial design or the scope of the development program; ● inability to develop studies that are acceptable in all markets of interest; ● inability to come to an agreement on clinical trial design or execution factors with potential development partners; ● imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or the equivalent regulatory authorities in other countries; ● failures or 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 trial sites; ● delays associated with severe acute respiratory syndrome coronavirus 2, the causative agent in a novel strain of coronavirus, which have and may continue to impact our healthcare systems and our trial sites ability to conduct trials to varied degrees and times. Coronavirus creates risk of interrupting availability of necessary clinical supplies, local regulatory reviews, hospital ethics committee reviews, professional staff, site monitors and other necessary travel; ● delays in obtaining contracts with clinical sites and required IRB approval at each site; ● IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial; ● competition with other studies for study patients; ● changes to clinical trial protocol; ● delays in recruiting suitable patients to participate in a trial; ● subjects choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials; ● delays in having subjects complete participation in a trial or return for post- treatment follow- up; ● clinical sites deviating from trial protocol or dropping out of a trial to the detriment of enrollment; ● subjects experiencing severe or unexpected adverse events; ● occurrence of serious adverse events in trials of the same class of agents conducted by other companies; ● selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data; ● third- party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, GCPs, or other regulatory requirements; ● third- party contractors not performing data collection or analysis in a timely or accurate manner; ● third- party contractors lacking adequate certification to provide services in all regions where we conduct our business activities; ● third- party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; ● manufacturing timing and / or obtaining sufficient quantities of product candidate or obtaining sufficient quantities of combination therapies for use in clinical trials or changes in the manufacturing process or inability to meet analytical standards for product release or use that may be necessary or desired; ● time required to add new clinical sites; or ● delays by our contract manufacturers to produce and deliver a sufficient supply of clinical trial materials or being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMP regulations or other

applicable requirements, or infections or cross- contaminations of product candidates in the manufacturing process. In addition, we may not reach agreement with the FDA, or a foreign regulator on the extent of our ~~phase~~ **Phase** 3 programs, the design of any one or more of the clinical trials necessary for approval, or we may be unable to reach agreement on a single design that would permit us to conduct a common pivotal ~~phase~~ **Phase** 3 clinical development program in all markets of interest. For example, we may not be able to design a study that is acceptable to both the FDA and the EMA regulators, which would cause us to limit the scope of our geographical activities or greatly increase our investment. Even if we complete the clinical trial within our anticipated time, if our results are inconclusive or non- compelling or otherwise insufficient to support a strategic or financing transaction, we potentially could be forced to limit or cease our development activities, which would have a material adverse effect on our business. We have conducted, and may in the future conduct, clinical trials for our product candidates at clinical sites located in the U. S. and outside of the U. S. If the FDA and other foreign equivalents raise concerns about certain of the clinical sites based on location and regulatory environment, they may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business. We have conducted and are expecting in the future to conduct one or more of our clinical trials for our product candidates at clinical sites located in the U. S. and outside of the U. S., including the EU, China, Russia, Israel, and South America. Although the FDA may accept data from clinical trials conducted outside the U. S., acceptance of this data may be subject to certain conditions imposed by the FDA. For example, the FDA requires the clinical trial to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. Where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U. S., the FDA will not approve the application on the basis of foreign data alone unless those data are considered applicable to the U. S. patient population and U. S. medical practice, the clinical trials were performed by clinical investigators of recognized competence, and the data is considered valid without the need for an onsite inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an onsite inspection or other appropriate means. There can be no assurance the FDA will accept data from clinical trials conducted outside of the U. S. If the FDA does not accept data from our clinical trials of our product candidates, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our development of our product candidates. For example, we have previously conducted clinical trials in Russia. The February 2022 invasion of Ukraine by Russia and the resulting imposition of economic and other sanctions by the U. S., EU, and many other nations on Russia, individuals in Russia, Russian businesses, and the Russian central bank, has impacted the way we executed certain trial procedures as we completed the first part of our trial in early cardiogenic shock. This geopolitical disruption could also disrupt or delay our ability to conduct clinical trial activities in Russia in the future. Although the length and impact of any military action are highly unpredictable, making them unavailable for follow- up could result in increased costs and could delay our anticipated timeline for the completion of our future clinical trials. ~~The~~ **Our business could be adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business activities and could cause significant disruption in the operations of third- party contract manufacturers and contract research organizations upon whom we rely, as well as our ability to recruit patients for our clinical trials. For example, the** impact of the COVID- 19 pandemic resulted in, and may in the future result in, significant disruptions to the global economy, as well as businesses and capital markets around the world. **Health epidemics** ~~Efforts to contain the spread of COVID- 19 have intensified at times to manage surges in the infection rate and deaths, and many countries have at times implemented severe travel restrictions, social distancing, and delays or cancellations of elective surgeries at different times. Notwithstanding the introduction of effective vaccines, COVID- 19~~ may in the future affect our ability and the ability of our employees, contractors, suppliers, and other partners in the U. S. and abroad to conduct normal business activities from time to time, including due to shutdowns that may be requested or mandated by governmental authorities. The **global** spread of COVID- 19 **had** ~~globally has previously~~ adversely impacted trial conduct and operations and may do so again in the future. We have, in the past, initiated several clinical trials for istaroxime in the EU and other worldwide locations impacted by the COVID- 19 outbreak. Our clinical trials have suffered delays and interruptions and our previous decision to cease enrollment in the AEROSURF clinical trial was partially due to such delays and escalating expenses. Our efforts to conduct trials could be materially delayed in the future by governmental restrictions and enrollment difficulties as hospitals reduce and divert staffing, divert resources to patients suffering from the infectious disease and limit hospital access for nonpatients **, whether as a result of COVID- 19 or other health epidemics** . Similarly, there is a risk that clinical supplies of our product candidates may be significantly delayed or may become unavailable as a result of **any pandemic** ~~COVID- 19~~ and the resulting impact on our suppliers' labor forces and operations, including as a result of governmental restrictions on business operations and the movement of people and goods in an effort to curtail the spread of the virus. There can be no assurance that we would be able to timely implement any mitigation plans. Disruptions in our supply chain, whether as a result of restricted travel, quarantine requirements or otherwise, could negatively impact clinical supplies of our product candidates, which could materially adversely impact our clinical trial and development timelines. The effects of ~~COVID- 19 or~~ any ~~other~~ pandemic, including identification of potential new variants, has led and may in the future lead to periodic disruption and volatility in the global capital markets, which could increase our cost of capital and adversely affect our ability to access the capital markets in the future. It is possible that the spread of **an infectious disease, including** COVID- 19 **,** in the future could cause an economic slowdown or recession or cause other unpredictable events, each of which could adversely affect our business, results of operations or financial condition. The extent to which ~~COVID- 19 or~~ any ~~other~~ pandemic impacts our financial results going forward will depend on future developments, which are highly uncertain and cannot be predicted ~~, including new information which may emerge concerning the severity of the COVID- 19 outbreak, the rise of variants, which may be more contagious and potentially more lethal, and the actions recommended to contain the outbreak or treat its impact, among others~~ . Moreover, **epidemics have** ~~the COVID- 19 outbreak has~~ had and may in the future have indeterminable adverse effects on general commercial activity and the

world economy, and our business and results of operations could be adversely affected to the extent that ~~COVID- 19 or~~ any ~~other~~ pandemic harms the global economy generally. Use of our product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition. As is the case with pharmaceuticals generally, there may be adverse events in patients treated with our product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. 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 or comparable foreign regulatory authorities. Adverse events could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Moreover, if our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective, which may limit the commercial expectations for the product candidate if approved. We may also be required to modify our study plans based on findings in our clinical trials. Many compounds that initially show promise in early- stage testing have later been found to cause side effects that prevented further development of the compound. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as the use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition and prospects significantly. In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including: ● regulatory authorities may withdraw, suspend or limit approvals of such product; ● we may be required to recall a product or change the way such product is administered to patients; ● regulatory authorities may require additional warnings on the label, such as a " black box " warning or a contraindication; ● we may be required to implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients; ● we may be required to change the way a product is distributed or administered, conduct additional clinical trials or change the labeling of a product or be required to conduct additional post- marketing studies or surveillance; ● we could be sued and held liable for harm caused to patients; ● sales of the product may decrease significantly, or the product could become less competitive; 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. Our product candidates are subject to extensive regulation and compliance, which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates. The clinical development, manufacturing, labeling, storage, record- keeping, advertising, promotion, import, export, marketing and distribution of investigational new drugs and approved new drugs are subject to extensive regulation by the FDA in the U. S. and by comparable foreign regulatory authorities in foreign markets. In the U. S., the process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. We are not permitted to market any of our product candidates in the U. S. until we receive approval of an NDA from the FDA. Prior to obtaining approval to commercialize a product candidate, if approved, in the U. S. or abroad, we must demonstrate with substantial evidence from adequate and well- controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses **. Results from nonclinical studies and clinical trials can be interpreted in different ways** . Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post- approval, or may object to elements of our clinical development program. The FDA or comparable foreign regulatory authorities can delay, limit, or deny approval of a product candidate for many reasons, including: ● such authorities may disagree with the design or implementation of our clinical trials; ● negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval; ● such authorities may disagree with our interpretation of data from preclinical studies or clinical trials; ● such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support approval; ● serious and unexpected adverse events may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates; ● the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval; ● such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care or patient characteristics are potentially different from that of the U. S.; ● we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks or the safety data base may not be large enough; ● such authorities may not accept the submission of an NDA or other submission to obtain regulatory approval in the U. S. or

elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials; ● such authorities may disagree regarding the formulation, labeling and / or the specifications of our product candidates; ● approval may be granted only for indications that are significantly more limited than what we apply for and / or with other significant restrictions on distribution and use; ● such authorities may find deficiencies in the manufacturing processes or facilities of our third- party manufacturers with which we contract for clinical and, if approved, commercial supplies; or the approval policies; ● regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval; or ● such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission. We may conduct clinical development in the U. S., Canada, the EU, Eastern Europe, Latin America, and Asia Pacific regions and sell our products, if approved, in the U. S. and potentially in other major markets. To accomplish this objective, we must **first** obtain ~~and maintain~~ regulatory approvals and comply with regulatory requirements in each jurisdiction ~~. To avoid the significant expense and lengthy time required to complete multiple regional clinical development programs, we expect to meet with relevant regulatory authorities~~ . While we would prefer to design a single, global clinical development program that ~~would~~ **could** satisfy the regulators in all of our target markets, there can be no assurance that our efforts will be successful. If we are unable to reach agreement with the various regulatory authorities, we may not be able to pursue regulatory approval of our product candidates in all of our selected markets. With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our potential future collaborators from commercializing our product candidates ~~. In addition, delays associated with COVID- 19 may impact local regulatory reviews occurring in a timely manner and result in delays for trial and site initiations~~ . Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects. Although we have multiple product candidates or potential indications of those candidates in our clinical pipeline, we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on other product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we may focus on specific product candidates, indications and development programs at any time. As a result, we may forgo or delay pursuit of opportunities with other product candidates that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaborations, license agreements and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Additionally, we may pursue additional in- licenses or acquisitions of development- stage assets or programs, which entails additional risk to us. For example, in connection with the Asset Purchase Agreement entered into on April 2, 2024, we acquired certain assets from Varian, which includes topical and oral formulations of our aPKCi inhibitor. Because we were not involved in the preclinical development of these drug candidates prior to such date, we have relied on Varian having conducted such research and development in accordance with the applicable protocol, legal, regulatory and scientific standards, having accurately reported the results of all preclinical studies conducted prior to our agreement with Varian and having correctly collected and interpreted the data from these studies. To the extent any of these has not occurred, expected development time and costs may be increased which could adversely affect any future revenue from the assets acquired from Varian. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management' s time and the expenditure of our resources with no resulting benefit. If we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital, management and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment. Even though some of our product candidates have Fast Track designation, the FDA may not approve them at all or any sooner than other product candidates that do not have Fast Track designation. We have received Fast Track designation from the FDA for istaroxime for the treatment of AHF. Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development, regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. Additionally, the FDA may withdraw Fast Track designation, for reasons such as it comes to believe a drug candidate no longer adequately addresses an unmet medical need. Fast Track designation alone does not guarantee qualification for the FDA' s priority review procedures. If we seek Fast Track designation for other product candidates, we may not receive such a designation from the FDA. Although we may pursue expedited regulatory programs for a product candidate or an indication, it may not qualify for expedited development or, if it does qualify for expedited development, it may not actually lead to a faster development or regulatory review or approval process. Although we have received Fast Track designation for certain of our product candidates, we believe there may be an opportunity to expedite the development of other product candidates or indications through one or more of the FDA' s expedited programs, such as Fast Track, Breakthrough Therapy or priority review, we cannot be assured that any of our product candidates or indications will qualify for such programs. For example, a

product candidate may be eligible for designation as a Breakthrough Therapy if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life- threatening condition and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Although Breakthrough Therapy designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. If we apply for Breakthrough Therapy designation or any other expedited program for our product candidates, the FDA may determine that our proposed target indication or other aspects of our clinical development plans do not qualify for such expedited program. For example, we believe that istaroxime may fulfill an unmet medical need in early and more severe cardiogenic shock based on the profile observed in prior ~~phase~~ **Phase** 2 clinical studies in AHF and early cardiogenic shock, in which increases in SBP as well as improvements in cardiac function were observed suggesting that istaroxime could potentially contribute to the clinical improvement of select patients in cardiogenic shock due to heart failure. However, the FDA may not agree with our assessment, and we may not be able to obtain Breakthrough Therapy designation. Even if we are successful in obtaining a Breakthrough Therapy designation or access to any other expedited program, we may not experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited program does not ensure that we will ultimately obtain regulatory approval for such product candidate. We may not be able to obtain or maintain Orphan Drug exclusivity for our product candidates. Regulatory authorities in some jurisdictions, including the U. S. and Europe, may designate drugs for relatively small patient populations as Orphan Drugs. In the U. S., Orphan Drug designation entitles a party to financial incentives such as tax advantages and user- fee waivers. In addition, if a product candidate that has Orphan Drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to Orphan Drug exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same indication for seven years, except in limited circumstances, including if the FDA concludes that the later drug is clinically superior to the approved drug. A drug is clinically superior if it is safer, more effective, or makes a major contribution to patient care. The FDA has granted Orphan Drug designation for our (i) KL4 surfactant (lucinactant) for the treatment of RDS in premature infants, (ii) our KL4 surfactant for the prevention and treatment of BPD in premature infants, (iii) our KL4 surfactant for the treatment of ARDS in adults, and (iv) our KL4 surfactant for the treatment of cystic fibrosis. If we obtain Orphan Drug exclusivity, we may lose such exclusivity if the FDA or the European Commission, or EC, determines that the request for designation was materially defective or if we are unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Moreover, Orphan Drug exclusivity may not effectively protect our product candidates from competition because different drugs can be approved for the same condition. Even after an Orphan Drug is approved, the FDA or comparable foreign regulatory authority can subsequently approve the same drug for the same condition if such regulatory authority concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a product candidate nor gives the product candidate any advantage in the regulatory review or approval process. Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose preliminary or topline or data from our clinical studies, which is based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Even if we receive regulatory approval for any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved. Following potential approval of any our product candidates, the FDA may impose significant restrictions on a product' s indicated uses or other aspects of the directions for use or marketing or impose ongoing requirements for potentially costly and time- consuming post- approval studies, post- market surveillance or clinical trials to monitor the safety and efficacy of the product. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post- approval. Later discovery of previously unknown problems with our products, including

adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things: ● restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls; ● restrictions on product distribution or use, or requirements to conduct post- marketing studies or clinical trials; ● fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters, Form 483s, or holds on clinical trials; ● refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals; ● product seizure or detention, or refusal to permit the import or export of our products; and ● injunctions or the imposition of civil or criminal penalties. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates, if approved, and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. In addition, if any of our product candidates is approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product' s approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off- label uses, we may become subject to significant liability. The FDA' s and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. If we fail to obtain and maintain regulatory approval in foreign jurisdictions, our market opportunities will be limited. In order to market our product candidates in the EU or other foreign jurisdictions, we must obtain and maintain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies from country to country and can involve additional testing. The time required to obtain approval abroad may be longer than the time required to obtain FDA clearance or approval. Foreign regulatory approval processes include many of the risks associated with obtaining FDA clearance or approval and we may not obtain foreign regulatory approvals on a timely basis, if at all. FDA clearance or approval does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. However, the failure to obtain clearance or approval in one jurisdiction may have a negative impact on our ability to obtain clearance or approval elsewhere. If we do not obtain or maintain necessary approvals to commercialize our product candidates in markets outside the U. S., it would negatively affect our overall market penetration. If the FDA or other applicable regulatory authorities approve generic products with claims that compete with our product candidates, it could reduce our sales of our product candidates if approved. In the U. S., after an NDA is approved, the product covered thereby becomes a " listed drug " which can, in turn, be cited by potential competitors in support of approval of an abbreviated NDA, or ANDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non- infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredients, dosage form, strength, route of administration, and conditions of use, or product labeling, as our product candidates and that the generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our product candidates. These generic equivalents would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product. Accordingly, competition from generic equivalents to our product candidates would substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our product candidates. Even if we receive regulatory approval for any of our product candidates, we may not be able to successfully commercialize the product and the revenue that we generate from its sales, if any, may be limited. If approved for marketing, the commercial success of our product candidates will depend upon the acceptance of each product by the medical community, including physicians, patients and health care payors. The degree of market acceptance for any of our product candidates, if approved, will depend on a number of factors, including: ● demonstration of clinical safety and efficacy; ● efficacy of our product candidates compared to competing products; ● relative convenience, dosing burden and ease of administration; ● the prevalence and severity of any adverse effects; ● the willingness of physicians to prescribe our product candidates, if approved, and the target patient population to try new therapies; ● our ability to obtain and maintain sufficient third- party coverage or reimbursement from government health care programs, including Medicare and Medicaid, global government payors, private health insurers and other third- party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; ● the willingness of patients to pay out- of- pocket in the absence of third- party coverage or reimbursement or government pricing approvals; ● government health care payor imposed mandatory pricing discounting and reductions; ● delays in achieving hospital formulary acceptance or limitations of use that are more restrictive than the approved label; ● the introduction of any new products that may in the future become available targeting indications for which our product candidates may be approved; ● new procedures or therapies that may reduce the incidences of any of the indications in which our product candidates, if approved, may show utility; ● pricing and cost-effectiveness; ● the inclusion or omission of our product candidates, if approved, in applicable therapeutic guidelines; ● the effectiveness of our own or any future collaborators' sales and marketing strategies; and ● limitations or warnings contained in approved labeling from regulatory authorities. If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third- party payors on the benefits of

our product candidates may require significant resources and may never be successful. In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our product candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render our product candidates not commercially viable. For example, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve any of our product candidates with a label that does not include the labeling claims necessary or desirable for the successful commercialization for that indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals or require risk management plans or a REMS to assure the safe use of the drug. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of our product candidates, if approved. Moreover, product approvals may be withdrawn for non- compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our product candidates, if approved. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. If we are found or alleged to have improperly promoted any of our products, if approved, for off- label uses, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, as our product candidates would be, if approved. In general, a product may not be promoted for uses that are not approved by the FDA or in ways that may not be consistent with the product' s approved labeling. If we are found to have promoted such off- label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off- label promotion. The FDA and other regulatory agencies have also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. We currently have no sales and marketing organization. If we are unable to establish satisfactory sales and marketing capabilities or secure a sales and marketing partner, we may not successfully commercialize any of our product candidates. We may not be able to enter into collaboration agreements on terms acceptable to us or at all. In addition, even if we enter into such relationships, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties. If we elect to establish a sales and marketing infrastructure, we may not realize a positive return on this investment. In addition, we will have to compete with established and well- funded pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize our product candidates, if approved, without strategic partners or licensees include: ● the inability of sales personnel to obtain access to or educate and appropriately persuade adequate numbers of physicians to prescribe any of our product candidates, if approved; ● inability to obtain a competitive share of voice and frequency of meeting with physicians against multiple, larger competitors; ● unforeseen costs and expenses associated with creating an independent sales and marketing organization; and ● inability to control or influence partner sales and marketing personnel or their prioritization of promotion of our product candidates, if approved. The successful commercialization of our product candidates, if approved, will depend in part on the extent to which hospitals and hospital systems, governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those product candidates and decrease our ability to generate revenue. The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third- party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our product candidates by third- party payors will have an effect on our ability to successfully commercialize our product candidates, if approved. Even if we obtain coverage for a given product candidate, if approved, by a third- party payor, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the U. S., the EU or elsewhere will be available for any product candidate that we may develop and for which we receive approval, and any reimbursement that may become available may be decreased or eliminated in the future. See the section titled, " Item 1. Business – Reimbursement. " Third- party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third- party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third- party payor may consider our product candidates, if approved, as substitutable and only offer to reimburse patients for the less expensive product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our product candidates, if approved, pricing of existing drugs may limit the amount we will be able to charge for our product candidates, if approved. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, if approved and may not be able to obtain a satisfactory financial return on products that we may develop. Obtaining and maintaining reimbursement status is time consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third- party payors in the U. S. Therefore, coverage and reimbursement 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 will require us to provide scientific and clinical support for the use of our product candidates, if approved, to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely. Outside the U. S., international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost- containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our product candidates, if approved. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Additional foreign price controls, discounts or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates, if approved. Accordingly, in markets outside the U. S., the reimbursement for product candidates for which we receive approval may be reduced and experience continual mandatory price reductions compared with the U. S. and may be insufficient to generate commercially reasonable revenue and profits. Moreover, increasing efforts by governmental and third- party payors in the U. S. and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates, if approved. We expect to experience pricing pressures in connection with the sale of any of our product, candidates, if approved, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. **Disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business. The ability of the FDA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, a government agency' s ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency' s ability to perform routine functions. Average review times at the FDA and other government agencies have fluctuated in recent years as a result. In addition, government funding of other government agencies 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 drugs and or modifications to approved drugs or to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. With the change in presidential administrations in 2025, there is substantial uncertainty as to how, if at all, the new administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. The impending uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates. Changes in funding for the FDA, the SEC and other government agencies 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 functions. 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, ability to hire and retain key personnel and accept 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. On January 20, 2025, President Trump signed an executive order creating an advisory commission, the " Department of Government Efficiency, " to reform federal government processes and reduce expenditures. Pressures on and uncertainty surrounding the U. S. federal government' s budget, and potential changes in budgetary priorities and spending levels, could adversely affect staffing levels and the funding for the FDA. Disruptions at the FDA and other agencies due to these policies may slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the past decade, the U. S. government has shut down, at least partially, several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. 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.** Risks Related to Our Reliance on Third Parties We rely on third parties, primarily outside of the U. S., to conduct many of our preclinical studies and clinical trials. Any failure by a third party to conduct the clinical trials according to **good clinical practices, or** GCPs **,** and other requirements and in a timely and quality manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize our product candidates. We are dependent on third parties to conduct our clinical trials and preclinical studies for our development programs. Specifically, we have used and relied on, and intend to continue to use and rely on, medical institutions, clinical investigators, CROs and consultants to conduct our clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. While we have agreements governing the activities of our third- party contractors, we have

limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and any third- party that we rely upon are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any third- party that we rely on or trial sites fail to comply with applicable GCPs or to provide adequate data with respect to such trials, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP and / or Quality System Regulation requirements. Our failure or our vendors' failure to comply with these regulations may require us to delay or to repeat clinical trials, which would delay the regulatory approval process. There is no guarantee that any such CROs, investigators or other third parties will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA we submit. Any such delay or rejection could prevent us from commercializing our product candidates, if approved. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional CROs, investigators and other third parties involves additional costs and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. ~~Our agreement with Universita Degli Studi di Milano- Bicocca, the institution that has performed many preclinical studies with istaroxime and our preclinical families of compounds, expired on July 31, 2022. If additional preclinical work is required for any reason, we will need to re- engage with Bicocca or find another vendor to provide those services.~~ We currently do not have a back- up facility for our **contract manufacturing organization, or** CMO **,** for our drug product candidates, or our suppliers of API. If the parties we depend on for supplying our APIs and manufacturing our drug product candidates do not supply these products in a timely and quality manner, it may delay or impair our ability to execute our development plans for our current and potential pipeline products ~~. Such delays could adversely impact our operations and financial condition~~ . In most cases, we are dependent upon a single supplier to provide all of our requirements for each of our active pharmaceutical ingredients, or APIs. We rely on a single CMO, located in China, to manufacture each of our cardiovascular drug product candidates that meets appropriate content, quality and stability standards for use in preclinical programs and clinical trials. Legislative proposals are pending that, if enacted, could negatively impact U. S. funding for certain biotechnology providers having relationships with foreign adversaries or which pose a threat to national security. The potential downstream adverse impacts on entities having only commercial relationships with any impacted biotechnology providers is unknown but may include supply chain disruptions or delays. In most cases, we submit purchase orders to our CMO and API suppliers as needed and do not have contractual commitments to manufacture for us in the future. Additionally, we intend to rely on CMOs to produce topical or oral formulations of our aPKCi inhibitor. If we do not establish or maintain these manufacturing and service relationships that are important to us and are not able to identify replacement suppliers, vendors and laboratories, our ability to obtain regulatory approval for our product candidates could be impaired or delayed and our costs could substantially increase. We may be unable to identify additional manufacturers with whom we might establish appropriate arrangements on acceptable terms, if at all, because the number of potential CMOs is limited. Even if we are able to find replacement manufacturers, suppliers, vendors and service providers when needed, we may not be able to enter into agreements with them on terms and conditions favorable to us or there could be a substantial delay before such manufacturer, vendor or supplier, or a related new facility is properly qualified and registered with the FDA or other foreign regulatory authorities. A new manufacturer currently not qualified with the FDA would have to be educated in, or develop substantially equivalent processes for, production of our approved products after receipt of FDA approval. To qualify and receive regulatory approval for a new manufacturer could take as long as two years. The process of changing a supplier could have an adverse impact on our current clinical development programs if supplies of drug substances or materials on hand are insufficient to satisfy demand. Such delays could have a material adverse effect on our development activities and our business. Our product candidates are temperature sensitive and may have other attributes that lead to limited shelf life. These attributes may pose risks to supply, inventory and waste management and increased cost of goods. Our product candidates may prove to have a stability profile that leads to a lower than desired shelf life. This poses risk in supply requirements, wasted stock, and higher cost of goods. Our product candidates are temperature sensitive, and we may learn that any or all of our product candidates are less stable than desired. It is also possible that we may find that transportation conditions negatively impact product quality. This may require changes to the formulation or manufacturing process for one or more of our product candidates and result in delays or interruptions to clinical or

commercial supply. In addition, the cost associated with such transportation services and the limited pool of vendors may also add additional risks of supply disruptions. We have established a number of analytical testing strategies, and may have to establish several more, to assess the quality of our product candidates. We may identify gaps in our analyses that might prevent release of product or could require product withdrawal or recall. For example, new or existing impurities that have an impact on product safety, efficacy, or stability may be discovered. This may lead to an inability to release or use our product candidates until the manufacturing or testing process is rectified or specifications are changed. This could potentially result in delays to our key program. We plan to rely on third parties, some of which are located outside the U. S., to manufacture our drug product candidates, which exposes us to risks that may affect our ability to maintain supplies of our clinical materials, and subject us to uncertainty associated with the international political climate, and could potentially delay or cease our research and development activities, as well as eventual regulatory approval and commercialization of our drug product candidates. Our manufacturing strategy involves manufacturing our drug product candidates using a CMO. We do not own or operate manufacturing facilities and have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of our drug product candidates and related raw materials for clinical and preclinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. The facilities used by third- party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, third- party manufacturers for compliance with cGMP requirements for manufacture of drug products and other government regulations and corresponding international standards. If these third- party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, including requirements related to the manufacturing of high potency compounds, they will not be able to secure and / or maintain regulatory approval for their manufacturing facilities. Istaroxime and rostafuroxin are currently manufactured by an affiliate of Lee' s Pharmaceutical (HK) Ltd., or Lee' s (HK), in Hefei, China. We expect that Lee' s (HK) will manufacture KL4 surfactant drug product candidate at an affiliate of Lee' s (HK) in Hefei, China. The APIs for istaroxime and rostafuroxin are manufactured in China. If the FDA is unable to inspect the manufacturing site in China or if it is able to inspect the site but finds it deficient in any way, to secure marketing approval for our product candidates in the U. S., and potentially other markets, we may be required to designate a different manufacturer for each of our drug product candidates. A technology transfer of a manufacturing process from one CMO to another can be time consuming and expensive and there can be no assurance that such a transfer will be successful or that a new manufacturer will be able to manufacture our drug product candidates successfully. Moreover, a technology transfer from one country to another may be subject to changing international legal and regulatory requirements in a potential difficult political climate. In addition, we have limited control over the ability of third- party manufacturers to maintain adequate quality control, quality assurance and qualified personnel and the third- party manufacturers may fail to manufacture our product candidate according to our schedule or at all. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. In addition, any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our product candidates. If our current third- party manufacturer cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. A third party' s failure to execute on our manufacturing requirements, technology transfers of our manufacturing and our planned future reliance on CMOs exposes us, among other things, to the following risks: ● an inability to initiate or continue clinical trials of istaroxime or any future product candidates under development; ● subjecting third- party manufacturing facilities to additional inspections by regulatory authorities; ● we may implement a plan to execute a technology transfer of our manufacturing process to a CMO and, after investing significant time and resources, learn that the CMO we chose is unable to successfully complete the technology transfer and thereafter manufacture our product candidates in accordance with our plan; ● CMOs might be unable to manufacture our product candidates in the volume and to our specifications to meet our clinical and commercial needs, or we may have difficulty scheduling the production of drug product in a timely manner to meet our timing requirements; ● if we desire to make our drug product candidates available outside the U. S. for clinical or commercial purposes, our CMOs would become subject to, and may not be able to comply with, corresponding manufacturing and quality system regulations or standards of the various foreign regulators having jurisdiction over our activities abroad. Such failures (such as in- country quality testing) could result in not only a loss of approved supply to that country, but a total loss of a lot (or lots) of materials globally and could restrict our ability to execute our business strategies; ● we may have difficulty implementing changes or necessary modifications to our manufacturing processes that may be required by the FDA or foreign regulator or our CMO, if, for example, such changes would burden our CMO or otherwise disrupt operations, or our CMO could impose significant financial terms to implement any such change that could adversely affect our business. We may fail to adequately develop new manufacturing processes. Failure to achieve such required changes or modifications could delay or prevent our gaining regulatory approval for our product candidates or prevent us from continuing to market our approved products, which would have a material adverse effect on our business, financial condition and operations; ● we may fail to adequately scale manufacturing to achieve our objectives for cost of goods and profit margins; ● we may be subject to disputes arising with respect to the ownership of rights to any technology

developed with third parties; and ● we may be subject to the misappropriation of our proprietary information, including our trade secrets and know- how. Each of the foregoing risks and others could delay our development programs and, if approved, commercial manufacturing plans, limit our ability to maintain continuity of supply for our approved products, delay or impair the approval, if any, of our product candidates by the FDA, or result in higher costs or deprive us of potential product revenues. In addition, our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Our current and anticipated future dependence upon others for the manufacture of our product candidates or products, if approved, may adversely affect our future profit margin and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. Our ability to manufacture our product candidates depends upon receiving adequate supplies and related services, which may be difficult or uneconomical to procure. Supply chain or manufacturing interruptions could negatively impact our operations and financial performance. We do not have fully redundant systems and equipment to respond promptly in the event of a significant loss at a CMO' s manufacturing operations. Under certain conditions, we may be unable to produce our drug product candidates at the required volumes or to appropriate standards, if at all. The supply of any of our manufacturing materials may be interrupted because of supply shortages, poor vendor performance or other events outside our control, which may require us, among other things, to identify alternate vendors, which could involve a lengthy process, and result in increased expenses. We are dependent on Lee' s (HK) and Zhaoke for the successful development and commercialization of our KL4 surfactant products. If Lee' s (HK) and Zhaoke do not devote sufficient resources to the development of those product candidates, are unsuccessful in their efforts, or chooses to terminate their agreement with us, the potential licensing revenue will not materialize. On August 17, 2022, we entered into an Amended and Restated License, Development and Commercialization Agreement, or the A & R License Agreement, with Lee' s (HK) and Zhaoke effective as of August 9, 2022. The A & R License Agreement amends, restates and supersedes the Original License Agreement. Under the A & R License Agreement, Lee' s is solely and exclusively responsible for all costs and activities related to the development, manufacturing, regulatory approval and commercialization of KL4 surfactant products, including SURFAXIN ®, the lyophilized dosage form of SURFAXIN, and aerosolized KL4 surfactant. Lee' s (HK) and Zhaoke may determine however, that it is commercially reasonable to de- prioritize or discontinue the development of the KL4 surfactant products. These decisions may occur for many reasons, including internal business reasons, results from clinical trials or because of unfavorable regulatory feedback. Further, on review of the safety and efficacy data, the FDA may impose requirements on the programs that render them commercially nonviable. In addition, under the A & R License Agreement, Lee' s (HK) and Zhaoke have certain decision- making rights in determining the development and commercialization plans and activities for the programs. We may disagree with Lee' s (HK) and Zhaoke about the development strategy they employ, but we will have limited rights to impose our development strategy on Lee' s (HK) and Zhaoke. Similarly, they may decide to seek marketing approval for, and limit commercialization of, the KL4 surfactant products to narrower indications than we would pursue. More broadly, if Lee' s (HK) and Zhaoke elect to discontinue the development of the KL4 surfactant products, we may be unable to advance the product candidate ourselves. On January 12, 2024, we entered into a License, Development and Commercialization Agreement with Lee' s (HK) effective as of January 7, 2024 under which we granted an exclusive license, with a right to sublicense, to develop, register, make, use, sell, offer for sale, import, distribute and otherwise commercialize products that incorporate istaroxime for intravenous administration, rostafuroxin for oral administration, and our proprietary dual- mechanism SERCA2a activators for intravenous or oral administration, in each case for the prevention, mitigation and / or treatment of any disease, disorder or condition in humans including acute decompensated heart failure, cardiogenic shock, and chronic use following discharge of an individual hospitalized for acute decompensated heart failure in the Greater China region. Risks Related to our Business and Operations Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide. Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to: ● the timing and cost of, and level of investment in, research, development, including manufacturing development regulatory approval and commercialization activities relating to our product candidates, which may change from period to period; ● the timing and success or failure of preclinical studies or clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners; ● the level of investment funding we are able to achieve and apply to our development operations; ● the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with third- party manufacturers; ● the potential for our identifiable intangible assets to become impaired, and the timing of such impairments, if any; ● the timing and amount of the milestone or other payments we must make to the licensors and other third parties from whom we have in- licensed our acquired our product candidates; ● expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies; ● our allocation of resources and ability to raise additional capital; ● future changes in requirements to achieve regulatory approval; ● future accounting pronouncements or changes in our accounting policies. ● the capital markets stability and openness to investing; ● delays associated with COVID- 19 or future pandemics which will impact the ability of our healthcare systems and trial sites to conduct trials to varied degrees and times; ● coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products; and ● the level of demand for any approved products, which may vary significantly. The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or

financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide. Our acquisition of Varian' s assets may divert resources away from existing operations or expose us to liabilities, which could adversely affect our business, results of operations and financial condition. On April 2, 2024, we entered into the Asset Purchase Agreement with Varian. Pursuant to the Asset Purchase Agreement, we purchased all of the assets of Varian' s business associated with a Licence Agreement, dated as of July 5, 2019, by and between Varian and Cancer Research Technology Limited, or the Licence Agreement, including the Licence Agreement, all rights in molecules and compounds subject to the Licence Agreement, know- how and inventory of drug substance, or the Transferred Assets. We also assumed all liabilities arising on or after April 2, 2024, relating to the research, development, manufacturing, registration, commercialization, use, handling, supply, storage, import, export or other disposition or exploitation of any and all products associated with the Transferred Assets. We may invest a substantial amount of time, resources and efforts in connection with our acquisition of the Transferred Assets. All of these actions divert resources away from our other initiatives and operations. These efforts may not result in product candidates, efficiencies or revenues for our company, which could adversely affect our business, operating results and financial condition as a result. **Our new corporate strategy may not be successful. In January 2025, we launched a new corporate strategy to become a revenue generating biotech company through acquisitions of small companies and their FDA- approved products while we continue to progress our cardiovascular and oncology development pipeline. We will seek to use equity to acquire such targets, which could result in dilution for existing stockholders. There can be no assurances that we will be able to complete suitable acquisitions for a variety of reasons, including the identification of, and competition for, acquisition candidates, the need for regulatory approvals, the inability of the parties to agree to the structure or purchase price of the transaction, and the inability to finance the transaction on commercially acceptable terms. If we are not able to identify suitable acquisition candidates or consummate potential acquisitions within a desired time frame or at acceptable terms, our new corporate strategy may be unsuccessful. Even if we are successful in acquiring businesses, the businesses we acquire may not be able to achieve the revenue, profitability, or growth that we anticipate, or we may experience challenges and risks in integrating these businesses into our existing business, including our governance and compliance framework. Our failure to address any of these risks could cause us to incur additional costs and fail to realize the anticipated benefits of our acquisitions and could adversely impact our results of operations and financial position.** We are continually evaluating our business strategy and may modify this strategy to respond to developments in our business and other factors, and any such modification, if not successful, could have a material adverse effect on our business, financial condition, and results of operations. We plan to continually evaluate our business strategy and will modify our plans as necessary to achieve our objectives. As part of our shift in priorities, we entered into a global licensing agreement in 2022 to support the development of our KL4 surfactant platform and were able to eliminate the remaining costs associated with the KL4 surfactant platform. If for any reason, our licensee does not proceed with development of the KL4 surfactant platform, such action could have a material adverse effect on our potential to realize licensing revenue. **In addition, in January 2025, we launched a new corporate strategy to become a revenue generating biotech company through acquisitions of small companies and their FDA- approved products. See the risk factor above captioned " Our new corporate strategy may not be successful. "** Similarly, our strategy currently contemplates that we will seek to out- license rostafuroxin and invest the proceeds in our other core programs. If we are not successful in our efforts, we may be forced to accept a significant write down of our rostafuroxin asset on our balance sheet and reassess our strategy. This action also could have a material adverse effect on our business, financial condition and results of operations. The execution of a clinical program is complex and involves the cooperation of many individuals and entities, including third parties that we may not be able to control, and require the coordination of a number of components, any one of which could experience delays or unforeseen events or circumstances that may require the development of alternative strategies. If we encounter such events or circumstances, if we believe that certain changes would be in our best interest, we will consider adjusting our strategy and planning. If we conclude that an alternative approach may improve our ability to achieve our objectives, we will consider adopting such other approach. Similarly, if a third party were to share observations or make recommendations concerning the focus, sequence or approach of any or all of our research and development programs, we may consider taking such recommendations into account in our planning process and future activities. There can be no assurance, whether or not we alter our strategy or plans, that we will be successful, or that we will secure regulatory approval for our product candidates and execute any product launches effectively and on time, if at all, in all markets that we may identify. Our ability to discover and / or develop new product candidates depends in part on our internal research capabilities and whether we have the resources required to conduct a development program or to acquire new product candidates. Our limited resources may not be sufficient to discover and develop or to acquire new product candidates. To support our efforts to develop our product candidates and, if approved, commercialize our products in the world markets, including the U. S., we continue to evaluate potential licensing transactions, collaboration arrangements and other strategic transactions. However, there can be no assurance that our efforts will be successful or that, even if we identify and enter into any strategic transactions, that such transactions will be successfully implemented, if at all, within our expected time frames. We plan to continue evaluating our business strategy and may modify our strategy again in the future. To respond to changing circumstances, we may expand or alter our research and development activities from time to time and allocate resources to work on development of different product candidates or may pace, delay or halt the development of potential product development programs. As a result of changes in our strategy, we may also change or refocus our existing drug development and manufacturing activities or our plans for commercialization of our product candidates, if approved. These decisions could require changes in our facilities and personnel and restructuring various financial

arrangements. There can be no assurances that any product development or other changes that we implement will be successful or that, after implementation of any such changes, that we will not refocus our efforts on new or different objectives. Our industry is highly competitive, and we have less capital and resources than many of our competitors, which may give them an advantage in developing and marketing products similar to ours or make our product candidates obsolete. Our industry is highly competitive and subject to rapid technological innovation and evolving industry standards. We compete with numerous existing companies in many ways. We need to successfully introduce new products to achieve our strategic business objectives. If we cannot successfully introduce new products, adapt to changing technologies or anticipate changes in our current and potential customers' requirements, our product candidates may become obsolete, and our business could suffer. Many of our competitors' companies have substantially greater research and development, manufacturing, marketing, financial, and technology personnel and managerial resources than we have. In addition, many of these competitors, either alone or with their collaborative partners, have significantly greater experience than we do in developing products, preclinical testing and human clinical trials management, obtaining FDA approval and other regulatory approvals, and manufacturing and marketing products. Accordingly, our competitors may succeed in receiving FDA or foreign regulatory approval or commercializing products and obtaining patent protection before us. Our competitors may successfully secure regulatory exclusivities in various markets, which could have the effect of barring us or limiting our ability to market our product candidates, if approved, in such markets. In addition, developments by our competitors may render our drug product candidates obsolete or noncompetitive. We also face, and will continue to face, competition from colleges, universities, governmental agencies and other public and private research organizations. These competitive forces frequently and aggressively seek patent protection and licensing arrangements to collect royalties for technologies that they develop. Some of these technologies may compete directly with the technologies that we are developing. These institutions will also compete with us in recruiting highly qualified scientific personnel. The political and healthcare policy and reimbursement environment is becoming more challenging for pharmaceutical companies and manufacturers and may adversely affect our business. Political, economic and regulatory influences globally are subjecting the healthcare industry to potential fundamental challenges that could substantially affect our business and results of operations. Government and private sector initiatives to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed- care arrangements, are continuing to arise in many countries where we potentially may seek to do business, including the U. S. There is increasing pressure on pricing, reimbursement and demands for value- based data to gain access to patients and healthcare funds globally. This may increase the costs of development, risks of commercialization and overall value of the opportunity. The Inflation Reduction Act of 2022 contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U. S. Department of Health and Human Services that would require manufacturers to charge a negotiated " maximum fair price " for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the Inflation Reduction Act of 2022. The Inflation Reduction Act of 2022 could have the effect of reducing the prices we can charge and reimbursement we receive for our product candidates, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The effect of Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known. We also cannot predict the likelihood, nature or extent of additional government regulation that may arise from future legislation, administrative, judicial, or executive action, either in the U. S. or abroad. In addition, we rely on our CMO located in China to manufacture drug product and APIs for us, such that the supply lines for our drug product, and APIs may be affected by trade and political considerations. Given the increasing uncertainty in the healthcare and pharmaceutical industries as well as increased regulatory scrutiny on foreign investment, capital investment in our industry and our ability to attract capital investment is becoming more challenging. This trend, if continued, may restrict or impair our ability to gain necessary funding for continued development and, if approved, commercialization of our product candidates. We depend upon key employees and consultants in a competitive market for skilled personnel. If we or our strategic partners or collaborators are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our product candidates. We have assembled a team of qualified personnel to advance the development programs for our product candidates. We have competed and will continue to compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is significant and attracting and retaining qualified personnel will be critical to our success, and any failure to do so successfully may have a material adverse effect on us. We are highly dependent upon the members of our executive management team and certain employees and consultants who are subject matter experts. Many of these individuals have been involved with us for many years, have played integral roles in our progress and we believe that they continue to provide value to us. We have over the last few years lost long-term members of our executive team and certain professional, scientific and management personnel, due to retirement, shifts in our focus and other causes. The loss of such personnel potentially exposes us to a lack of ready recall and knowledge of past corporate events, risks previously identified and related learnings. As such, loss of any of our remaining key personnel may further increase the associated risk and may have a material adverse effect on aspects of our business and clinical development and regulatory programs. The loss of services from any of our executives could significantly adversely affect our ability to develop and market our product candidates and obtain necessary regulatory approvals. Further, we do not maintain key man life insurance. Our future success also will depend on the continued service of our key professional, scientific and management personnel and our ability to recruit and retain additional personnel. While we attempt to provide competitive compensation packages to attract and retain key personnel at all levels in our organization, many of our competitors have greater resources and more experience than we do, making it difficult for us to compete successfully for key personnel. We may experience intense

competition for qualified personnel and the existence of non- competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to lawsuits brought by their former employers. If our business development activities are unsuccessful, our business could suffer, and our financial performance could be adversely affected. As part of our long- term growth strategy, we engage in business development activities intended to identify strategic opportunities, including potential strategic alliances, joint development opportunities, acquisitions, technology licensing arrangements and other similar opportunities. Such opportunities may result in substantial investments in our business. Our success in developing product candidates or expanding into new markets from such activities will depend on a number of factors, including our ability to find suitable opportunities for investment, alliance or acquisition; whether we are able to complete an investment, alliance or acquisition on terms that are satisfactory to us; the strength of our underlying technology, product candidates and our ability to execute our business strategies; any intellectual property and litigation related to these product candidates or technology; and our ability to successfully integrate the investment, alliance or acquisition into our existing operations, including to fund our share of any IPR & D projects. If we are unsuccessful in our business development activities, we may be unable to secure needed capital and expertise to support our development programs and our financial condition could be adversely affected. We may seek to enter into licensing transactions, collaboration arrangements, and other similar transactions and strategic opportunities, and may not be successful in doing so, and even if we are, we may not realize the benefits of such relationships. We may seek to enter into licensing transactions, collaboration arrangements, and other similar transactions and strategic opportunities for the development or commercialization of our product candidates, or to secure the capital required to develop or commercialize a product candidate or address manufacturing constraints. We may not be successful in our efforts to establish such collaborations for our product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time consuming and complex. Further, any future collaboration agreements may restrict us from entering into additional agreements with potential collaborators. We cannot be certain that, following a strategic transaction or licensing agreement, we will achieve an economic benefit that justifies such transaction. Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed, the safety of a product candidate is questioned or sales of an approved product candidate are unsatisfactory. In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to our product candidates, could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations. We could be adversely affected by any interruption, including from breaches in cybersecurity, in our ability to conduct business at our current location. We are increasingly dependent on sophisticated information technology for our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance existing systems. Despite our implementation of security measures, our information systems, like those of other companies, are vulnerable to damages from computer viruses, natural disasters, unauthorized access, cyber- attack, including ransomware, and other similar disruptions. Any system failure, accident or security breach could result in disruptions to our operations. For example, third parties may attempt to hack into systems and may obtain our proprietary information or other sensitive information, which could cause significant damage to our reputation, lead to claims against us and ultimately harm our business. We do not have redundant facilities. We perform substantially all of our research and development and back office activity in a small number of locations, including our headquarters in Warrington, Pennsylvania, and a research laboratory at Chang Gung University in Taiwan under a separate collaboration agreement. We also depend upon third- party manufacturers and laboratories to manufacture our drug product candidates, APIs and perform important API and drug product release testing and stability work. Our facilities, equipment and inventory would be costly to replace and could require substantial lead time to repair or replace. Our facilities and those of our third- party manufacturers and laboratories may be harmed or rendered inoperable by natural or man- made disasters, including, but not limited to, tornadoes, flooding, fire and power outages, which may render it difficult or impossible for us to perform our research, development and commercialization activities for some period of time. The inability to perform those activities, combined with the time it may take to rebuild our inventory of finished product, may result in the loss of customers or harm to our reputation. Although we have insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all. The failure to prevail in litigation or the costs of litigation, including securities class actions, product liability claims and patent infringement claims, could harm our financial performance and business operations. We are potentially susceptible to litigation. For example, as a public company, we may be subject to claims asserting violations of securities laws. Even if such actions are found to be without merit, the potential impact of such actions, which generally seek unquantifiable damages and attorneys' fees and expenses, is uncertain. There can be no assurance that an adverse result in any future proceeding would not have a potentially material adverse effect on our business, results of operations and financial condition. Our business activities, including development, manufacture and, if our product candidates are approved, marketing of our drug products also exposes us to liability risks. Using our drug product candidates, including in clinical trials, may expose us to product liability claims. Even if approved, our products may be subject to claims resulting from unintended effects that result in injury or death. Product liability claims alleging inadequate disclosure and warnings in our package inserts also may

arise. We presently carry comprehensive general liability, property damage, product liability, workers' compensation, health benefits and other insurance coverage in amounts that we believe to be adequate for the protection of our assets and operations and customary for companies in our industry of comparable size and level of activity. However, our insurance policies contain various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. There can be no assurance that the insurance coverage we maintain is sufficient or will be available in adequate amounts or at a reasonable cost. A successful claim brought against us in excess of available insurance or not covered by indemnification agreements, or any claim that results in significant adverse publicity against us, could have an adverse effect on our business and our reputation. Product liability claims may be brought by individuals or by groups seeking to represent a class. The outcome of litigation, particularly class action lawsuits, is difficult to assess or quantify. Plaintiffs in these types of lawsuits often seek recovery of very large or indeterminate amounts, and the magnitude of the potential loss relating to such lawsuits may remain unknown for substantial periods of time. We face a potential risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any of our product candidates, if approved, or any other future product. For example, we may be sued if any product we develop, including any of our product candidates, or any materials that we use in our product candidates allegedly causes injury or is found to be otherwise unsuitable during product 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 and a breach of warranties. In the U. S., 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 commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: ● decreased demand for any of our product candidates, if approved, or any future products that we may develop; ● injury to our reputation; ● withdrawal of clinical trial participants; ● costs to defend the related litigation; ● a diversion of management' s time, attention and our resources; ● substantial monetary awards to trial participants or patients; ● product recalls, withdrawals or labeling, marketing or promotional restrictions; ● the inability to commercialize some or all of our product candidates, if approved; and ● a decline in the value of our stock. There can be no assurance that the insurance coverage we maintain is sufficient or will be available in adequate amounts or at a reasonable cost. A successful claim brought against us in excess of available insurance or not covered by indemnification agreements, or any claim that results in significant adverse publicity against us, could have an adverse effect on our business and our reputation. We may be required to obtain additional product liability insurance coverage. However, such insurance is expensive and may not be available when we need it. In the future, we may not be able to obtain adequate insurance, with acceptable limits and retentions, at an acceptable cost. Any product, general liability or product liability claim, even if such claim is within the limits of our insurance coverage or meritless and / or unsuccessful, could adversely affect the availability or cost of insurance generally and our cash available for other purposes, such as research and development. In addition, such claims could result in: ● uninsured expenses related to defense or payment of substantial monetary awards to claimants; ● a decrease in demand for our drug product candidates, if approved; ● damage to our reputation; and ● an inability to complete clinical trial programs or to commercialize our drug product candidates, if approved. Risks Related to Government Regulation Our activities are subject to various and complex laws and regulations, and we are susceptible to a changing regulatory environment. Violations or allegations of violations of these laws may result in large civil and criminal penalties, debarment from participating in government programs, diversion of management time, attention and resources and may otherwise have a material adverse effect on our business, financial condition and results of operations. Our product candidates and our operations are regulated by numerous government agencies, both inside and outside the U. S. Our drug product candidates must undergo lengthy and rigorous testing and other extensive, costly and time- consuming procedures mandated by the FDA and foreign regulatory authorities. Our facilities and those of our third- party providers must pass inspection and / or be approved or licensed prior to production and remain subject to inspection at any time thereafter. Failure to comply with the requirements of the FDA or other regulatory authorities could result in warning or untitled letters, Form 483s, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of our product candidates, if approved, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. Any of these actions could damage our reputation and have a material adverse effect on our sales. If our product candidates are approved for commercial sale, we will be required to comply with not only the requirements of applicable regulators, but also will become subject to various laws regulating the sales, marketing, and distribution of healthcare- related products. The sales and marketing of products and relationships that pharmaceutical companies have with healthcare providers are under increasing scrutiny by federal, state and foreign government agencies. The FDA and other federal regulators have increased their enforcement activities with respect to the Anti- Kickback Statute, False Claims Act, off- label promotion of products, and other healthcare related laws, antitrust and other competition laws. Foreign governments have also increased their scrutiny of pharmaceutical companies' sales and marketing activities and relationships with healthcare providers. Of particular importance, federal and state anti- kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. These laws can be complicated, are subject to frequent change and may be violated unknowingly. In addition, a number of states require that companies implement compliance programs or comply with industry ethics codes, adopt spending limits, and report to state governments any gifts, compensation, and other remuneration provided to physicians. Sanctions under these laws may include civil monetary penalties, exclusion of a manufacturer' s products from reimbursement under government programs (including Medicare and Medicaid), criminal fines, and imprisonment. Companies that have chosen to settle these alleged violations have typically paid multi- million- dollar fines to the government and agreed to abide by corporate integrity agreements, which often include significant and costly burdens. There has been a recent trend of increased federal and state

regulation of payments and transfers of value provided to healthcare professionals and entities. For example, the Physician Payment Sunshine Act imposes annual reporting requirements on certain manufacturers of drugs, biologics and medical supplies with respect to payments and other transfers of value provided by them, directly or indirectly, to physicians and teaching hospitals, as well as with respect to certain ownership and investment interests held by physicians and their family members. A manufacturer' s failure to submit timely, accurately and completely the required information regarding all payments, transfers of value or ownership or investment interests may result in civil monetary penalties. Certain states also mandate implementation of commercial compliance programs, impose restrictions on manufacturers' marketing practices, and require the tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities under certain circumstances. We are continually evaluating our compliance programs, including policies, training and various forms of monitoring, designed to address the requirements outlined above. However, no compliance program can mitigate risk in its entirety. Violations or allegations of violations of these laws may result in large civil and criminal penalties, debarment from participating in government programs, diversion of management time, attention and resources and may otherwise have a material adverse effect on our business, financial condition and results of operations. Failure in our information technology systems could disrupt our operations and cause the loss of confidential information and business opportunities. In the ordinary course of our business, we and our third- party contractors maintain sensitive data on our and their respective networks, including our intellectual property and proprietary or confidential business information relating to our business and that of our clinical trial participants and business partners and electronically stored work product, including clinical data, analyses, research, communications and other materials necessary to gain regulatory approval of our product candidates. The secure maintenance of this sensitive information is critical to our business and reputation. Despite the implementation of security measures, our internal computer systems and those of our third- party contractors are vulnerable to damage from cyber- attacks, computer viruses, unauthorized access, unintended loss, human error, natural disasters, terrorism, war and telecommunication and electrical failures. For information stored with our third- party contractors, we rely upon, and the integrity and confidentiality of such information is dependent upon, the risk mitigation and data preservation efforts such third- party contractors have in place. Our and our third- party contractors' respective network and storage applications and policies may not be sufficient to protect our sensitive business information and may be subject to loss, unauthorized access by hackers or breached due to operator error, malfeasance or other system disruptions. It is often difficult to anticipate or immediately detect such incidents and the damage caused by such incidents. Such incidents could compromise our intellectual property, expose sensitive business information, result in loss of data necessary to secure regulatory approval of our product candidates, cause interruptions in our operations, result in a material disruption of our operations, or require substantial expenditures of resources to remedy. We face risks related to our collection and use of data, including personal information, which could result in investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our privacy and data protection practices. Our business processes personal data, including some data related to health. When conducting clinical trials, we face risks associated with collecting trial participants' data, especially health data, in a manner consistent with applicable laws and regulations. We also face risks inherent in handling large volumes of data and in protecting the security of such data. We could be subject to attacks on our systems by outside parties or fraudulent or inappropriate behavior by our service providers or employees. Third parties may also gain access to users' accounts using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks or other means, and may use such access to obtain users' personal data or prevent use of their accounts. Data breaches could subject us to individual or consumer class action litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the U. S. and by international regulatory entities, resulting in exposure to material civil and / or criminal liability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed. Our business requires that we and our third- party service providers collect and store sensitive data, including legally protected health information, personally identifiable information about patients, credit card information, and our proprietary business and financial information. As a covered entity, we must comply with the HIPAA privacy and security regulations, which may increase our operational costs. Furthermore, the privacy and security regulations provide for significant fines and other penalties for wrongful use or disclosure of protected health information, or PHI, including potential civil and criminal fines and penalties. We face a number of risks relative to our protection of, and our service providers' protection of, this critical information, including loss of access, fraudulent modifications, inappropriate disclosure and inappropriate access, as well as risks associated with our ability to identify and audit such events. The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. If such event would occur and cause interruptions in our operations, our networks would be compromised and the information we store on those networks could be accessed by unauthorized parties, publicly disclosed, modified without our knowledge, lost or stolen. Additionally, we share PHI with third- party contractors who are contractually obligated to safeguard and maintain the confidentiality of PHI. Unauthorized persons may be able to gain access to PHI stored in such third- party contractors' computer networks. Any wrongful use or disclosure of PHI by us or our third- party contractors, including disclosure due to data theft or unauthorized access to our or our third- party contractors' computer networks, could subject us to fines or penalties that could adversely affect our business and results of operations. Although the HIPAA statute and regulations do not expressly provide for a private right of damages, we also could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information by us or our third- party contractors. Unauthorized access, loss, modification or dissemination could disrupt our operations, including our ability to process tests, provide test results, bill payers or patients, process claims, provide customer assistance services, conduct research and development activities, collect,

process and prepare company financial information, provide information about our solution and other patient and physician education and outreach efforts through our website, manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business. In addition, the interpretation and application of consumer, health-related and data protection laws in the U. S. are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices, systems and compliance procedures in a manner adverse to our business. As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities, including various domestic and international privacy and security regulations. The legislative and regulatory landscape for privacy and data protection continues to evolve. In the U. S., certain states may adopt privacy and security laws and regulations that may be more stringent than applicable federal law. A number of ~~US~~ **U. S.** states have proposed new privacy laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and / or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country 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. Our international operations are subject to international laws and regulations, regulatory guidance, and industry standards relating to data protection, privacy, and information security. This includes the EU General Data Protection Regulation, or GDPR, as well as other national data protection legislation in force in relevant EU member states (including the GDPR in such form as incorporated into the law of England and Wales, Scotland and Northern Ireland by virtue of the European Union (Withdrawal) Act 2018 and any regulations thereunder and the UK Data Protection Act 2018, or UK GDPR. The GDPR and UK GDPR are wide- ranging in scope and impose numerous additional requirements on companies that process personal data, including imposing special requirements in respect of the processing of health and other sensitive data, requiring that consent of individuals to whom the personal data relates is obtained in certain circumstances, requiring additional disclosures to individuals regarding data processing activities, requiring that safeguards are implemented to protect the security and confidentiality of personal data, creating mandatory data breach notification requirements in certain circumstances, requiring data protection impact assessments for high risk processing and requiring that certain measures (including contractual requirements) are put in place when engaging third- party processors. The GDPR and the UK GDPR also provide individuals with various rights in respect of their personal data, including rights of access, erasure, portability, rectification, restriction and objection. The GDPR and UK GDPR impose strict rules on the transfer of personal data to countries outside the European Economic Area, including the U. S. The UK and Switzerland have adopted similar restrictions. Although the UK is regarded as a third country under the EU' s GDPR, the EC has now issued a decision recognizing the UK as providing adequate protection under the EU **' s** GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU **' s** GDPR, the UK **' s** GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards must be implemented in compliance with European and UK data protection laws. On June 4, 2021, the EC issued new forms of standard contractual clauses for data transfers from controllers or processors in the EU / EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU / EEA (and not subject to the GDPR). The new standard contractual clauses replace the standard contractual clauses that were adopted previously under the EU Data Protection Directive. The UK is not subject to the EC' s new standard contractual clauses but has published a draft version of a UK- specific transfer mechanism, which, once finalized, will enable transfers from the UK. We will be required to implement these new safeguards when conducting restricted data transfers under the EU and UK GDPR and doing so will require significant effort and cost. The GDPR and UK GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR and UK GDPR. Implementing legislation in applicable EU member states and the UK, including by seeking to establish appropriate lawful bases for the various processing activities we carry out as a controller or joint controller, reviewing security procedures and those of our vendors and collaborators, and entering into data processing agreements with relevant vendors and collaborators, we cannot be certain that our efforts to achieve and remain in compliance have been, and / or will continue to be, fully successful. Given the breadth and depth of changes in data protection obligations, preparing for and complying with the GDPR and UK GDPR and similar laws' requirements are rigorous and time intensive and require significant resources and a review of our technologies, systems and practices, as well as those of any third- party collaborators, service providers, contractors or consultants that process or transfer personal data. Other countries around the world in which we conduct business have also enacted strict privacy and data protection laws. Further, in addition to general privacy and data protection requirements, many jurisdictions around the world have adopted legislation that regulates how businesses operate online and enforces information security, including measures relating to privacy, data security and data breaches. Many of these laws require businesses to notify data breaches to the regulators and / or to data subjects. These laws are not consistent, and compliance in the event of a widespread data breach is costly and burdensome. In many jurisdictions, enforcement actions and consequences for non- compliance with protection, privacy and information security laws and regulations are rising. In the EU and the UK, data protection authorities may impose large penalties for violations of the data protection laws, including potential fines of up to € 20 million (£ 17. 5 million in the UK) or 4 % of annual global revenue, whichever is greater. The authorities have shown a willingness to impose significant fines and issue orders preventing the processing of personal data on non- compliant businesses. Data subjects also have a private right of action, as do consumer associations, to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of applicable data protection laws. The risk of our being found in violation

of these laws is increased by the fact that the in interpretation and enforcement of them is not entirely clear. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and / or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. Compliance with data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. It could also require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business. Failure by us or our collaborators and third- party providers to comply with data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties and orders preventing us from processing personal data), private litigation and result in significant fines and penalties against us. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time- consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects. Healthcare reform measures in the U. S., as well as the general tightening of drug reimbursement pathways and levels of reimbursement globally, are expected to add additional pressure to achieve financial expectations for our product candidates, if approved. The U. S. 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 candidates, if approved. The U. S. 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. See the section titled, " Item 1. Business – Healthcare Reform. " Further changes to and under the Affordable Care Act remain possible. It is unknown what form any such changes or any law proposed to replace the Affordable Care Act would take, and how or whether it may affect our business in the future. We expect that changes 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. 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. The Inflation Reduction Act of 2022 contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U. S. Department of Health and Human Services that would require manufacturers to charge a negotiated " maximum fair price " for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the Inflation Reduction Act of 2022. The Inflation Reduction Act of 2022 could have the effect of reducing the prices we can charge and reimbursement we receive for our product candidates, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The effect of Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known. Our international operations subject us to additional regulatory oversight in foreign jurisdictions, as well as economic, social, and political uncertainties, which could cause a material adverse effect on our business, financial position, and operating results. We are subject to certain risks associated with having assets, both physical and intangible, and operations located in Taiwan. Our activity in Taiwan is subject to regulatory agencies, such as the Taiwan Food and Drug Administration. Our operations in foreign jurisdictions are conducted by our subsidiary, CVie Therapeutics, Taiwan, which also owns a substantial portion of our intellectual property. Our international operations may be adversely affected by general economic conditions and economic and fiscal policy, including changes in exchange rates and controls, interest rates and taxation policies, and increased government regulation, which could have a material adverse effect on our business, financial position, and operating results. In addition, the impacts of political unrest, including as a result geopolitical tension, such as a deterioration in the relationship between the U. S. and China, including any potential resulting sanctions, export controls, or other restrictive actions that may be imposed by the U. S. and / or other countries against governmental or other entities in, for example, China or Taiwan, also could have an adverse impact on our international operations. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates, if approved. We face an inherent risk of product liability as a result of the clinical trials of our product candidates and will face an even greater risk if we commercialize our product candidates if we receive approval. For example, we may be sued if our product candidates allegedly cause injury or are found to be otherwise unsuitable during product 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 candidate, negligence, strict liability and a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others using, administering or selling products that may be approved in the future. 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 or cease the commercialization of our product candidates, if approved. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: ● decreased demand for our product candidates, if approved; ● injury to our reputation and significant negative media attention; ● significant negative financial impact; ● the inability to commercialize our product candidates, if approved; and ● a decline in our stock price. We currently hold product liability insurance coverage at a level we believe to be consistent with our activities. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates, if approved. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our product candidates, if approved. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also 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. Our employees and independent contractors, including principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violate: (i) the laws and regulations of the FDA and other similar regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, including cGMP requirements, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the U. S. and abroad or (iv) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other 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 or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. We are subject to anti- bribery, anti- corruption, and anti- money laundering laws, including the U. S. Foreign Corrupt Practices Act, in which violations of these laws could result in substantial penalties and prosecution. We are exposed to trade and economic sanctions and other restrictions imposed by the U. S. and other governments and organizations. The U. S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the U. S. Foreign Corrupt Practices Act, or the FCPA, and other federal statutes and regulations, including those established by the Office of Foreign Assets Control. The Department of Justice, or DOJ, also **in the past** has increased its focus on the enforcement of the FCPA, particularly as it relates to the conduct of pharmaceutical companies. In addition, the U. K. Bribery Act of 2010, or the Bribery Act, prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that " fails to prevent bribery " by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the defense of having implemented " adequate procedures " to prevent bribery. Under these laws and regulations, as well as other anti- corruption laws, anti- money laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations would negatively affect our business, financial condition and results of operations. We and any of our third- party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly. We and any of our third- party manufacturers or suppliers will use biological materials, potent chemical agents and may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and the operations of our third- party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot eliminate the risk of accidental injury or contamination from these materials or wastes. We carry a limited amount of specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies offer limited coverage for damages and fines arising from biological or hazardous waste

exposure or contamination. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work- related injuries, this insurance may not provide adequate coverage against potential liabilities. We maintain a limited amount of insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects **. We may change or diversify the nature of our business from biotechnology to include a sector that may provide revenue opportunities in the near future, which could expose us to new risks and uncertainties. We are currently focused on advancing early and late- stage innovative therapies for critical conditions and diseases. However, we may decide to change or diversify the nature of our business and pursue sectors that may provide revenue opportunities in the near future, either in addition to or instead of our existing biotechnology business. The potential change or expansion of our business is a result of various factors, such as changes in market conditions, customer demand, regulatory environment, competitive landscape, availability of financing and strategic alternatives, as well opportunities management and the board of directors believe are available to, and in the best interest of, the Company. If we change or diversify the nature of our business to seek revenue opportunities, we will face significant challenges and risks, including, but not limited to: ● the need to recruit, retain and train qualified personnel with expertise and experience in a new industry, as well as to establish and maintain effective internal controls, systems, policies and procedures for operations in a new industry; ● the potential dilution of our existing shareholders or the incurrence of additional indebtedness if we issue equity or debt securities or incur other obligations to finance our new business; and ● the potential loss of, some or all of our existing biotechnology, suppliers, partners, employees, intellectual property, contracts, licenses, permits and other assets and resources that are essential to our biotechnology business, as well as the potential impairment of goodwill and long- lived assets associated with our biotechnology business. Accordingly, a change or expansion in the nature of our business, though potentially beneficial, could have a material adverse effect on our business, financial condition, results of operations and prospects, and could cause the market price of our common stock to decline. There can be no assurance that we will be able to successfully enter, compete or operate in the new industry, or that we will be able to realize any of the potential benefits of such a change in our business** . Risks Related to Intellectual Property Matters If we cannot protect our intellectual property, others could use our technology in competitive products. Even if we obtain patents to protect our product candidates, those patents may not be sufficiently broad, or they may expire and others could then compete with us. The patent position of biotechnology companies is highly uncertain and involves complex legal and factual questions for which important legal principles are unresolved. To date, the USPTO has not adopted a consistent policy regarding the breadth of claims that is accorded in biotechnology patents or the degree of protection that these types of patents afford. As a result, there are risks that we may not secure proprietary rights to products or processes that appear to be patentable. The parties who licensed technologies to us and we have filed various U. S. and foreign patent applications with respect to the products and technologies under our development, and the USPTO and foreign patent offices have issued patents with respect to our products and technologies. These patent applications include international applications filed under the Patent Cooperation Treaty. Our pending patent applications, as well as those we may file in the future or those we may license from third parties, may not result in the USPTO or foreign patent office issuing patents. In addition, if patent rights covering our products are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. For example, the core composition of matter patents covering istaroxime have expired. As such, istaroxime relies on data and market exclusivity, as well as method- of- use patents, which may offer a lesser scope of protection than the original core patents. Furthermore, even if the USPTO or foreign patent offices were to issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from third parties may not provide us any protection against competitors. The patents that we own or in- license have a limited life. Patents related to our cardiovascular drug products issued in the U. S., Europe and elsewhere have expired or will expire on various dates between 2028 and 2039. Further, we cannot guarantee that all patent applications related to our cardiovascular drug products that are still pending in U. S., Europe and elsewhere will be granted as patents. Intellectual property rights of third parties could limit our ability to develop and market our product candidates. Our success also depends upon our ability to operate our business without infringing the patents or violating the proprietary rights of others. Patent applications in most jurisdictions are not published until 18 months after filing. In certain cases, the USPTO keeps U. S. patent applications confidential for the entire time the applications are pending. As a result, we cannot determine in advance what inventions third parties may claim in their pending patent applications. We may need to defend or enforce our patent and license rights or to determine the scope and validity of the proprietary rights of others through legal proceedings, which would be costly, unpredictable and time consuming. Even in proceedings where the outcome is favorable to us, they would likely divert substantial resources, including management time, from our other activities. Moreover, any adverse determination could subject us to significant liability or require us to seek licenses that third parties might not grant to us or might only grant at rates that diminish or deplete the profitability of our products. An adverse determination could also require us to alter our products or processes or cease altogether any product sales or related research and development activities. We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. We may need to obtain licenses from third parties to advance our research or allow

commercialization of our product candidates, and we cannot provide any assurances that third- party patents do not exist which might be enforced against our product candidates in the absence of such a license. The licensing and acquisition of third- party intellectual property rights is a competitive practice and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and / or other forms of compensation. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates, which would have a material adverse effect on our business. We rely on agreements containing obligations regarding intellectual property, confidentiality and noncompetition provisions that could be breached and may be difficult to enforce. Although we take what we believe to be reasonable steps to protect our intellectual property, including the use of agreements relating to the non- disclosure of our confidential and proprietary information and trade secrets to third parties, as well as agreements that provide for disclosure and assignment to us of all rights to the ideas, developments, improvements, discoveries and inventions of our employees, consultants, advisors and research collaborators while we employ them, such agreements can be difficult and costly to enforce. We generally seek to enter into these types of agreements with consultants, advisors and research collaborators; however, to the extent that such parties apply or independently develop intellectual property in connection with any of our projects, disputes may arise concerning allocation of the related proprietary rights. Such disputes often involve significant expense and yield unpredictable results. Moreover, although all employees enter into agreements with us that include non- compete covenants, and our senior executive officers have agreements that include broader non- competition covenants and provide for severance payments that are contingent upon the applicable employee' s refraining from competition with us, such non- compete provisions can be difficult and costly to monitor and enforce, such that, if any should resign, we may not be successful in enforcing our noncompetition agreements with them. Despite the protective measures we employ, we still face the risk that: ● agreements may be breached; ● agreements may not provide adequate remedies for the applicable type of breach; ● our trade secrets or proprietary know- how may otherwise become known; ● our competitors may independently develop similar technology; or ● our competitors may independently discover our proprietary information and trade secrets. Patents covering our product candidates could be found invalid or unenforceable if challenged in court or before administrative bodies in the U. S. or abroad. Although an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar product candidates. Competitors could attempt to replicate the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around the relevant patents, or develop and obtain patent protection for more effective technologies, designs or methods. We may be unable to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. The laws of some non- U. S. countries do not protect our proprietary rights to the same extent as the laws of the U. S., and we may encounter significant problems in protecting our proprietary rights in these countries. In addition, proceedings to enforce or defend our patents, or patents to which we have ownership rights through licensing agreements, could put those patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of those patents are invalid or otherwise unenforceable. If any of the patents covering our product candidates are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our product candidates, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights. Third parties may assert ownership or commercial rights to inventions we develop. Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property or may lose our exclusive rights in such intellectual property. Either outcome could harm our business and competitive position. Litigation or other proceedings or third- party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling our product candidates or affect our stock price. Our commercial success will depend in part on not infringing the patents or violating other proprietary rights of others. Significant litigation regarding patent rights occurs in our industry. Our competitors may have applied for or obtained, or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. We do not always conduct independent reviews of patents issued to third parties. In addition, patent applications in the U. S. and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived, so there may be applications of others now pending or recently revived patents of which we are unaware. Patent applications in the U. S., the EU and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. These applications may later result in issued patents, or the revival of

previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to develop and market our product candidates. Third parties may assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from nonpracticing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. As we attempt to commercialize our product candidates in their current or updated forms, launch new product candidates and enter new markets, we expect competitors may claim that one or more of our product candidates infringe their intellectual property rights as a strategy to impede our commercialization and entry into new markets. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technologies involved, and the uncertainty of litigation may increase the risk of business resources and management' s attention being diverted to patent litigation. We may in the future receive, letters or other threats or claims from third parties inviting us to take licenses under, or alleging that we infringe, their patents. Moreover, we may become party to adversarial proceedings regarding our or third- party patent portfolios. Such proceedings could include supplemental examination or contested post- grant proceedings such as review, reexamination, inter parties review, interference or derivation proceedings before the USPTO and challenges in U. S. District Courts. Patents may be subjected to opposition, post- grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices. The legal threshold for initiating litigation or contested proceedings may be low, so that even lawsuits or proceedings with a low probability of success might be initiated. Litigation and contested proceedings can also be expensive and time- consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. We may also occasionally use these proceedings to challenge the patent rights of others. We cannot be certain that any particular challenge will be successful in limiting or eliminating the challenged patent rights of the third party. Any lawsuits resulting from such allegations could subject us to significant liability for damages and / or invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following: ● stop making, selling or using product candidates or technologies that allegedly infringe the asserted intellectual property; ● lose the opportunity to license our technology to others or to collect royalty payments; ● incur significant legal expenses, including, in some cases, the attorney' s fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; ● pay substantial damages (possibly treble damages) or royalties to the party whose intellectual property rights on which we may be found to be infringing; ● redesign product candidates that contain the allegedly infringing intellectual property; and ● attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our business and harm our reputation. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and / or substantial royalties and could be prevented from selling our product candidates unless we obtain a license or are able to redesign our product candidates to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our product candidates in a technically feasible way that would not infringe the intellectual property rights of others. We could encounter delays while we attempt to develop alternative methods or product candidates. If we fail to obtain any required licenses or make any necessary changes to our product candidates or technologies, we may be unable to commercialize one or more of our product candidates. Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. Intellectual property litigation, regardless of its outcome, may cause negative publicity, or prohibit us from manufacturing, importing, marketing or otherwise commercializing our product candidates, services and technology. In addition, if the breadth or strength of protection provided by the patents and patent applications we own or in- license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors view these announcements in a negative light, the price of our common stock could be adversely affected. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed. We also rely upon copyright and trade secret protection, as well as non- disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our product candidates that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time- consuming, and the outcome of any such claim is unpredictable. Trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, trade secrets may be independently developed or reverse engineered by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information were independently developed by a competitor, our business and competitive position could be harmed. We may be unable to enforce our intellectual property rights throughout the world. Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive, and the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U. S. Many companies have encountered significant problems in protecting and defending intellectual property

rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time- consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Additionally, in the event that our trademarks are successfully challenged, we could be forced to rebrand our product candidates, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks. Proceedings to enforce our patent or trademark rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets. In the future, we may employ individuals who previously worked with other companies, including our competitors. Although we try to ensure that our employees and consultants 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 our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property or personal data, including trade secrets or other proprietary information, of a former employer or other third party. Litigation may be necessary to defend against these claims. If we fail in defending any such claims or settling those claims, in addition to paying monetary damages or a settlement payment, 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 and other employees. Changes in U. S. patent laws may limit our ability to obtain, defend and / or enforce our patents. In 2011, the U. S. enacted and later implemented wide ranging patent reform legislation. The U. S. Supreme Court has ruled on several patent cases since that time, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U. S. Congress, the U. S. federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The USPTO and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and other patent agencies over the lifetime of the patent. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by additional payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non- compliance with such provisions will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our product or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, it can create opportunities for competitors to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our product candidates. We may be unable to obtain a patent term extension in the U. S. under the Hatch- Waxman Act and in foreign countries under similar legislation. In the U. S., a patent that covers a drug product approved by the FDA may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, it is possible, though unlikely, that one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch- Waxman Act, which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and 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, and only claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended, and only one patent may be extended. In the EU, it is possible, though unlikely, that our product candidates may be eligible for term extensions based on similar legislation. However, in either jurisdiction, if we were eligible to apply for patent term extension, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable product candidates could be substantial. 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 our patents or that incorporate certain technology in our product candidates that is in the public domain; ● we, or our future licensors or collaborators, might not have been the first to make the inventions covered by the applicable issued patent or pending patent application that we own now or may own or license in the future; ● we, or our future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions; ● we may not be able to successfully commercialize our product candidates before our relevant patents we may have, or to which we have ownership rights through licensing agreements, expire; ● others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; ● it is possible that our current or future pending 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; ● we may not develop additional proprietary technologies that are patentable; ● 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. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations. Risks Related to the Ownership of our Securities Our common stock is listed on the..... (a) (2). The **Series C Certificate** ~~Nasdaq deficiency letter had no immediate effect on the listing~~ of **Designation** ~~our common stock, and our common stock continued to trade on the Nasdaq Capital Market under the symbol " WINT ". We were initially given 180 calendar days, or until November 30, 2022, to regain compliance with Rule 5550 (a) (2), which was extended by an~~ **and certain warrants** ~~additional 180 calendar days, or May 29, 2023. On February 24, 2023, we effected a reverse stock split of our~~ issued **in July** ~~and outstanding shares of common stock, par value $ 0. 001 per share, at a ratio of 1 post- split share for every 50 pre- split shares. On March 10, 2023, we received written confirmation from Nasdaq notifying us that we had regained compliance with Nasdaq Listing Rule 5550 (a) (2). On January 22,~~ 2024, ~~we received a deficiency letter from the Staff of Nasdaq notifying us that, for~~ - **or** the ~~last 31 consecutive business days, the closing bid price for our common stock has been below the minimum $ 1. 00 per share required for continued listing on the Nasdaq Capital Market pursuant to Rule 5550 (a) (2). The Nasdaq deficiency letter has no immediate effect on the listing of our common stock, and our common stock will continue to trade on the Nasdaq Capital Market under the symbol " WINT " at this time. We have been given an initial 180 calendar days, or until~~ July ~~22,~~ 2024 , to regain compliance with Rule 5550..... and through the exercise of outstanding warrants **Warrants** , our stockholders may experience substantial dilution..... Series B Preferred Stock and the Notes , each contain anti- dilution provisions that may result in the reduction of the conversion price of the Series ~~B~~ **C** Preferred Stock and **exercise price of** the ~~Notes~~ **July 2024 Warrants** . These features may increase the **number of shares of our common stock issuable upon conversion of the Series C Preferred Stock and the exercise of the July 2024 Warrants. The Series C Certificate of Designation authorizes a total of 18, 820 shares of Series C Preferred Stock with an initial conversion price of $ 187. 00, which is subject to adjustment as provided in the Series C Certificate of Designations. As of April 15, 2025, the conversion price of the Series C Preferred Stock and the July 2024 Warrants is $ 1. 10. Both the conversion price of the Series C Preferred Stock and the exercise price of the July 2024 Warrants are subject to any stock split, stock dividend, stock combination, recapitalization or other similar transaction involving our common stock at a price below the then-applicable conversion price or exercise price, as applicable, each as described in further detail in the Series C Certificate of Designation or the July 2024 Warrants, respectively. The Series C Preferred Stock and the July 2024 Warrants also provide for adjustment to the conversion price and exercise price, respectively, to an amount equal to the quotient determined by dividing (x) the sum of the volume weighted average price, or the VWAP, of our common stock for each of the 5 trading days with the lowest VWAP of our common stock during the 15 consecutive trading day period ending and including the trading day immediately preceding the 16th trading day after any stock split, stock dividend, stock combination recapitalization or other similar transaction involving our common stock. In addition, in January 2025, we contacted all holders of the Series C Preferred Stock and notified them that the Company decided to offer to reduce the Conversion Price as defined in the Series C Certificate of Designation of each share of Series C Preferred Stock to $ 8. 04 pursuant to the Series C Certificate of Designation. As a result, approximately 1, 895 shares of Series C Preferred Stock were converted into approximately 0. 2 million shares of common stock at a reduced Conversion Price, and the exercise price of the July 2024 Warrants was also reduced to $ 8. 04. We may in the future enter into similar transactions that would result in a reduction to the conversion price of the Series C Preferred Stock or the exercise price of the July 2024 Warrants. If in the future, while any of our Series C Preferred Stock or July 2024 Warrants are outstanding, we grant, issue or sell any shares of our common stock for a consideration per share of our common stock (the " New Issuance Price "), less than a price equal to the conversion price of the Series C Preferred Stock or the exercise price of the July 2024 Warrants, respectively, as then in effect immediately prior to such granting, issuance or sale, we will be required, subject to certain limitations and adjustments (as provided in the Series C Certificate of Designation or the July 2024 Warrants) to reduce the conversion price of the Series C Preferred Stock or the exercise price of the July 2024 Warrants, as applicable, to be equal to the New Issuance Price, which will result in a greater** number of shares of our common stock being issuable upon conversion ~~of the Series B Preferred Stock and the Notes. The Certificate of Designation, or the Series B Certificate of Designation, authorizes a total of 5, 500 Series B Preferred Stock, with an initial conversion price of $ 0. 3603, the Preferred Conversion Price. Similarly, our 10 % senior convertible notes, or the Notes, have an initial conversion price of $ 0. 3603, the Notes Conversion Price. Both the Preferred Conversion Price and the Notes Conversion Price are subject to adjustment upon the occurrence of specified events to no lower than $ 0. 0721, subject to any stock split, stock dividend, stock~~

~~combination, recapitalization or other similar transaction involving our common stock at a price below the then- applicable Preferred Conversion Price or Notes Conversion Price, as applicable, each as described in further detail in the Certificate of Designation or the Notes, respectively. If in the future, while any of our Series B Preferred Stock or Notes are outstanding, we grant, issue or sell any shares of our common stock for a consideration per share of our common stock, the New Issuance Price, less than a price equal to the Preferred Conversion Price or Notes Conversion Price, respectively, as then in effect immediately prior to such granting, issuance or sale, we will be required, subject to certain limitations and adjustments (as provided in the Series B Certificate of Designation or the Note) to reduce the Preferred Conversion Price or the Notes Conversion Price, as applicable, to be equal to the New Issuance Price, which will result in a greater number of shares of our common stock being issuable upon conversion~~ , which in turn will increase the dilutive effect of such conversion on existing holders of our common stock. It is possible that we will not have a sufficient number of shares available to satisfy the conversion of the Series ~~B~~ **C** Preferred Stock and / or the ~~Notes~~ **July 2024 Warrants** if we enter into a future transaction that reduces the applicable **conversion price of the Series C** Preferred ~~Conversion~~ **Stock or the exercise** ~~Price~~ **price** ~~or Notes Conversion Price~~ **of the July 2024 Warrants** . If we do not have a sufficient number of available shares for the conversion of any Series ~~B~~ **C** Preferred Stock or ~~Notes~~ **exercise of any July 2024 Warrants** , we may need to seek ~~shareholder~~ **stockholder** approval to increase the number of authorized shares of our common stock, which may not be possible and will be time consuming and expensive. The potential for such additional issuances may depress the price of our common stock regardless of our business performance and may make it difficult for us to raise additional equity capital while any of our Series ~~B~~ **C** Preferred Stock or ~~Notes~~ **July 2024 Warrants** are outstanding. The Series ~~B~~ **C** Preferred Stock have a liquidation preference senior to our common stock. Subject to certain exceptions, in accordance with the Series ~~B~~ **C** Certificate of Designation, shares of our capital stock are junior in rank to the Series ~~B~~ **C** Preferred Stock with respect to the preferences as to dividends, distributions and payments upon our liquidation, dissolution and winding up. The payment of the liquidation preferences could result in common stockholders and warrant holders not receiving any consideration if we were to liquidate, dissolve or wind up, either voluntarily or involuntarily. This liquidation preference may increase over time based on the payment of dividends. **If we issue any additional preferred stock in the future, it may also have similar liquidation preferences.** The existence of the liquidation preferences may reduce the value of our common stock, make it harder for us to sell shares of common stock in offerings in the future, or prevent or delay a change of control. **In July** ~~Under the terms of the Notes, we are subject to certain restrictive covenants that may make it difficult to procure additional financing. On April 2,~~ 2024, we entered into ~~a Securities~~ **the PIPE** Purchase ~~Agreement~~ **Agreements** ~~, or the~~ **. The PIPE** Purchase ~~Agreement~~ **Agreements** ~~, with the buyers named therein. The Purchase Agreement~~ , pursuant to which we issued the ~~Notes~~ **July 2024 Warrants** , ~~contains~~ **contain** ~~the~~ restrictive covenants, subject to certain exceptions. For example, without the consent of the holders holding at least a majority of the certain registrable securities for the period commencing on ~~April 2~~ **July 18** , 2024 **and July 26, 2024, respectively,** and ending on the date immediately following the 90th trading day after the Applicable Date (as defined in the **PIPE** Purchase ~~Agreement~~ **Agreements**) ~~, or the Restricted Period~~ , neither we nor any of our subsidiaries will directly or indirectly issue, offer, sell, grant any option or right to purchase, or otherwise dispose of (or announce any issuance, offer, sale, grant of any option or right to purchase or other disposition of) any equity security or any equity- linked or related security ~~(~~ **,** including, without limitation, any " equity security " (as that term is defined under Rule 405 promulgated under the Securities Act ~~of 1933, as amended~~), any Convertible Securities (as defined in the **PIPE Purchase Agreements), any debt, any preferred stock or any purchase rights (other than pursuant to the Common Stock Purchase Agreement entered into with the purchaser in June 2024, or the ELOC** Purchase Agreement), ~~any debt, any preferred stock or any purchase rights),~~ or a Subsequent Placement **(as defined in the PIPE Purchase Agreements)** . Subject to the limitations described in the **PIPE** Purchase ~~Agreement~~ **Agreements** , for so long as ~~the Notes~~ **shares of Series C Preferred Stock** are outstanding, we are prohibited from effecting or entering into an agreement to effect any Subsequent Placement involving a Variable Rate Transaction (as defined in the **PIPE** Purchase ~~Agreement~~ **Agreements**). Additionally, the **PIPE** Purchase ~~Agreement~~ **Agreements** ~~contains~~ **contain** a participation right, which provides that, subject to certain exceptions, at any time on or prior to ~~April 2, 2028~~ **the fourth anniversary of the respective closing dates** , neither we nor our subsidiaries shall, directly or indirectly, effect any Subsequent Placement unless we comply with certain notice procedures as outlined in the **applicable** Purchase Agreement with respect to each ~~buyer~~ **investor** , providing the opportunity for such ~~buyer~~ **investor** to participate in such Subsequent Placement on a pro rata basis as described in the **PIPE** Purchase Agreement. Any of these restrictions on our ability to operate our business in our discretion could adversely affect our business by, among other things, limiting our ability to adapt to changing economic, financial, or industry conditions and to take advantage of corporate opportunities, including opportunities to obtain debt financing, repurchase stock, refinance or pay principal on our outstanding debt, or complete acquisitions for cash or debt. If we require additional funding while these restrictive covenants remain in effect, we may be unable to effect a financing transaction while remaining in compliance with the terms of the **applicable** Purchase Agreement, or we may be forced to seek a waiver from the ~~buyers~~ **investors** party to the **applicable** Purchase Agreement. ~~the issuance of additional equity securities and through the exercise of outstanding warrants~~ ,our stockholders may experience substantial dilution.We may sell shares of preferred stock or common stock in one or more transactions at prices that may be at a discount to the then- current market value of our common stock and on such other terms and conditions as we may determine from time to time.Any such transaction could result in substantial dilution of our existing stockholders.If we sell shares of our common stock in more than one transaction,stockholders who purchase our common stock may be materially diluted by subsequent sales.Such sales could also cause a drop in the market price of our common stock.The issuance of shares of our common stock in connection with a public or private financing,in connection with our compensation programs,and upon exercise of outstanding warrants will have a dilutive impact on our other stockholders and the issuance,or even potential issuance,of such shares could have a negative effect on the market price of our common stock.The exercise of stock options and other securities could also cause our stockholders to experience substantial dilution.Moreover,holders of our

stock options and warrants are likely to exercise them,if ever,at a time when we otherwise could obtain a price for the sale of our securities that is higher than the exercise price per security of the options or warrants.Such exercises,or the possibility of such exercises,may impede our efforts to obtain additional financing through the sale of additional securities or make such financing more costly.It may also reduce the price of our common stock. **The Certificate of Designation for the Series B Preferred Stock and the Notes** Provisions of our **Amended and Restated Certificate of Incorporation as amended, or the** Certificate of Incorporation, our Amended and Restated By- Laws, or **the** By- Laws, and Delaware law could deter a change of our management and thereby discourage or delay offers to acquire us. Provisions of our Certificate of Incorporation, our By- Laws and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management and might discourage a third party from offering to acquire us, even if a change of control or in management would be beneficial to our stockholders. Such provisions may make it costlier for a potential acquirer to engage in a business combination transaction with us. Provisions that have the effect of discouraging, delaying or preventing a change of control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock. Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to file in a different judicial forum to resolve disputes with us or our directors, officers or employees. Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our Certificate of Incorporation or our By- Laws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. These choice of forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock. We are a " smaller reporting company, " and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors. We are a " smaller reporting company " as defined in the Exchange Act and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies, which include, among other things, audited financial statements and Management Discussion and Analysis for two years instead of three years, an update of the general development of the business for such period that is material to an understanding of the company, simplified executive compensation disclosures, and exemption from the provisions of Section 404 (b) of the Sarbanes- Oxley Act requiring that an independent registered accounting firm provide an attestation report on the effectiveness of internal control over financial reporting. We cannot predict whether investors will find our common stock less attractive because of our reliance on any of 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.