Risk Factors Comparison 2024-04-22 to 2023-03-23 Form: 10-K

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You should carefully consider the following risk factors, as well as the other information in this Annual Report on Form 10- K, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and / or growth prospects or cause our actual results to differ materially from those contained in forward- looking statements we have made in this report and those we may make from time to time. When evaluating our business, you should consider all of the factors described as well as the other information in our Annual Report on Form 10- K, including our financial statements and the related notes and " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. Risks Related to **Our Financial Position and Need for Additional Capital We need substantial additional funding to complete the development of rezafungin and to advance CD388, CBO421 and our** ~~the~~ **other** ~~COVID Financial Position and Need for Additional Capital We need substantial additional funding to complete the development of rezafungin and to advance CD388,CD421 and our~~ Cloudbreak ~~program~~ **programs** .In connection with the preparation of our financial statements for the period ended December 31, ~~2022~~ **2023** ,we performed an analysis of our ability to continue as a going concern.We believe,based on our current business plan,that our existing cash and cash equivalents will not be sufficient to fund our obligations for the next twelve months **,which raises substantial doubt about our ability to continue as a going concern** .Our ability to continue to fund the development of rezafungin through completion of our planned Phase 3 trials depends on our ability to obtain additional funding.Our ability to advance CD388, ~~CD421~~ **CBO421** and other product candidates from our **other** Cloudbreak ~~program~~ **programs** is also dependent on our ability to obtain additional funding.On September 3,2019,we entered into **a Collaboration and License Agreement,or** the Mundipharma Collaboration Agreement **,with Mundipharma Medical Company,or Mundipharma** ,pursuant to which we granted Mundipharma exclusive commercialization rights to rezafungin outside the **United States,or** U.S. **,** and Japan in exchange for a $ 30.0 million upfront payment,near ~~- term funding to support the global Phase 3 - 19 Mundipharma Collaboration Agreement,pursuant to which we granted Mundipharma exclusive commercialization rights to rezafungin outside the U.S.and Japan in exchange for a $ 30.0 million upfront payment,near-~~ term funding to support the global Phase 3 ReSTORE and ReSPECT trials,and the potential to receive development,regulatory and commercial milestone payments and double- digit royalties in the teens on tiers of annual net sales.The Mundipharma Collaboration Agreement requires,among other things,that we complete the rezafungin development program.On March 31,2021,we entered into **an exclusive,worldwide license and collaboration agreement,or** the Janssen Collaboration Agreement **,with Janssen Pharmaceuticals,Inc.,or Janssen,one of the Janssen Pharmaceutical Companies of Johnson & Johnson** ,to develop and commercialize our Cloudbreak **drug- Fc conjugates,or** DFCs **,** for the prevention and treatment of seasonal and ~~pandemic Pandemic~~ **pandemic** ~~DFCs for the prevention and treatment of seasonal and pandemic~~ influenza.Under the collaboration,we will be responsible for the development and manufacturing of the first influenza DFC,CD388,into the clinic and through Phase 2 clinical development,and Janssen will be responsible for late- stage development,manufacturing,registration and global commercialization.We received an upfront payment of $ 27.0 million.Janssen will fund all future research,development,manufacturing and commercialization for CD388,of which Janssen has funded $ ~~25~~ **44** . ~~1~~ **5** million as of December 31, ~~2022~~ **2023** .On July 26,2022,we entered into **a** ~~the Melinta~~ License Agreement **,or the Melinta License Agreement,with Melinta Therapeutics,LLC,or Melinta** ,pursuant to which we granted Melinta an exclusive license to develop,register and commercialize rezafungin in the U.S.in exchange for a $ 30.0 million upfront payment and the potential to receive regulatory and commercial milestone payments and tiered royalties on U.S.sales in the low double digits to mid- teens.The Melinta License Agreement requires,among other things,that we complete the rezafungin development program. ~~Our ability to meet~~ Our **ability** to meet our development obligations under the Mundipharma Collaboration Agreement,the Janssen Collaboration Agreement and the Melinta License Agreement depends on our ability to obtain additional funding.There can be no assurance that additional funds will be available from any source or,if available,will be available on terms that are acceptable to us.There can also be no assurance that additional funds will be available to us without first obtaining the approval of our stockholders,which can be a difficult and lengthy process with an uncertain outcome.Even if we raise additional capital,our expenses may increase in connection with our ongoing activities beyond what is currently expected.Our future capital requirements will depend on many factors,including:• the ~~ongoing effect of the COVID- 19 global pandemic and the resulting impact on our rezafungin phase 3 clinical development program;• the~~ costs and timing to complete our Phase 3 ReSPECT trial,the remaining Chinese portion of the ReSTORE trial and the CD388 Phase 1 and Phase 2a trials;• the costs,timing and outcome of any regulatory review of rezafungin,CD388, ~~CD421~~ **CBO421** or future development candidates; **CIDARA THERAPEUTICS,INC.** • our ability to establish and maintain collaborations,when and if necessary,on favorable terms,if at all;• the costs and timing of commercialization activities,including manufacturing,marketing,sales and distribution,for rezafungin or any future product candidates that receive marketing approval;• the costs of preparing,filing and prosecuting patent applications,maintaining and enforcing our intellectual property rights and defending intellectual property- related claims;• the scope,progress,results and costs of drug discovery,preclinical development,manufacturing development,laboratory testing and clinical trials for our product candidates,for the Cloudbreak platform;and • the extent to

which we acquire or in- license other product candidates and technologies.Identifying potential development candidates and conducting preclinical studies,manufacturing development and clinical trials are time consuming,expensive and uncertain processes that take years to complete,and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales for any of our current or future product candidates.In addition,our product candidates,if approved,may not achieve commercial success.Our commercial revenue,if any,will be derived from sales of products that we do not expect to be commercially available for many **years,if at all.Accordingly,we need substantial additional funding in connection with our continuing** operations **and to achieve our goals. As of December 31** , ~~of December 31,2022~~ **2023** ,we had cash and cash equivalents of $ ~~32~~ **35** . ~~7~~ **8** million. **The** ~~As a result of the COVID- 19 pandemic and actions taken to slow its spread,the~~ global credit and financial markets have recently experienced extreme volatility and disruptions,including diminished liquidity and credit availability,declines in consumer confidence,declines in economic growth,increases in unemployment rates and uncertainty about economic stability.If the equity and credit markets continue to deteriorate,it may make any additional debt or equity financing more difficult,more costly and more dilutive.In addition,we may not be able to access a portion of our existing cash ~~,~~ **and** cash equivalents ~~and investments~~ due to market conditions ~~.~~ **such as recent and potential future disruptions in access to bank deposits** ~~For~~ **or** ~~example~~ **lending commitments due to bank failures** , **which could have a material adverse effect** on ~~March~~ **our** business and financial ~~insolvent in~~ **condition.In addition,if** the ~~future in response financial market disruptions and economic slowdown deepen or persist,we may not be able~~ to **access additional capital on favorable terms,or at all,which could negatively affect our** financial ~~conditions~~ **condition** ~~affecting the banking system~~ and ~~financial markets,~~ our ability to **pursue** ~~access our existing cash,cash equivalents and investments may be threatened and could have a material adverse effect on~~ our business **strategy** ~~and financial condition~~ .If we are unable to raise additional capital on attractive terms or at all,we may be forced to delay,reduce or eliminate our development programs,including CD388, ~~CD421~~ **CBO421** or one or more of our other Cloudbreak DFC programs,be unable to continue the development of rezafungin,complete the ReSPECT Phase 3 clinical trial and meet our development obligations under the Mundipharma Collaboration Agreement,the Janssen Collaboration Agreement and the Melinta License Agreement,or our other current and future license or collaboration agreements,and / or be forced to make reductions in spending,extend payment terms with suppliers,and / or liquidate or grant rights to assets where possible.Any of these actions could materially harm our business, ~~results of operations and~~ results ~~have been~~ **of operations** and ~~could continue~~ **future prospects. Raising additional capital may cause dilution** to ~~be adversely impacted by~~ **our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity, debt or** ~~the~~ **other** ~~current public health pandemic related to COVID- 19~~ **financing structures, receipt of payments under the Mundipharma Collaboration Agreement, the Janssen Collaboration Agreement and the Melinta License Agreement, as well as potentially entering into other collaborations, strategic alliances or licensing arrangements with third parties or receiving government and / or charitable grants or contracts** . In ~~January 2020~~ **November 2018** , **we entered into** ~~the World Health Organization, or WHO, announced a global health emergency because of~~ a new ~~strain~~ **controlled equity offering sales agreement with Cantor Fitzgerald & Co., or the Sales Agreement, which currently has an aggregate offering price** of ~~novel coronavirus known~~ up to $ 50.0 million,and,other than the Mundipharma Collaboration Agreement,the Janssen Collaboration Agreement and the Melinta License Agreement,it is our only current external source of potential financing.In September 2019,we issued $ 9.0 million of our common stock to Mundipharma in connection with entering into the Mundipharma Collaboration Agreement.In February 2020,we issued $ 30.0 million of our common stock and Series X Convertible Preferred Stock upon the closing of a rights offering.In October 2021,we issued $ 38.5 million of our common stock and Series X Convertible Preferred Stock upon the closing of concurrent but separate public offerings.In March 2023,we issued shares of our common stock and Series X Convertible Preferred Stock upon the closing of concurrent but separate public offerings,for gross proceeds of $ 19.5 million.As of December 31, ~~2022~~ **2023** ,we have issued ~~14~~ **20** , ~~550~~ **769** , ~~113~~ **854** shares of common stock pursuant to the Sales Agreement with an aggregate offering price of approximately $ ~~32~~ **41** .1 million.To the extent that we raise additional capital through the sale of equity or convertible debt securities,like the sale of our common stock to Mundipharma,the sale of our common stock and Series X Convertible Preferred Stock issued in our rights offering,the sale of our common stock and Series X Convertible Preferred Stock in our concurrent **underwritten** public offerings or the sale of common stock under the Sales Agreement,your ownership interest will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights ~~as~~ as ~~COVID~~ a common stockholder.Debt 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 and may be secured by all or a portion of our assets.If we raise funds by entering into collaborations,strategic alliances or licensing arrangements with third parties,we may have to relinquish valuable rights to our technologies,future revenue streams,research programs or product candidates or to grant licenses on terms that may not be favorable to us.On September 3,2019,we licensed all rights to rezafungin outside of the U.S.and Japan to Mundipharma in exchange for certain payments and double - **digit royalties** ~~19 and,~~ in **the teens on tiers of annual net sales. In** March ~~2020~~ **2021** , **we granted exclusive worldwide rights to CD388 and** ~~the~~ **other** ~~WHO declared~~ **influenza DFCs to Janssen in exchange for certain payments and royalties on tiers of annual net sales at rates from** the ~~COVID~~ **mid** - ~~19~~ **single digits to the high- single digits. In July 2022, we licensed all rights to rezafungin inside of the U. S. to Melinta in exchange for certain payments and tiered royalties on U. S. sales in the low double digits to mid- teens. We may need to enter into similar agreements with other third parties for the development and commercialization of rezafungin outside of the Mundipharma and Melinta territories, or for the development of DFCs identified from our** ~~outbreak~~ **Cloudbreak program outside the scope of the Janssen Collaboration Agreement, which may require we relinquish valuable rights to these products. If we raise funds through government grants and contracts, we may be subject to restrictions on our operations or certain unfavorable terms. U. S.**

government grants and contracts, if available, typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion, which will subject us to additional risks. If we receive a **U** ~~pandemic, or the COVID- 19 pandemic~~ . **S.** ~~The COVID- 19 pandemic has resulted in significant governmental~~ -- **government** ~~measures being implemented~~ **grant or contract, we would be required** to ~~control~~ **comply with numerous laws and regulations relating to the formation, administration and performance of the grant or contract, which can make it more difficult for us to retain our rights under such grant or contract and result in increased costs. If we are unable to raise additional funds through equity, debt or** ~~the~~ **other** ~~spread of the virus~~ **financing structures, or through collaborations, strategic alliances or licensing arrangements with third parties, or through receiving government and / or charitable grants or contracts, we may be required to delay, reduce or terminate our rezafungin development program** , including ~~quarantines, travel restrictions and business interruptions and shutdowns. These precautions have disrupted~~ our ~~business operations and prospects. For example, we have experienced, and expect to continue to experience, trial site activation and enrollment delays for the~~ ReSPECT **Phase 3** clinical trial ~~due to facility restrictions~~ , ~~quarantines~~ **be unable to meet our development obligations under the Mundipharma Collaboration Agreement and the Melinta License Agreement** , ~~travel restrictions, focus~~ **and be unable to continue advancing the Cloudbreak program for** ~~on~~ **non** ~~COVID-~~ ~~specific~~ **influenza** DFCs,or be forced to grant rights in the Cloudbreak program for non- influenza DFCs that we would otherwise prefer to retain for ourselves.We have incurred significant operating losses since our inception,and we anticipate that we will continue to incur substantial operating losses for the foreseeable future.We may never achieve or maintain profitability.Since our inception,we have incurred significant operating losses. ~~Our~~ **We had** net ~~losses~~ -- **loss** ~~were~~ **of** $ ~~29~~ **22** . **9** ~~8 million,$ 42.5~~ million and $ ~~72~~ **33** . ~~1~~ **6** million for the years ended December 31, **2023 and** 2022 ~~,2021 and 2020~~ ,respectively.As of December 31, ~~2022~~ **2023** ,we had an accumulated deficit of $ ~~407~~ **441** . ~~0~~ **4** million.To date,we have financed our operations primarily through sale of our stock in public offerings and private placements,through borrowings under loan facilities,and through payments received in connection with the Mundipharma Collaboration Agreement,the Janssen Collaboration Agreement and the Melinta License Agreement.We are currently conducting the ReSPECT **and ReSTORE China Phase 3 clinical** trials **of rezafungin, Phase 1** and **Phase 2a studies of CD388, and preclinical studies of our** other ~~obstacles~~ **DFCs, including CBO421** . ~~The COVID before we receive regulatory approval and have a product candidate available for commercialization.~~ We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future.Our net losses may fluctuate significantly from quarter to quarter and year to year.We anticipate that our expenses will increase substantially if and as we:• submit **investigational new drug applications,or** INDs **,** to the **U.S.Food and Drug Administration,or** FDA **,** and equivalent filings to other regulatory authorities,and seek approval of our clinical protocols by institutional review boards at clinical trial sites;• continue to advance rezafungin and CD388 through clinical development;• continue the preclinical development of our other DFCs from our Cloudbreak platform or otherwise,and advance one or more of such product candidates into clinical trials;• seek marketing approvals for rezafungin,CD388, ~~CD421~~ **CBO421** and other product candidates;• establish or contract for a sales,marketing and distribution infrastructure to commercialize any product candidates for which we obtain marketing approval;• maintain,expand and enforce our intellectual property portfolio;• hire additional manufacturing,clinical,regulatory,quality assurance and scientific personnel;• add operational,financial and management systems and personnel,including personnel to support product development;and • acquire or in ~~- license other product - 19 outbreak~~ **license other product candidates** and ~~mitigation measures~~ technologies.To become and remain profitable,we must develop and eventually commercialize one or more products with significant market potential.This will require us to be successful in a range of challenging activities,including completing preclinical studies and clinical trials of our product candidates,obtaining marketing approval for these product candidates,manufacturing,marketing and selling those product candidates for which we may obtain marketing approval,and satisfying any post- marketing requirements.We may never succeed in these activities and,even if we do,may never generate revenue that is significant or large enough to achieve profitability.Our failure to become and remain profitable would decrease our value and could impair our ability to raise capital,maintain our research and development efforts,expand our business or continue our operations.A decline in the value of our company could also **cause you** ~~have had and may continue~~ to ~~have an adverse impact on~~ **lose all or part of your investment. Unfavorable** global economic conditions ~~which~~ could ~~impair~~ **adversely affect our business, financial condition or results of operations. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the recent global financial crisis, could result in a variety of risks to our business, including** our ability to raise **additional** capital when needed **on acceptable terms, if at all** . ~~While the~~ **This is particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers, possibly resulting in supply** disruption ~~supply disruption~~ .Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. **The** ~~Further,as a result of the COVID- 19 pandemic and actions taken to slow its spread,the~~ global credit and financial markets have recently experienced extreme volatility and disruptions,including diminished liquidity and credit availability,declines in consumer confidence,declines in economic growth,rising inflation,bank failures,increases in unemployment rates and uncertainty about economic stability.If the equity and credit markets continue to deteriorate,it may make access to our liquidity within the U.S.banking system and any additional debt or equity financing more difficult,more costly and more dilutive.The **Israel- Hamas war and the** conflict between Russia and Ukraine could lead to disruption,instability and volatility in global markets and industries that could negatively impact our operations. ~~The~~ **For example,in connection with the conflict between Russia and Ukraine,the** U.S.government and other governments in jurisdictions in which we operate have imposed severe sanctions and export controls against Russia and Russian interests and threatened additional sanctions and controls.The impact of these measures,as well as potential responses to them by

Russia,is currently unknown and they could adversely affect our business,supply chain,partners or customers.We have no history of commercializing pharmaceutical products,which may make it difficult for you to evaluate the prospect for our future viability.We have not yet demonstrated an ability to **conduct** ~~successfully complete large- scale~~ **sales and marketing activities necessary** ~~,pivotal clinical trials required~~ for ~~regulatory approval of our~~ **successful commercialization.Typically,it takes many years to develop one new** product ~~candidates,obtain~~ from ~~COVID~~ **the time it is discovered to when it is commercially available. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or if we had product candidates in advanced clinical trials. In addition we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors that may alter or delay our plans. We will need to continue to transition from a company with a research focus to a company capable of supporting late** ~~- 19 has unforeseen expenses,difficulties,complications,delays and other known and unknown factors that may alter or delay our plans.We will need to continue to transition from a company with a research focus to a company capable of supporting late-~~ stage development activities and,if a product candidate is approved,a company with commercial activities.We may not be successful in any step of such a transition.If we are unable to continue to satisfy the applicable continued listing requirements of Nasdaq,our common stock could be delisted.Our common stock is currently listed on The Nasdaq Capital Market under the symbol " CDTX." In order to maintain this listing,we must continue to satisfy minimum financial and other continued listing requirements and standards.We cannot assure you that we will be able to continue to comply with the applicable listing standards.If we are not able to comply with applicable listing standards,our shares of common stock will be subject to delisting.For example, ~~we~~ **one of the continued listing requirements for The Nasdaq Capital Market is a minimum bid price of at least $ 1.00 per share,or the Minimum Bid Price Requirement.We** were first notified by **the Listing Qualification Staff of the** Nasdaq **Stock Market LLC,or Nasdaq,** on February 28,2022,that our common stock ~~had failed~~ had **failed to maintain the Minimum Bid Price Requirement for 30 consecutive business days. Following extension periods to regain compliance, on February 9, 2023, the Nasdaq Hearings Panel notified us that we had regained compliance with the Minimum Bid Price Requirement subject to a discretionary Panel Monitor until November 9, 2023. On November 9, 2023, we were notified by Nasdaq that our common stock had once again failed to maintain the Minimum Bid Price Requirement for the 30 consecutive business days preceding November 6, 2023. On November 17, 2023, Nasdaq granted us a hearing date with the Nasdaq Hearings Panel on February 1, 2024. The hearing was conducted on February 1, 2024, and on February 8, 2024, the Nasdaq Hearings Panel granted our request for continued listing on The Nasdaq Capital Market, pursuant to** ~~and~~ **an** ~~we expect~~ **extension, through May 7, 2024, to regain compliance with the Minimum Bid Price Requirement. The extension is subject to certain specified conditions and our submission of certain interim updates to the Nasdaq Hearings Panel. If** it **were** to ~~continue to~~ **occur, the delisting of our common stock from trading on Nasdaq could** have ~~an~~ **a material** adverse effect on ~~our business, financial condition and results of operations, we are unable to predict~~ the ~~extent~~ **market** ~~or~~ **for** ~~nature of these impacts at this time. In addition~~ , ~~to the extent the ongoing COVID- 19 outbreak continues to adversely affect our business, financial condition, results of operations~~ and ~~growth prospects~~ **liquidity and price of** , ~~it may~~ **our common stock and impair our ability to raise capital. Delisting from Nasdaq could** also have ~~the effect of heightening many of the~~ other ~~risks~~ **negative results, including, without limitation, the potential loss of confidence by customers and employees, the loss of institutional investor interest and fewer business development opportunities. In the event that our common stock is delisted from Nasdaq and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over- the- counter market or on** ~~and~~ **an** ~~uncertainties described elsewhere in this " Risk Factors "~~ **electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a** ~~section~~ **reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further** . Risks Related to Drug Discovery, Development and Commercialization We depend heavily on the success of rezafungin and CD388, which is currently in Phase 1 and Phase 2a clinical development, and we are very early in our efforts to develop other product candidates from our Cloudbreak program, none of which may be successful. We are currently conducting two Phase 3 clinical trials of rezafungin. We have completed the ReSTORE trial and conducted the primary analyses required for ~~potential~~ approval in U. S. and Europe but are continuing to **conduct the ReSTORE** ~~enroll and treat patients in~~ China **trial** to support Chinese regulatory filings. We also continue to enroll patients in the ReSPECT trial, which is designed to assess the safety and efficacy of rezafungin for the prevention of serious fungal infections in patients undergoing blood and marrow transplants. The ~~U. S. Food and Drug Administration, or~~ FDA ~~,~~ approved our ~~New~~ **new** ~~Drug~~ **drug** ~~Application~~ **application** , or NDA, for rezafungin for the treatment of candidemia and invasive candidiasis in adults with limited or no treatment options, in March 2023. Even though rezafungin has been approved for the treatment indication, we may not be successful in obtaining approval for a supplemental **NDA** ~~New Drug Application~~ , or sNDA, for the expanded prophylaxis indication. In addition, the European Medicines Agency, or EMA, may not approve rezafungin for any indication. The ReSPECT trial is currently enrolling globally. We received IND clearance for CD388, our DFC for prevention and treatment of influenza, from the FDA in March 2022 and subsequently initiated a Phase 1 clinical trial. In September 2022, we initiated a Phase 2a trial of CD388 to evaluate the pre- exposure prophylactic activity of CD388 against influenza virus and a separate Phase 1 Japanese bridging study has been initiated. We are also conducting in vitro and in vivo preclinical studies of other product candidates from our Cloudbreak program for viral infections and oncology indications. Our assumptions about why rezafungin and CD388 are worthy of continued development, as well as our assumptions about the markets for rezafungin, CD388 **, CBO421** or any other potential products from our Cloudbreak program, are based on data primarily collected by other companies. The timing and costs of our preclinical and clinical development programs, the likelihood of **European** marketing approval for rezafungin and **any marketing approval for** CD388, and the regulatory paths for marketing approval for additional products from our

Cloudbreak program remain uncertain. Our ability to generate product revenue, which we do not expect ~~CIDARA THERAPEUTICS, INC.~~ will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of rezafungin, CD388 **, CBO421** and any other product candidates we may develop will depend on many factors, including the following: ~~• the impact of the COVID- 19 pandemic on our operations;~~ • our ability to secure adequate additional funding; • agreement with regulatory authorities on study designs and other requirements for study initiation; • successful completion of preclinical studies; • successful enrollment and completion of clinical trials; • demonstration of safety and efficacy; • receipt of marketing approvals from applicable regulatory authorities; • negotiation of favorable indications and other key elements of the product labeling; • establishing clinical and commercial manufacturing capabilities or making arrangements with third- party manufacturers; • obtaining and maintaining patent and trade secret protection and non- patent exclusivity for our product candidates and technologies; • launching commercial sales of the product candidates if and when approved; • acceptance of the product candidates, if and when approved, by patients, the medical community and third- party payors; • effectively competing with other therapies; • a continued acceptable safety profile of the products following approval; and • enforcing and defending intellectual property rights and claims. If we do not timely enroll the ReSPECT Phase 3 clinical trial, or if we are unable to secure significant additional funding, we will not be able to complete the clinical development plans for the prophylaxis indication for rezafungin. If we do not accomplish one or more of any of the other goals in a timely manner, or at all, we could experience significant delays or an inability to successfully complete the development of and commercialize our product candidates, which would harm our business. If we experience delays or difficulties in enrolling patients in our clinical trials our receipt of necessary regulatory approvals could be delayed or prevented. We may not be able to complete the ReSPECT clinical trial ~~or the ongoing portion of the ReSTORE trial in China~~ if we are unable to identify and enroll a sufficient number of eligible patients, as required by the FDA or similar regulatory authorities outside the U. S., or if we do not believe that the number of patients required by such regulatory authorities can be enrolled in a reasonable timeframe. Our rezafungin Phase 3 clinical development program is a global program and, as such, our ability to timely enroll the clinical trials may be affected by many different factors specific to those global localities, such as, delays in our receipt of approval to commence trials in a particular country from applicable regulatory authorities and ethics committees, timely completion of clinical trial site initiation within each country, delays in local importation and receipt of necessary clinical trial supplies, and our ongoing compliance with local regulations, which may change during the course of the clinical trial. In addition, the rezafungin clinical trials are heavily reliant on third- party contractors, including contractors that import clinical trial materials, and contract research organizations, or CROs, that conduct and monitor our clinical trials, and interact with regional or local regulators and ethics committees on our behalf. If we experience significant difficulties with any of our key contractors such that we determine it is in the best interests of the clinical trials to replace a key contractor, this could result in a significant delay in enrollment. **The** ~~Additionally, timely enrollment in the ReSPECT trial is reliant on global clinical trial sites, most of which have been adversely affected by the~~ COVID- 19 global pandemic ~~. For example, the COVID- 19 global pandemic has~~ significantly impacted our ability to activate sites and enroll patients in the ReSPECT trial ~~in Europe and the U. S.~~ , resulting in substantial delays and increases in the cost of completing the trial ~~. Our enrollment of patients in ReSTORE in China was also delayed in part due to the pandemic. Some factors from the COVID- 19 coronavirus outbreak that have adversely affected enrollment in our Phase 3 trials include: • the diversion of healthcare resources away from the conduct of clinical trial matters to focus on pandemic concerns, including the attention of infectious disease physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials; • the decision of some clinical trial sites to focus on the conduct of COVID- 19 clinical trials; • limitations imposed by hospitals serving as our clinical trial sites that prohibit entry on hospital premises by persons other than those supporting the hospital' s COVID- 19 efforts; • limitations on travel that interrupt key trial activities, such as clinical trial site initiations and monitoring; • interruption in global shipping affecting the transport of clinical trial materials, such as investigational drug product and comparator drugs used in our trials; and • employee quarantine or isolation days that delay necessary interactions with local regulators, ethics committees and other important agencies and contractors. These and other factors arising from the COVID- 19 coronavirus could worsen in countries that are already afflicted with the virus or could continue to spread to additional countries, each of which may further adversely impact our Phase 3 trials. The global outbreak of the COVID- 19 coronavirus continues to evolve and the conduct of our Phase 3 trials may continue to be adversely affected, despite efforts to mitigate this impact~~ . In addition, some of our competitors may have ongoing or new clinical trials for product candidates that would treat the same indications as rezafungin, or be used in the same patients and, therefore, patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Patient enrollment may also be affected by other factors, including: • eligibility criteria, including regional or local practices that place additional limitations on patient eligibility; • availability, safety and efficacy of approved medications or other investigational medications being studied clinically for the disease under investigation; • perceived risks and benefits of rezafungin; • efforts to facilitate timely enrollment in clinical trials; • reluctance of physicians to encourage patient participation in clinical trials; • the ability to monitor patients adequately during and after treatment; • the proximity and availability of clinical trial sites for prospective patients; • delays or failures in maintaining an adequate supply of quality drug product for use in clinical trials; and • changing treatment patterns that may reduce the burden of disease which rezafungin addresses. Our inability to enroll and retain a sufficient number of patients in a reasonable timeframe may require us to abandon the entire rezafungin Phase 3 clinical development program or terminate the ReSPECT trial ~~or the ReSTORE trial in China~~ . Enrollment delays have and will continue to result in increased development costs, which could cause the value of our company to decline and could limit our ability to obtain necessary additional financing **. For example, in the ReSPECT trial, a blinded interim analysis is planned in the first quarter of 2024 which will inform the current fungal free survival rates, or FFS. The FFS will determine if the 462 patients planned to be enrolled will be sufficient to power the trial to maintain non- inferiority. If the number of**

patients planned to be enrolled are not sufficient, the trial may need to enroll more patients which may potentially impact the overall timing to top- line data and increase trial costs. The study is currently enrolling in the EU, Canada and the U. S . If clinical trials for rezafungin, CD388, ~~CD421~~ **CBO421** or any other product candidates are delayed, terminated or suspended, or fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities, we may incur additional costs, or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A delay in starting or completing our clinical trials would materially impact our timelines and our ability to complete development of our product candidates in a timely manner or at all. For example, our entire rezafungin clinical development program **was** ~~has been~~ severely impacted by the effects of ~~the~~ COVID- 19 ~~global pandemic~~ . Additionally, our ability to complete our rezafungin Phase 3 development program is dependent on our ability to secure adequate additional funding. A failure of one or more clinical trials could occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a particular clinical trial do not necessarily predict final results of that trial. Moreover, preclinical and clinical data are often susceptible to multiple interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. For example, the historically observed high rate of correlation for clinical efficacy for anti- infectives based on preclinical data may not apply for our current or future product candidates, and any of the potential benefits that we anticipate for human clinical use may not be realized. We do not know whether either the ReSPECT trial or the Phase 1 ~~of~~ **or** Phase 2a trials of CD388 will be completed on schedule. We ~~have experienced significant delays in these trials arising from the COVID- 19 global pandemic. We~~ may experience numerous ~~other~~ unforeseen events that could delay or prevent our ability to commence or complete our clinical trials, which could then delay or prevent our ability to receive marketing approval or commercialize our product candidates, including: • regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial on our expected timeline, or at all, or conduct a clinical trial at a prospective trial site or in a given country; • regulators may disagree with our interpretation of preclinical data, which may impact our ability to commence our trials on our expected timeline or at all; • regulators may require that trials or studies be conducted, or sized or otherwise designed in ways, that were unforeseen in order to begin planned studies or to obtain marketing authorization; • we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites; • clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, modify planned clinical trial designs or abandon product development programs; • the number of patients required for clinical trials of our product candidates may be larger than we anticipate; • enrollment in these clinical trials may be slower than we anticipate, clinical sites may drop out of our clinical trials or participants may drop out of these clinical trials at a higher rate than we anticipate; • our third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • regulators, institutional review boards or the data safety monitoring board assembled by us to oversee our rezafungin clinical trials may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks due to serious and unexpected side effects; • the cost of clinical trials of our product candidates may be greater than we anticipate; • the FDA or comparable foreign regulatory authorities could require that we perform more studies than, or evaluate clinical endpoints other than, those that we currently expect; • the supply of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be delayed or insufficient, or the quality of such materials may be inadequate; and • we may be required to delay or terminate studies due to financial constraints. If the FDA or similar regulatory authorities outside the U. S. do not agree with the design and implementation of our planned or ongoing clinical trials, including the safety database to support an NDA submission, or if we are unable to secure additional funding, we may not be able to complete the overall Phase 3 clinical development program for rezafungin as currently envisioned ~~. For example, in response to feedback from the FDA, we considered supplementing the ReSTORE safety database with safety data from patients enrolled in the ReSPECT study who shared similar comorbidities and concomitant medications with patients in the ReSTORE study. This approach was ultimately unnecessary, but if we had implemented it, the timing of our NDA submission and the timing of completion of the ReSPECT study might have been impacted. If we do not accomplish one or more of any of the other goals in a timely manner, or at all, we could experience significant delays or an inability to successfully complete the development of and commercialize our product candidates, which would harm our business~~ . If we are required to conduct additional clinical trials, or other tests of our product candidates beyond those that we currently contemplate, if we are unable to complete clinical trials of our product candidates or other tests successfully or in a timely manner, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may: • be delayed in obtaining marketing approval for our product candidates; • not obtain marketing approval at all; • obtain approval for indications or patient populations that are not as broad as intended or desired; • obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings; • be subject to additional post- marketing testing requirements; • be subject to significant restrictions on reimbursement from public and / or private payors; or • have the product removed from the market after obtaining marketing approval. Product development costs will also increase if we experience delays in testing or in receiving marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates, could allow our competitors to bring products to market before we do, could increase competition from generics of the same class, and could impair our ability to

successfully commercialize our product candidates, any of which may harm our business and results of operations. If serious adverse reactions or unexpected characteristics of our product candidates are identified during development, we may need to abandon or limit our development of some or all of our product candidates. Because it is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval, the risk of each of our programs is high. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain 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. For example, the pharmacokinetic properties, such as a longer half- life or less frequent dosing regimen, that differentiate rezafungin from other echinocandins could have side effects that we have not anticipated and the consequences of such side effects could be more severe than have been seen with other echinocandins that have shorter half- lives or more frequent dosing regimens, or are dosed at lower concentrations than we expect for rezafungin. Further, the treatment advantages that we are predicting for rezafungin, such as lower healthcare costs resulting from an ability to administer rezafungin once-weekly, which could allow earlier hospital discharge, or the predicted ability of rezafungin to be effective against resistant strains of fungal pathogens, may not be realized. For our DFCs, the bispecific mechanism of action, including the use of the immune system, may lead to side effects that are not anticipated based on the preclinical work we have conducted to date. In the biotechnology industry, many agents that initially show promise in early stage testing may later be found to cause side effects that prevent further development of the agents. In addition, infections can occur in patients with co- morbidities and weakened immune systems, and there may be adverse events and deaths in our clinical trials that are attributable to factors other than investigational use of our product candidates. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. We have limited financial resources. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential than opportunities we pursue. For example, we believe that an sNDA filing for rezafungin adding the prophylaxis indication can be supported by one Phase 3 trial in prophylaxis, however, financial constraints may require us to delay our prophylaxis program. In support of the global effort to identify effective therapeutics to treat and prevent the COVID- 19 coronavirus ~~and stem the current global pandemic,~~ we have expended financial resources to identify DFCs which may be effective in this area. In addition, we have recently expended financial resources on identification of DFCs targeting multiple potentially synergistic oncology targets. We have limited experience in identification and nonclinical and clinical testing of oncology therapeutics. Our resource allocation decisions may not result in us identifying valuable products or 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 markets for a particular product candidate or opportunity, we may relinquish valuable rights to that product candidate or opportunity through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate or opportunity. **Any** ~~Even if any~~ of our product candidates **that** receive marketing approval ~~, they~~ may fail to achieve the degree of market acceptance by physicians, patients, formulary committees, third- party payors and others in the medical community necessary for commercial success. **Any** ~~If any~~ of our product candidates **that** receive marketing approval ~~, they~~ may nonetheless fail to gain sufficient market acceptance by hospitals and hospital pharmacies, physicians, patients, third- party payors and others in the medical community for us to achieve commercial success. If our product candidates do not achieve an adequate level of acceptance, we may not generate sufficient product revenue to become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including: • the efficacy and potential advantages compared to alternative therapies; • the size of the markets in the countries in which approvals are obtained; • terms, limitations or warnings contained in any labeling approved by the FDA or other regulatory authority; • our ability to offer any approved products for sale at competitive prices; • convenience and ease of administration compared to alternative treatments; • the willingness of the target patient population to try new therapies or dosing regimens; • the willingness of physicians to prescribe these therapies and, in the case of rezafungin, transition to a once- weekly dosing regimen from traditional once- daily dosing; • the strength of marketing and distribution support; • the success of competing products and the marketing efforts of our competitors; • sufficient third- party payor coverage and adequate reimbursement; and • the prevalence and severity of any side effects. If, in the future, we are unable to establish sales and marketing capabilities or to selectively enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates, if and when they are approved. **In addition, if we enter into agreements with third parties to sell and market our product candidates, such third parties may not be successful in commercializing our products.** We do not have a sales or marketing infrastructure. To achieve commercial success for any approved product, we must license the rights to third parties with such capabilities, develop a sales and marketing organization or outsource these functions to third parties. There are risks involved both with establishing our own sales and marketing capabilities and with entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly and our investment would be lost if we cannot reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our product candidates on our own include: • our inability to recruit and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to physicians or to achieve adequate numbers of prescriptions for any future products; and • costs and expenses associated with creating an independent sales and marketing organization. If we enter into

arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability of these product revenues to us may be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties and any of them may fail to market and sell our products effectively, including by failing to devote the necessary resources and attention. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates **. If we do establish relationships with third parties to sell and market our product candidates, such third parties may not be successful in commercializing those products. For example, in the U. S. we are entirely dependent on Melinta to commercialize rezafungin. While Melinta has significant experience in commercialization of anti- infective drugs, they have limited experience with commercialization of antifungal drugs and may be unable to hire individuals with the requisite expertise or develop and execute an appropriate commercialization plan** . We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Regulatory incentives to develop drugs for treatment of infectious diseases have increased interest and activity in this area and will lead to increased competition for clinical investigators and clinical trial subjects, as well as for future prescriptions, if any of our product candidates are successfully developed and approved. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the indications on which we are focusing our product development efforts. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. We expect that rezafungin will primarily compete with certain antifungal classes of drugs, which include polyenes, azoles and echinocandins. Approved branded echinocandin antifungal therapies include Cancidas (caspofungin, marketed by Merck & Co.), Eraxis (anidulafungin, marketed by Pfizer, Inc.), and Mycamine (micafungin, marketed by Astellas Pharma US, Inc.). We expect that there will be generics of all of the current echinocandins available at the time of rezafungin market approval, which will create added competition. In addition, there are other generic products approved for candidemia, marketed by companies such as Baxter Healthcare Corporation, Mylan Inc. and Glenmark Generics Inc., among others. In addition to approved therapies, we expect that rezafungin will compete with product candidates that we are aware of in clinical development by third parties, such as fosmanogepix (PF- 07842805), which is being developed by Pfizer, Inc. and ~~brexafungerp~~ **ibrexafungerp** , which is approved for other indications and is being developed for invasive candidiasis by Scynexis, Inc. We expect that CD388 will compete against approved and investigational agents for the treatment or prevention of viral influenza infections, including influenza vaccines, neuraminidase inhibitors such as Tamiflu, Relenza and Peramivir, and endonuclease inhibitors such as Xofluza. We may develop other product candidates through our Cloudbreak platform for the treatment or prevention of other serious diseases, such as **solid tumor** ~~RSV, HIV, the SARS- CoV- 2 strains causing COVID- 19 and various~~ cancers **and viral infections** . We are aware of a large number of approved and investigational therapies in these areas also. We expect that ~~CD421~~ **CBO421** will compete against approved anticancer therapeutics as well as investigational CD- 73 targeting small molecule drugs, including Oric- 533 being developed by Oric Pharmaceutical, Inc. and quemliclustat being developed by Arcus Biosciences, Inc. as well as monoclonal antibodies, including oleclumab being developed by AstraZeneca PLC. Our competitors may develop products that are more effective, safer, more convenient or less costly than any that we are developing or that would render our product candidates obsolete or non- competitive. Our competitors may also obtain marketing approval from the FDA or other regulatory authorities for their products sooner than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Many of our competitors have significantly greater name recognition, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early **-** stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These same competitors may invent technology that competes with our rezafungin program, CD388, ~~CD421~~ **CBO421** , or our Cloudbreak platform. These third parties may compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. 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 publicly disclose interim, preliminary or topline 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 analysis 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. Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. Even if we are able to commercialize any product candidates, these products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business. The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. In the U. S., new and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product- licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial marketing approval is granted. As a result, we might obtain marketing approval for a drug in a particular country but then be subject to price regulations that delay its commercial launch, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to commercialize and generate revenue from one or more product candidates, even if our product candidates obtain marketing approval. Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health programs, private health insurers, integrated delivery networks and other third- party payors. Third- party payors decide which medications they will pay for and establish reimbursement levels. A significant trend in the U. S. healthcare industry and elsewhere is cost containment. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of payment for particular medications. Increasingly, third- party payors are requiring that drug companies provide predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement may not be sufficient for commercial success. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. There may be significant delays in obtaining coverage and adequate reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or similar regulatory authorities outside the U. S. Moreover, eligibility for coverage and reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Coverage and reimbursement rates may vary according to the use of the drug and the medical circumstances under which it is used may be based on reimbursement levels already set for lower cost products or procedures or may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U. S. Commercial third- party payors often rely upon Medicare coverage policies and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government- funded programs and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize our approved products and our overall financial condition. Further, coverage policies and third- party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. Product liability lawsuits against us could cause us to incur substantial liabilities and could limit the commercialization of any product candidates we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and we ~~will~~ face an even greater risk **for our** ~~if we commercially sell any~~ products that receive marketing approval. If we cannot successfully defend ourselves against claims that our product candidates **and products** caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any product candidates that we may develop; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants; • significant costs and distraction of management to defend any related litigation; • the initiation of investigations by regulatory bodies; • substantial monetary awards to trial participants or patients; • loss of revenue; • product recalls, withdrawals or labeling, marketing or promotional restrictions; and • the inability to commercialize any products we may develop. Although we have product liability insurance for our clinical trials, such insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as we continue or expand our clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive. We may not be

able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees in our workplace, including those resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, chemical, 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. 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. We may not be successful in our efforts to identify, discover, and develop potential product candidates through our Cloudbreak platform or otherwise. Through our Cloudbreak platform, we are developing DFCs for the treatment and prevention of serious diseases, including influenza ~~, the SARS- CoV- 2 strains causing COVID- 19,~~ and various cancers. We have nominated the DFC CD388 as our lead development candidate for influenza, and we have nominated ~~CD421~~ **CBO421** as our lead oncology DFC candidate. In applying our Cloudbreak platform, we may not be successful in identifying additional DFCs that could be developed as drug therapies. In addition, our Cloudbreak platform may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons. In particular, our research methodology used may not be successful in identifying compounds with sufficient potency, bioavailability or efficacy to be potential product candidates. In addition, our potential product candidates may, on further study, be shown to have harmful side effects or other negative characteristics. Research programs to identify new product candidates require substantial technical expertise and human resources. For example, we have limited experience with the use of the Cloudbreak platform applied to viral pathogens and oncology targets. A failure to optimize our expertise using the Cloudbreak platform for the development of our Cloudbreak program may limit our ability to successfully advance this program and identify future product candidates. Research programs to identify new product candidates also require substantial financial resources. We may choose to expend our financial resources on potential product candidates that ultimately prove to be unsuccessful. For example ~~, in response to the immediate global pandemic crisis~~ , we have expended financial resources to identify therapeutics to treat or prevent the COVID- 19 coronavirus, and we may be unsuccessful in identifying such a DFC. If we are unable to identify successful product candidates from our Cloudbreak platform for preclinical and clinical development, we will have spent financial resources on programs that did not yield viable products and therefore generate product revenue, which would harm our financial position and adversely impact our stock price. Risks Related to Our Financial Position and Need for Additional Capital..... decline further. Risks Related to Our Dependence on Third Parties We are dependent on our collaboration partners to provide funding to continue the development of rezafungin and CD388; for the commercialization of rezafungin outside Japan; and for the late- stage development, manufacturing, registration and commercialization of CD388. If the collaborations are not successful, we may not be able to complete the development of rezafungin and CD388, or capitalize on the full market potential for rezafungin and CD388. On September 3, 2019, we licensed the rights to rezafungin outside of the U. S. and Japan to Mundipharma, a large international pharmaceutical company, and on July 26, 2022, we licensed the rights to rezafungin inside the U. S. to Melinta. Our ability to complete the development of rezafungin is dependent, in part, on funds provided by Mundipharma and Melinta. Additionally, our ability to receive payments from these arrangements will depend on Mundipharma' s and Melinta' s ability to successfully commercialize rezafungin in their respective territories. The Mundipharma Collaboration Agreement and the Melinta License Agreement pose many risks to us, including that our collaborator, Mundipharma, and our licensee, Melinta: • have significant discretion in determining the efforts and resources they will apply to commercializing rezafungin in their respective territories, and may not commit sufficient resources to the marketing and distribution of rezafungin; • may **be unable to successfully commercialize rezafungin in one or more territories because, following regulatory approval, they may be unable to obtain formulary pricing approval, reimbursement approval, and / or formulary placement; • have limited experience commercializing antifungal therapeutics and therefore may be unsuccessful in developing and implementing commercial launch plans for rezafungin; • may** terminate the Mundipharma Collaboration Agreement ~~at will~~ and ~~may terminate~~ the Melinta License Agreement at will ~~after July 26, 2023~~ ; • may be subject to changes in key personnel or strategic focus, have limited available funding or be subject to other external factors diverting resources or creates competing priorities, all of which could negatively impact the commercialization of rezafungin in their respective territories; • may independently develop, or develop with third parties, products that compete directly or indirectly with rezafungin if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; • may use our intellectual property or proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or proprietary information or expose us to potential litigation; • may not agree with certain development decisions resulting in the delay or termination of the programs, or that result in costly litigation or arbitration that diverts management attention and resources; • could be involved in a business combination and the continued pursuit and emphasis on rezafungin could be delayed, diminished or terminated; and • could be financially impacted by ~~the~~

~~COVID- 19 pandemic,~~ inflation or bank failures. If our ability to generate revenue under the Mundipharma Collaboration Agreement and the Melinta License Agreement is adversely impacted by these or any other risks, our right to receive additional payments from the Mundipharma Collaboration Agreement and the Melinta License Agreement, including our share of the revenues generated by net sales of rezafungin, if approved, could be insufficient to allow us to complete our rezafungin development program including the ReSPECT Phase 3 clinical trial, to achieve or maintain profitability or may result in rezafungin being less valuable to us than if we had not entered into the Mundipharma Collaboration Agreement and the Melinta License Agreement. On March 31, 2021, we licensed the exclusive worldwide rights to CD388 and other influenza DFCs to Janssen. Our ability to complete the development of CD388 is dependent, on funds provided by Janssen. **As part of a recent prioritization of its R & D business, in July 2023 Janssen disclosed its intention to discontinue internal development of multiple product candidates in its infectious disease pipeline, including CD388. However, in September 2023 Janssen delivered its Election to Proceed Notice for CD388 whereby Janssen will assume the future development, manufacturing and commercialization activities of CD388 but intends to transfer its rights and obligations under the Janssen Collaboration Agreement to another transferee. Following Janssen' s Election to Proceed Notice, Janssen, or any third-party transferee, is obligated at its sole expense to diligently continue development and commercialization either itself or through the transferee to whom it sublicenses or assigns the rights. If Janssen sublicenses or assigns the rights to a transferee, then all terms under the current Janssen Collaboration Agreement will survive without modification. However, there is no guarantee that Janssen will execute an agreement with a transferee and may ultimately decide to terminate the Janssen Collaboration Agreement.** Additionally, our ability to receive payments from this arrangement will depend in part on Janssen' s **, or any third- party transferee' s,** ability to successfully commercialize CD388. The Janssen Collaboration Agreement poses many risks to us, including that our collaborator, Janssen: • has significant discretion in determining the efforts and resources it will apply to developing, manufacturing, registering and commercializing CD388; • may terminate the collaboration agreement at will, subject to certain limitations; • may be subject to changes in key personnel or strategic focus, have limited available funding or be subject to other external factors diverting resources or creates competing priorities, all of which could negatively impact the development, manufacturing, registration and commercialization of CD388; • may independently develop, or develop with third parties, products that compete directly or indirectly with CD388 if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; • may not agree with certain development decisions resulting in the delay or termination of the program, or that result in costly litigation or arbitration that diverts management attention and resources; • could be involved in a business combination and the continued pursuit and emphasis on CD388 could be delayed, diminished or terminated; and If our ability to generate revenue under the Janssen Collaboration Agreement is adversely impacted by these or any other risks, our right to receive additional payments under the Janssen Collaboration Agreement, including milestone payments and royalties on tiers of annual net sales at rates from the mid- single digits to the high- single digits, could be insufficient to allow us to achieve or maintain profitability or may result in CD388 being less valuable to us than if we had not entered into the Janssen Collaboration Agreement. We may seek to selectively establish other collaborations and, if we are unable to establish them on commercially reasonable terms or at all, we may have to alter our research, clinical development and commercialization plans. We may seek to collaborate with other pharmaceutical and biotechnology companies to advance the Cloudbreak program for DFCs outside the scope of the Janssen Collaboration Agreement, or for the completion of development and commercialization of rezafungin in Japan. We may also seek funding from government grants or contracts to advance the Cloudbreak program for DFCs outside of the Janssen Collaboration Agreement. We cannot be certain that we will be successful in completing any such collaboration or obtaining any such government grants or contracts, or completing any of them on commercially reasonable terms. We face significant competition in seeking appropriate pharmaceutical or biotech collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, on the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include: • the design or results of preclinical studies, **chemistry, manufacturing and controls, or** CMC **,** development activities or clinical trials; • the likelihood of approval by the FDA or similar regulatory authorities outside the U. S.; • the potential market for the product candidate in the territories that are the subject of the collaboration; • the costs and complexities of manufacturing and delivering such product candidate to patients; • the potential of competing products; • the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge; and • industry and market conditions generally. The collaborator may also consider alternative product candidates for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We also face significant competition for government grants and contracts for the Cloudbreak program, and there can be no assurances that such funding would be available to us if and when needed, or at all. For instance, government funding may be available only at certain phases of research and development, such as only after Phase 1 clinical trials have been completed. In order to advance the Cloudbreak program for DFCs outside of the Janssen Collaboration Agreement, we will need to obtain significant funding to complete IND-enabling studies, manufacturing development and Phase 1 clinical trials. Government grants and contracts may not be available to fund our activities at this earlier phase of the research and development process. We intend to continue to rely on third parties to conduct our clinical trials and to conduct some aspects of our research and preclinical testing and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing. We currently rely and expect to continue to rely on third parties, such as CROs, contract manufacturers of clinical supplies, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials and to conduct some aspects of our research and preclinical testing. Many of these third parties may terminate their engagements with us at any time. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in

accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If we need to enter into alternative arrangements, it would delay our product development activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other international regulatory authorities require us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government- sponsored database, available at www. clinicaltrials. gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. ~~In addition, the ability of these third parties to conduct certain of their operations, including monitoring of clinical sites, may be limited by the COVID- 19 pandemic, and to the extent that such third parties are unable to fulfil their contractual obligations as a result of the COVID- 19 pandemic or government orders in response to the pandemic, we may have limited or no recourse under the terms of our contractual agreements with such third parties. Further, if any of the third parties with whom we engage were to experience shutdowns or other substantial disruptions due to the COVID- 19 pandemic, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operation and financial condition.~~ We have no experience manufacturing product candidates on a clinical or commercial scale and will be dependent on third parties for the manufacture of our product candidates. If we experience problems with any of these third parties, they could delay clinical development or marketing approval of our product candidates or our ability to sell any approved products. We do not have any manufacturing facilities. We currently rely, and expect to continue to rely, on third- party manufacturers for the manufacture of our product candidates for preclinical studies and clinical trials and for commercial supply of any of these product candidates should we obtain marketing approval. We have established agreements with third- party manufacturers for production of our products for clinical and commercial use, and our reliance on these- manufacturers entails additional risks, including: • reliance on the third party for regulatory compliance and quality assurance; • the possible breach of the manufacturing agreement by the third party, including the inability to supply sufficient quantities or to meet quality standards or timelines; and • the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. Third- party manufacturers may not be able to comply with current U. S. Good Manufacturing Practice requirements, or cGMPs, or similar regulatory requirements outside the U. S. Our failure, or the failure of our third- party manufacturers, to comply with cGMPs or other applicable regulations, even if such failures do not relate specifically to our product candidates or approved products, could result in sanctions being imposed on us or the manufacturers, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could adversely affect supplies of our product candidates and harm our business and results of operations. Any product that we develop may compete with other product candidates and products for access to these manufacturing facilities. There are a limited number of manufacturers that operate under cGMPs and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers, including a failure that may not relate specifically to our product candidate or approved product ~~or a failure due to the COVID- 19 pandemic~~ , could delay clinical development or marketing approval or adversely impact our ability to generate commercial sales. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer. Some of our ~~third- party~~ manufacturers **and suppliers are located in China. Trade tensions and conflict between the United States and China have been escalating in recent years and, as such, we are exposed to the possibility of product supply disruption and increased costs and expenses in the event of changes to the laws, rules, regulations, and policies of the governments of the United States or China, or due to geopolitical unrest and unstable economic conditions. Certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements, or proposed legislation by the U. S. Government,** which ~~we use~~ **could restrict** ~~for~~ **or even prohibit our ability to work with such entities, thereby potentially disrupting** ~~the~~ **their** supply of ~~materials~~ **material** ~~for~~ **to us. Such disruption could have adverse effects on the development of our** product candidates **and** ~~or~~ **our business operations. In addition,** ~~other~~ **the** ~~materials necessary to manufacture product to conduct preclinical tests and clinical trials~~ **recently proposed BIOSECURE Act introduced in House of Representatives, as well as a substantially similar bill in the Senate, targets certain Chinese biotechnology companies. If these bills become law, or similar laws** are **passed** ~~located in countries affected by COVID- 19~~ , ~~and should~~ they ~~experience disruptions, such as temporary closures or suspension of services, we~~ would **have** ~~likely experience delays in advancing these~~ **the** ~~tests and trials~~ **potential to severely restrict the ability of companies to contract with certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U. S. government** . Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis. We currently rely, and expect to continue to rely, on third parties to release, label, store and distribute drug supplies for our clinical trials. Any performance failure on the part of these third parties, including a failure that may not relate specifically to our product candidate or approved product, could delay or otherwise adversely impact clinical development or marketing approval of our product candidates or commercialization of our drugs, producing additional losses and depriving us of potential revenue. Moreover, our manufacturers and suppliers may experience difficulties related to their overall businesses and financial stability, which could result in delays or interruptions of supply of our product candidates

or approved products. We do not have alternate manufacturing plans in place at this time. If we need to change to other manufacturers, the FDA and comparable foreign regulators may have to approve these manufacturers' facilities and processes prior to our use, which would require new testing and compliance inspections. In addition, the new manufacturers would have to be educated in or independently develop the processes necessary for production. This would result in delays and costs, and in the case of approved products, the potential loss of revenue. Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters ~~If we are unable to take full advantage of regulatory programs designed to expedite drug development or provide other incentives, our development programs may be adversely impacted. There are a number of incentive programs administered by the FDA and other regulatory bodies to facilitate development of drugs in areas of unmet medical need. In the U. S., rezafungin has been designated a Qualified Infectious Disease Product, or QIDP, a fast track product, and, with respect to the indication for treatment of candidemia and invasive candidiasis, rezafungin has also been designated as an orphan drug. Our product candidates may not qualify for, or maintain, designations under these or other similar incentive programs. For example, rezafungin may not receive orphan drug designation in the U. S. for the prophylaxis indication. Our inability to fully take advantage of these incentive programs may require us to run larger trials, incur delays, lose opportunities that may not otherwise be available to us, lose marketing exclusivity for which we would otherwise be eligible and incur greater expense in the development of our product candidates.~~ If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, our product candidates and our ability to generate revenue will be impaired. Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, release, safety, efficacy, regulatory filings, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the U. S. and by comparable authorities in other countries. For example, in order to commence clinical trials of our product candidates in the U. S., we must file an IND and obtain FDA agreement to proceed. The FDA may place our development program on clinical hold and require further preclinical testing prior to allowing our clinical trials to proceed. We must obtain marketing approval in each jurisdiction in which we market our products. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have ~~not submitted a marketing application or received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have~~ only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third- party CROs to assist us in this process. As a company we may not be able to prepare our contract manufacturers and clinical sites for inspection associated with NDA review, or appearing before an FDA advisory committee. **We** ~~Our NDA~~ may receive a Complete Response Letter rather than approval. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each indication to establish the product candidate' s safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process, testing and release and inspection of manufacturing facilities and personnel by the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. The process of obtaining marketing approvals, both in the U. S. and elsewhere, is expensive, may take many years and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. We cannot assure you that we will ever obtain any marketing approvals in any jurisdiction. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical or other studies, changes in the manufacturing process or facilities or clinical trials. Moreover, approval by the FDA or an equivalent foreign authority does not ensure approval by regulatory authorities in any other countries or jurisdictions, but a failure to obtain marketing approval in one jurisdiction may adversely impact the likelihood of approval in other jurisdictions. In addition, varying interpretations of the data obtained from preclinical testing, manufacturing and product testing and clinical trials could delay, limit or prevent marketing approval of a product candidate. Additionally, any marketing approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable ~~. The COVID- 19 pandemic could also potentially affect the business of the FDA and comparable authorities in other countries, which could result in delays in meetings related to planned clinical trials and ultimately of reviews and approvals of our product candidates~~ . Any product candidate for which we obtain marketing approval could be subject to marketing restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products. Any product candidate for which we obtain marketing approval, along with the manufacturing processes and facilities, post- approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of promotional materials and safety and other post- marketing information and reports, registration and listing requirements, cGMP requirements for product facilities, quality assurance and corresponding maintenance of records and documents and requirements regarding the distribution of samples to physicians and related recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for costly post- marketing testing and surveillance to monitor the safety or efficacy of the medicine. The FDA closely regulates the post- approval marketing and promotion of drugs to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with the product' s FDA approved labeling. The FDA

imposes stringent restrictions on manufacturers' communications regarding off- label use and if we do not comply with these restrictions, we may be subject to enforcement actions. In addition, later discovery of previously unknown problems with our products, manufacturers or manufacturing processes and facilities or failure to comply with regulatory requirements, may result in, among other things: • restrictions on such products, manufacturers or manufacturing processes or facilities; • restrictions on the labeling, marketing, distribution or use of a product; • requirements to conduct post- approval clinical trials, other studies or other post- approval commitments; • warning or untitled letters; • withdrawal of the products from the market; • refusal to approve pending applications or supplements to approved applications that we submit; • recall of products; • fines, restitution or disgorgement of profits or revenue; • suspension or withdrawal of marketing approvals; • refusal to permit the import or export of our products; • product seizure; and • injunctions or the imposition of civil or criminal penalties. Our relationships with customers, health care professionals and third- party payors may be subject to applicable healthcare laws, which could expose us to penalties, including administrative, civil or criminal penalties, damages, fines, imprisonment, exclusion from participation in federal healthcare programs such as Medicare and Medicaid, reputational harm, the curtailment or restructuring of our operations and diminished future profits and earnings. Healthcare professionals and third- party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with customers, healthcare professionals and third- party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research, market, sell and distribute our medicines for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following, among others: • the federal healthcare anti- kickback statute, which prohibits persons and entities from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid; • the federal false claims laws, which impose criminal and civil penalties, including civil whistleblower or qui tam actions under the federal civil False Claims Act, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; • the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA **created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U. S. federal anti- kickback statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • HIPAA** , as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, ~~which~~ **also** imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective business associates and their covered subcontractors that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; • the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; • the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, which require, among other things, certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and information regarding physician ownership and investment interests; and • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to our business activities, including sales or marketing arrangements and claims involving healthcare items or services including, in some states, those reimbursed by non- governmental third- party payors, including private insurers, some state laws which require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments or other transfers of value provided to physicians and other health care providers and entities, marketing expenditures, or drug pricing, state and local laws that require the registration of pharmaceutical sales representatives, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Interpretations of standards of compliance under these laws and regulations are rapidly changing and subject to varying interpretations and it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other laws that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, imprisonment, additional reporting

obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws and the curtailment or restructuring of our operations, any of which could diminish our future profits or earnings. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. If our information technology systems ~~or sensitive data~~ , or those of third parties upon which we rely, **or our data** are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences. In the ordinary course of our business, we and the third parties upon which we rely, may collect, store, use, transmit, receive, generate, transfer, disclose, make accessible, protect, secure, dispose of, process, and share (collectively, ~~processing~~ --- **process**) **personal data and other** sensitive information, including ~~personal data,~~ proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third- party data (collectively, sensitive ~~information~~ **data**). As a result, we and the third parties upon which we rely face a variety of evolving threats **that** ~~, including but not limited to ransomware attacks, which~~ could cause security incidents. Cyberattacks, malicious internet- based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent ~~,~~ **and** continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer " hackers, " threat actors, " hacktivists, " organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation- state- supported actors. Some actors now engage and are expected to continue to engage in cyberattacks, including without limitation ~~,~~ nation- state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyberattacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products. We and the third parties upon which we rely are subject to a variety of **evolving** threats, including ~~,~~ but not limited to, social- engineering attacks (including through **deep fakes, which may be increasingly more difficult to identify as fake, and** phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), ~~ransomware, viruses, worms,~~ denial- of- service attacks **,** ~~(such as~~ credential stuffing ~~)~~ , credential harvesting, personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods **, attacks enhanced or facilitated by artificial intelligence, or AI** , and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, **ability to provide our products or services,** loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit ~~,~~ and in public locations. Additionally, future **or past** business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. In addition, our reliance on third- party service providers could introduce new cybersecurity risks and vulnerabilities, including supply- chain attacks, and other threats to our business operations. We rely on third- party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, CROs, contract manufacturers of clinical and commercial supplies, clinical data management organizations, medical institutions, clinical investigators, cloud- based infrastructure, data center facilities, encryption and authentication technology, employee email, and other functions. We also rely on third- party service providers to provide other products, services, parts, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third- party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third- party partners' supply chains have not been compromised. Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to manufacture or deliver our products. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry- standard or reasonable security measures to protect our information technology systems and sensitive data. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We ~~may~~ take steps **designed** to detect **, mitigate** and remediate vulnerabilities **in our information systems (such as our hardware and / or software** , ~~but~~ **including that of third parties upon which** we **rely). We** may not ~~be able to~~ **, however,** detect and remediate all ~~vulnerabilities because~~

~~the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore,~~ such vulnerabilities **including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities** could be exploited **and result in** ~~but may not be detected until after~~ a security incident ~~has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities~~. Applicable data privacy and security obligations may require us to notify relevant stakeholders **, including affected individuals, customers, regulators, and investors,** of security incidents. Such disclosures are costly, and the ~~disclosures~~ **disclosure** or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences **, such as** ~~. These consequences may include:~~ government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; **diversion of management attention;** interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may negatively impact our ability to grow and operate our business. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive ~~information~~ **data** about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. **Additionally, sensitive data of the Company could be leaked, disclosed, or revealed as a result of or in connection with our employee' s, personnel' s, or vendor' s use of generative artificial intelligence, or AI, technologies.** We are subject to stringent and evolving U. S. and foreign laws, regulations, **and** rules, contractual obligations **, industry standards** , policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation **(including class claims) and mass arbitration demands** ; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; ~~loss of customers or sales;~~ and other adverse business consequences. In the ordinary course of business, we process sensitive ~~information~~ **data** , and as a result, ~~we may be~~ **our data processing activities** subject **us** to numerous data privacy and security obligations, such as various **laws** , regulations, guidance, industry standards, external and internal privacy and security policies, contractual ~~obligations~~ **requirements** , and other obligations ~~related~~ **relating** to **data** privacy and security. In the ~~United States~~ **U. S.** , federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), and other similar laws (e. g., wiretapping laws). For example, HIPAA, as amended by HITECH, and their respective implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information. ~~Such~~ **In the past few years, at least ten U. S. states have enacted comprehensive privacy** laws **that impose certain obligations on covered businesses** ~~may apply to us, our customers or our service providers. Most healthcare providers in the U. S.~~ , including ~~institutions from which we may obtain customer~~ **providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal** data **. As applicable** , ~~are subject~~ **such rights may include the right** to **access, correct, or delete certain personal data, and to opt- out of certain data processing activities, such as targeted advertising, profiling, and automated decision- making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting** data privacy **impact assessments** ~~and security regulations promulgated under HIPAA, as amended by HITECH~~ . **These state laws allow** ~~A person may be prosecuted~~ for **statutory fines** ~~alleged HIPAA violations either directly or indirectly, such as under aiding- and- abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial civil and criminal penalties and liabilities if we knowingly receive individually identifiable health information from a HIPAA- covered healthcare provider that has not satisfied HIPAA' s requirements~~ for **noncompliance** ~~disclosure of individually identifiable health information~~ . ~~Additionally~~ **For example** , the California Consumer Privacy Act of 2018, **as amended by the California Privacy Rights Act of 2020,** or **CPRA, collectively** CCPA, applies to personal ~~information~~ **data** of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of ~~California residents~~ **such individuals** to exercise certain privacy rights. The CCPA ~~also~~ provides for **fines** ~~civil penalties~~ of up to $ 7, 500 per **intentional** violation and allows private litigants affected by certain data breaches to recover significant statutory damages. ~~In addition~~ **Although the CCPA exempts some data processed in the context of clinical trials** , **the CCPA increases compliance costs and potential liability with respect to** ~~the~~ **other personal data we maintain about** California **residents** ~~Privacy Rights Act of 2020, or CPRA, expands the CCPA' s requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the CPRA~~ . ~~Other states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and similar~~ **Similar** laws are being considered in several other states **,** as well as at the federal and local levels **, and we expect more states to pass similar laws in the future** . **While** ~~These~~ **these states, like the CCPA, may also exempt some data processed in the context of clinical trials, these** developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. Outside the ~~United States~~ **U. S.** , an increasing number of laws, regulations, and industry standards may govern **data** privacy and security. For example, the EU' s General Data

Protection Regulation, or EU GDPR, the United Kingdom' s GDPR, or UK GDPR, and Brazil' s General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or LGPD) (Law No. 13, 709 / 2018) impose strict requirements for processing personal data. **For example, under GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17. 5 million pounds sterling under the UK GDPR or, in each case, 4 % of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.** We also conduct clinical trials in China and may be subject to new and emerging data privacy regimes in China, including China' s Personal Information Protection Law, or PIPL, Cybersecurity Law, Data Security Law, Measures for Cybersecurity Review, Measures on the Security Assessment of Cross- border Data Transfer, and Measures for the Standard Contract on the Cross- border Transfer of Personal Information. **In Canada, the Personal Information Protection and Electronic Documents Act,** ~~For~~ **or** ~~example~~ **PIPEDA** , ~~under the EU GDPR, companies may face temporary or definitive bans on data processing~~ and **various** ~~other corrective actions; fines of up to 20 million Euros or 4 % of annual global revenue, whichever is greater; or private litigation~~ related **provincial** ~~to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law~~ **laws , as well as Canada' s Anti- Spam Legislation, or CASL, may apply** to **our operations** ~~represent their interests~~ . In addition, we may be unable to transfer personal data from Europe ~~(including the EEA and UK)~~ , China, and other jurisdictions to the ~~United States~~ **U. S.** or other countries due to data localization requirements or limitations on cross- border data flows. Europe, China and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area, or EEA, and the United Kingdom, or UK, have significantly restricted the transfer of personal data to the ~~United States~~ **U. S.** and other countries whose privacy laws it **generally** believes are inadequate. China also requires entities to rely on a transfer mechanism to lawfully transfer personal data overseas and ensure that the overseas data recipients can meet the same data protection standards as required under the PIPL. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross- border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the ~~United States~~ **U. S.** in compliance with law, such as the EEA and UK' s standard contractual clauses, **the UK' s International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U. S.- based organizations who self- certify compliance and participate in the Framework),** these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the ~~United States~~ **U. S** . If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the ~~United States~~ **U. S.** , or if the requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions **(such as Europe)** at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the ~~United States~~ **U. S.** , are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR' s cross- border data transfer limitations. In addition to data privacy and security laws, we may be contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. **Our employees and personnel may use generative AI technologies to perform their work, and the disclosure and use of personal information in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Any use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages. We use AI and machine learning, or ML, to assist us in making certain decisions, which is regulated by certain privacy laws. Due to inaccuracies or flaws in the inputs, outputs, or logic of the AI / ML, the model could be biased and could lead us to make decisions that could bias certain individuals (or classes of individuals), and adversely impact their rights, employment, and ability to obtain certain pricing, products, services, or benefits.** We publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self- regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences. Obligations related to data privacy and security **(and consumers' data privacy expectations)** are quickly changing, becoming increasingly stringent, and creating ~~regulatory~~ uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e. g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class- action claims) **and mass arbitration demands** ; additional reporting requirements and / or oversight; bans on processing personal data; and orders to destroy or not use personal

data **. In particular, plaintiffs have become increasingly more active in bringing privacy- related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations** . Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; **interruptions or stoppages in our business operations (including, as relevant, clinical trials);** inability to process personal data or to operate in certain jurisdictions (including in relation to clinical trials); limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations. We are subject to U. S. and certain foreign export and import controls, sanctions, embargoes, anti- corruption laws and anti- money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, various economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Controls, the U. S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act and other state and national anti- bribery and anti- money laundering laws in the countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the U. S., to sell our products abroad once we enter a commercialization phase and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. The pharmaceutical industry in China is highly regulated and such regulations are subject to change which may affect approval and commercialization of our drugs. Currently, we conduct the ReSTORE trial in China and have exclusively licensed the rights to commercialize rezafungin, our investigational drug studied in the ReSTORE trial, in China to our third- party collaborator, Mundipharma. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. For example, in order to conduct a clinical trial in China, sponsors must not only obtain the approval of the National Medical Product Administration of China, but also a separate approval from or filing with the Ministry of Science and Technology under the Administrative Regulations on Human Genetic Resources of the People' s Republic of China, or HGR Regulation, for clinical trials involving HGR Materials or Information. Any failure to comply with these requirements could cause our ReSTORE trial to be suspended by governing authorities, may result in fines and also may constitute a breach under our agreements with third parties assisting us in the conduct of the trial in China, such as our CRO. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Certain changes or amendments to policy or law may result in increased compliance costs on our business **,** or cause delays in the timely completion of the ReSTORE trial in China, or prevent the approval of rezafungin in China. Chinese authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our clinical activities in China. Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain. In the U. S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system, including cost- containment measures, that could reduce or limit coverage and reimbursement for newly approved drugs, prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. For example, in March 2010, President Obama signed into law the Affordable Care Act, a sweeping law intended to, among other things, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Affordable Care Act and subsequent regulations revised the definition of " average manufacturer price " for reporting purposes, which could increase the amount of Medicaid drug rebates to states. However, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, beginning January 1, 2024. Further, the Affordable Care Act imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance were also enacted under the Affordable Care Act, which may affect our business practices with healthcare practitioners. There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, **legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or** the Tax Act, included a provision which repealed, effective January 1, 2019, the tax- based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the " individual mandate. " On June 17, 2021, the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. Further, on

August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any additional healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business. In addition, legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. Further, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $ 1. 2 trillion for the years 2013 through 2021, triggering the legislation' s automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2 % per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments will remain in effect until ~~2031~~ **2032** unless additional Congressional action is taken ~~. Under current legislation, the actual reduction in Medicare payments will vary from 1 % in 2022 to up to 4 % in the final fiscal year of this sequester~~. Additionally, in January 2013, the President signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. In July 2021, the Biden administration released an executive order, " Promoting Competition in the American Economy, " with multiple provisions aimed at prescription drugs. In response to Biden' s executive order, on September 9, 2021, the Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single- source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions ~~will~~ take effect progressively starting in fiscal year 2023 ~~, although~~ **. Under** ~~they~~ **the** ~~may~~ **new Drug Price Negotiation Program, the number of drugs subject to price negotiation will be 10 Part D drugs for 2026, another 15 Part D drugs for 2027, another 15 Part D and Part B drugs for 2028, and another 20 Part D and Part B drugs for 2029 and later years. These drugs will be selected from among the 50 drugs with the highest total Medicare Part D spending and the 50 drugs with the highest total Medicare Part B spending. The number of drugs with negotiated prices available will accumulate over time. On August 29, 2023, HHS announced the list of the first ten drugs that will** be subject to **price negotiations, although the Medicare drug price negotiation program is currently subject to** legal challenges **. The IRA permits HHS to implement many of the statutory provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented** . It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. ~~Further,~~ **In response to** the Biden administration ~~released an additional~~ **' s October 2022** executive order **,** on ~~October~~ **February** 14, ~~2022~~ **2023** , ~~directing~~ HHS **released** ~~to submit~~ a report ~~on how~~ **outlining three new models for testing by** the Center for Medicare and Medicaid Innovation ~~can~~ **which will** be ~~further leveraged~~ **evaluated on their ability** to ~~test new models for lowering~~ --- **lower** ~~drug~~ **the** ~~costs~~ **cost** ~~for Medicare~~ **of drugs, promote accessibility,** and ~~Medicaid beneficiaries~~ **improve quality of care** . It is unclear whether **the models** ~~this executive order or similar policy initiatives~~ will be ~~implemented~~ **utilized in any health reform measures** in the future **. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that will continue under the new framework** . At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing **. For example, on January 5, 2024, the FDA approved Florida' s Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs** . We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U. S. Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. We expect that additional healthcare reform measures will be adopted within and outside the U. S. in the future, any of which could add difficulty to the regulatory approval processes for our product candidates or limit the amounts that governments will pay for healthcare products and services, which could result in reduced demand for our product

candidates or additional pricing pressures. The continuing efforts of third- party payors to contain or reduce costs of healthcare may adversely affect the demand for any drug products for which we may obtain regulatory approval, our ability to set a price that we believe is fair for our products, our ability to obtain coverage and reimbursement approval for a product, our ability to generate revenues and achieve or maintain profitability and the level of taxes that we are required to pay. Risks Related to Our Intellectual Property If our efforts to protect the proprietary nature of the intellectual property related to rezafungin, CD388, ~~CD421~~ **CBO421** , our other Cloudbreak compounds or our other product candidates or compounds are not adequate, we may not be able to compete effectively in our markets. We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to rezafungin and our other product candidates and compounds. Any involuntary disclosure to or misappropriation by third parties of our proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our markets. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain and our commercial success will depend on our ability to obtain patents and maintain adequate protection for rezafungin, our DFCs and other compounds and product candidates in the U. S. and other countries. We currently hold issued U. S. utility and foreign patents and multiple pending U. S. utility patent applications, pending U. S. provisional patent applications and pending international, foreign national and regional counterpart patent applications covering various aspects of rezafungin and our DFCs. The patent applications may fail to result in issued patents in the U. S. or in foreign countries or jurisdictions. Even if the applications do successfully issue, third parties may challenge the patents. Further, the existing and / or future patents, if any, may be too narrow to prevent third parties from developing or designing around these patents. If the sufficiency of the breadth or strength of protection provided by the patent and patent applications we own with respect to rezafungin or our DFCs or the patents we pursue related to any of our other product candidates or compounds is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize the product candidates or compounds. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced, although a patent term extension or supplementary protection certificate having varied scope may be available in certain jurisdictions to compensate for some of the lost patent term. In addition, we do not know whether: • we were the first to make the inventions covered by each of our pending patent applications or our issued patents; • we were the first to file patent applications for these inventions; • others will independently develop similar or alternative technologies or duplicate any of our technologies; • any of our pending patent applications will result in issued patents; • any of our patents, once issued, will be valid or enforceable or will issue with claims sufficient to protect our products, or will be challenged by third parties; • any patents issued to us will provide us with any competitive advantages; • we will develop additional proprietary technologies that are patentable; or • the patents of others will have an adverse effect on our business. In addition, patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In September 2011, the Leahy- Smith America Invents Act, or the Leahy- Smith Act, was signed into law. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U. S. Patent and Trademark Office, or USPTO, developed new regulations and procedures to govern administration of the Leahy- Smith Act and many of the substantive changes to patent law associated with the Leahy- Smith Act and, in particular, the first to file provisions, only became effective in March 2013. The Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and prospects. In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable in one or more jurisdictions, inventions for which patents are difficult to enforce and any other elements of our drug discovery program that involve proprietary know- how, information and technology that is not covered by patents. Although we require all of our employees, consultants, advisers and third parties who have access to our proprietary know- how, information and technology to enter into confidentiality agreements, we cannot be certain that this know- how, information and technology will not be disclosed or used in an unauthorized manner or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. There also may be challenges or other disputes concerning the inventorship, ownership or right to use our intellectual property. For example, our consultants and advisors may have obligations to assign certain inventions and / or know- how that they develop to third- party entities in certain instances, and these third parties may challenge our ownership or other rights to our intellectual property, which would adversely affect our business. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the U. S. We may encounter significant problems in protecting, enforcing and defending our intellectual property both in the U. S. and abroad. If we are unable to prevent unauthorized material disclosure of the intellectual property related to our technologies to third parties or are otherwise unable to protect, enforce or defend our intellectual property, we will not be able to establish or, if established, maintain a competitive advantage in our markets, which could materially adversely affect our business, operating results and financial condition. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and / or applications will be due to be paid to the USPTO and various foreign or jurisdictional governmental patent agencies in several stages over the lifetime of the patents and / or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm to pay these fees due to foreign patent agencies. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary,

fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. Such noncompliance events are outside of our direct control for (1) non- U. S. patents and patent applications owned by us and, (2) if applicable in the future, patents and patent applications licensed to us by another entity. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business. Third- party claims of intellectual property infringement may prevent or delay our drug discovery and development efforts. Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. There may be third- party patents with claims to materials, methods of manufacture or methods of treatment related to the use or manufacture of rezafungin, our DFCs and / or our other product candidates or compounds. If any third- party patents were held by a court of competent jurisdiction to cover the rezafungin or DFC manufacturing process, any molecules formed during these processes or the final products or any use thereof, the holders of any such patents may be able to block our ability to commercialize the product unless we obtained a license under the applicable patent or patents or until such patents expire. These same issues and risks arise in connection with any other product candidates we develop as well. We cannot predict whether we would be able to obtain a license on commercially reasonable terms, or at all. Any inability to obtain such a license under the applicable patents on commercially reasonable terms, or at all, would have a material adverse effect on our ability to commercialize the affected product until such patents expire. In addition, third parties may obtain patents in the future and claim that our product candidates and / or the use of our technologies infringes upon these patents. Furthermore, parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees in the case of willful infringement, obtain one or more licenses from third parties, pay royalties and / or redesign our infringing products, which may be impossible and / or require substantial time and monetary expenditure. In addition, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of one or more of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, or at all. In that event, we would not be able to further develop and commercialize such product candidates, which could harm our business significantly. We may be required to file lawsuits or take other actions to protect or enforce our patents, which could be expensive, time consuming and unsuccessful. Competitors may infringe our current or future patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that one or more of our asserted patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing. Pursuit of these claims would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business. Interference proceedings or derivative proceedings provoked by third parties or brought by the USPTO may be necessary to determine the entitlement to patent protection with respect to our patents or patent applications. An unfavorable outcome could result in a loss of our patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Litigation or patent office proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws or legal process may not protect those rights as fully as in the U. S. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Issued patents covering our product candidates and technologies could be found invalid or unenforceable if challenged in court or the USPTO. If we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or our technologies, the defendant could counterclaim that the patent covering our product candidate or our technology, as applicable, is invalid and / or unenforceable. In patent litigation in the U. S., defendant counterclaims alleging invalidity and / or unenforceability are commonplace and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the U. S. or abroad, even outside the context of litigation. Such mechanisms include re- examination, post grant review, and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates or our technologies. The outcome following legal assertions of invalidity and / or unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art or that prior art that was cited during prosecution, but not relied on by the patent examiner, will not be revisited. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least

part, and perhaps all, of the patent protection directed to our product candidates or technologies. Such a loss of patent rights could have a material adverse impact on our business. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve both technological and legal complexity, and are therefore costly, time- consuming and inherently uncertain. In addition, the U. S. has implemented wide- ranging patent reform legislation, including patent office administrative proceedings that offer broad opportunities to third parties to challenge issued patents. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. 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 decisions by the U. S. Congress, the federal courts, the USPTO and foreign governmental bodies and tribunals, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U. S. Supreme Court held in 2013 that certain claims to DNA molecules are not patentable and lower courts have since been applying this case in the context of other types of biological subject matter. We cannot predict how future decisions by the courts, the U. S. Congress, the USPTO or foreign governmental bodies or tribunals may impact the value of our patent rights. We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world. We have limited intellectual property rights outside the U. S. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive and our intellectual property rights in some countries outside the U. S. can be less extensive than those in the U. S. In addition, the laws and legal processes of some foreign countries do not protect intellectual property to the same extent as federal and state laws in the U. S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U. S. or from selling or importing products made using our inventions in and into the U. S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patents to develop their own products and further, may export otherwise infringing products to territories where we have patents but enforcement is not as strong as that in the U. S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property in foreign jurisdictions. The legal systems of certain countries, particularly China and certain other developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any of our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. The requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of any of our current or future patents, requiring us to engage in complex, lengthy and costly litigation or other proceedings. Certain countries in Europe and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if any of our patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors, and academic or research institutions. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. Risks Related to U. S. Government Contracts and Grants If we are unable to generate revenues from partnerships, government funding or other sources of funding, we may be forced to suspend or terminate one or more of our preclinical Cloudbreak programs. In order to continue our Cloudbreak programs for DFCs outside the scope of the Janssen Collaboration Agreement, we will need to seek funding from partnerships, the government or other sources of funding. There can be no assurances that we will be able to obtain funding from partnerships, or enter into new contracts with the U. S. government or obtain other sources of funding to support such programs. The process of completing a partnership or obtaining government contracts is lengthy and uncertain and we will have to compete with other companies and institutions in each instance. Further, with respect to government contracting, changes in government budgets and agendas may result in a decreased and de- prioritized emphasis on supporting the discovery and

development of anti- infective products. If we cannot obtain or maintain government or other funding for our Cloudbreak programs for DFCs outside the scope of the Janssen Collaboration Agreement, we may be forced to discontinue those programs. Our use of government funding adds uncertainty to our research and commercialization efforts and may impose requirements that increase our costs. Contracts funded by the U. S. government and its agencies include provisions that reflect the government' s substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to: • terminate agreements, in whole or in part, for any reason or no reason; • reduce or modify the government' s obligations under such agreements without the consent of the other party; • claim rights, including intellectual property rights, in products and data developed under such agreements; • audit contract- related costs and fees, including allocated indirect costs; • suspend the contractor from receiving new contracts pending resolution of alleged violations of procurement laws or regulations; • impose U. S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements; • suspend or debar the contractor from doing future business with the government; • control and potentially prohibit the export of products; and • pursue criminal or civil remedies under the Federal Civil Monetary Penalties Act and the federal civil False Claims Act and similar remedy provisions specific to government agreements. In addition, government contracts contain additional requirements that may increase our costs of doing business, reduce our profits and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example: • specialized accounting systems unique to government contracts; • mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent; • public disclosures of certain contract information, which may enable competitors to gain insights into our research program; and • mandatory socioeconomic compliance requirements, including labor standards, anti- human- trafficking, non- discrimination, and affirmative action programs and environmental compliance requirements. If we fail to maintain compliance with these requirements, we may be subject to potential liability and to termination of our contracts. Changes in funding for the FDA, the Securities and Exchange Commission, or SEC, and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business. 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. Disruptions at the FDA and other agencies may also 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 last several years, including beginning on December 22, 2018 and ending on January 25, 2019, the U. S. government has shut down several times and certain regulatory authorities, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If repeated or prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Our business is subject to audit by the U. S. government and a negative audit could adversely affect our business. U. S. government agencies routinely audit and investigate government contractors and recipients of Federal grants. These agencies review a contractor' s performance under its contracts, cost structure and compliance with applicable laws, regulations and standards. Government agencies also review the adequacy of, and a contractor' s compliance with, its internal control systems and policies, including the contractor' s purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while such costs already reimbursed must be refunded. If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including: • termination of contracts; • forfeiture of profits; • suspension of payments; • fines; and • suspension or prohibition from conducting business with the U. S. government. In addition, we could suffer serious reputational harm if allegations of impropriety were made against us, which could cause our stock price to decrease. Laws and regulations affecting government contracts make it more expensive and difficult for us to successfully conduct our business. We must comply with numerous laws and regulations relating to the formation, administration and performance of government contracts, which can make it more difficult for us to retain our rights under our government grant contracts. These laws and regulations affect how we conduct business with government agencies. Among the most significant government contracting regulations that affect our business are: • the Federal Acquisition Regulations, or FAR, and agency- specific regulations supplemental to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts; • business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and include other requirements such as the **federal** Anti- Kickback Statute and Foreign Corrupt Practices Act; • export and import control laws and regulations; and • laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data. Any changes in applicable laws and regulations could restrict our ability to obtain new contracts, which could limit our ability to conduct our business and materially adversely affect our results of operations. Risks Related to Employee Matters and Managing Growth ~~Our ability to manage our business operations, to execute our strategic plan and to recruit talented employees may be adversely impacted by COVID- 19. Since early March 2020, we have taken precautionary measures intended to help minimize the risk of COVID- 19 to our employees and their families. In accordance with state and federal guidelines, we reduced those precautionary measures in 2022 and have permitted employees to return to the office, work~~

remotely, or adopt hybrid schedules based on job responsibilities. Further measures may be taken as the COVID- 19 outbreak continues. These measures could negatively affect our business. For instance, remote work may disrupt our operations, limit our ability to interact with and effectively manage our third- party manufacturers CROs or current and planned clinical trial sites. The measures taken now or in the future to contain the COVID- 19 pandemic could negatively affect our ability to recruit and engage new employees and contractors necessary to the successful operation of our business. Our future success depends on our ability to retain our senior management team and to attract, retain and motivate qualified personnel. We are highly dependent upon our senior management team, as well as the other principal members of our research and development teams. All of our executive officers are employed " at will, " meaning we or they may terminate the employment relationship at any time. We do not maintain " key person " insurance for any of our executives or employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. Recruiting and retaining qualified scientific, clinical, manufacturing, regulatory, quality assurance and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisers, including scientific, regulatory, quality assurance and clinical advisers, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisers may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. We expect to expand our operations, and may encounter difficulties in managing our growth, which could disrupt our business. We expect to expand the scope of our operations, particularly in the areas of drug development, manufacturing, clinical, regulatory affairs, quality assurance and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. We may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, the expected expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources. In the future, we may enter into transactions to acquire other businesses, products or technologies and our ability to do so successfully is unproven. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may fail to strengthen our competitive position and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and non- disruptive manner. Acquisitions may also divert management attention from day- to- day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results. Risks Related to Ownership of our Common Stock The price of our stock may be volatile, and you could lose all or part of your investment. The trading price of our common stock is highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this " Risk Factors " section and elsewhere in this report, these factors include: • changes in the market valuations of similar companies; • the commencement, timing, enrollment or results of the current and planned clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates; • any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such filings, including without limitation the FDA' s issuance of a " refusal to file " letter, " complete response " letter, or a request for additional information; • adverse results, suspensions, terminations or delays in pre- clinical or clinical trials; • our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial or development program; • adverse regulatory decisions, including failure to receive regulatory approval of our product candidates; • the impact of the COVID- 19 pandemic on our business and industry as well as the global economy; • changes in laws or regulations applicable to our products, including but not limited to requirements for approvals; • changes in the structure of healthcare payment systems or limitations on the ability of hospitals and outpatient treatment centers to receive adequate reimbursement for the purchase and use of our products; • adverse developments concerning our contract manufacturers; • our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices or acceptable quality; • our inability to establish collaborations, if needed; • our failure to commercialize our product candidates successfully, or at all; • additions or departures of key scientific or management personnel; • unanticipated serious safety concerns related to the use of our product candidates; • the introduction of new products or services offered by us or our competitors; • announcements of significant acquisitions, strategic partnerships, joint ventures, government grants or contracts or capital commitments by us or our competitors; • our ability to effectively manage our growth; • the size and growth of our fungal infection, bacterial infection or other target markets; • our ability to successfully enter new markets or develop additional product candidates; • actual or anticipated variations in quarterly operating results; • our cash position and our ability to raise additional capital and the manner and terms on which we raise it, and the expectation of future fundraising activities by us; • our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public; • publication of research reports or other media coverage about us or our industry or our therapeutic approaches in particular or positive or negative recommendations or withdrawal of research coverage by securities analysts; • overall performance of the

equity markets; • sales of our common stock by us or our stockholders in the future or the expectation of such sales; • the trading volume of our common stock; • changes in accounting practices; • ineffectiveness of our internal controls; • disputes or other developments relating to proprietary rights, including patent rights, litigation matters and our ability to obtain patent protection for our technologies; • significant lawsuits, including patent or stockholder litigation; • general political and economic conditions including the military conflict in Ukraine and Russia **, the Israel- Hamas war** and bank failures; and • other events or factors, many of which are beyond our control. In addition, the stock market in general, and The Nasdaq Capital Market, pharmaceutical companies and companies in the anti- infective sector in particular, have experienced extreme price and volume fluctuations that may or may not have been related or proportionate to the operating performance of these companies or their product potential. Broad market and industry factors ~~, such as the COVID- 19 pandemic and actions taken to slow its spread,~~ may negatively affect the market price of our common stock, regardless of our actual operating performance. You may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company' s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management' s attention and resources, which would harm our business, operating results or financial condition. **The restatement of our consolidated financial statements has subjected us to a number of additional risks and uncertainties, including increased possibility of legal proceedings. As discussed elsewhere in this Annual Report on Form 10- K, on April 11 and April 15, 2024, the Audit Committee determined, based on management' s recommendation, that our Prior Financial Statements filed with the SEC should no longer be relied upon and should be restated.** We **have restated the Prior Financial Statements in this Annual Report on Form 10- K. The restatement of the Prior Financial Statements has caused us to incur additional expenses for legal, accounting, and other professional services and has diverted our management' s attention from our business and could continue to** do ~~not intend to pay dividends on our common stock,~~ so ~~any returns will be limited to the value of our stock~~ . **In addition** ~~We currently anticipate that we will retain future earnings for the development~~ , operation and expansion of our business and..... our stockholders. We incur significant costs as a result of ~~operating as a public company, and our management devotes substantial time to compliance initiatives. As a public company, we incur significant legal, accounting and other~~ -- **the** ~~expenses. We are~~ **restatement, investors may lose confidence in our financial reporting, the price of our common stock could decline, and we may be** subject to **litigation** ~~the reporting requirements of the Securities Exchange Act of 1934, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our~~ - **or** business and financial condition. In addition..... and the level of government intervention and regulatory **enforcement actions** reform may lead to substantial new regulations..... our board committees or as executive officers . If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired and our public reporting may be unreliable. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Based on our evaluation of the effectiveness of our internal control over financial reporting as of ~~September 30~~ **December 31** , ~~2022~~ **2023** , we determined that we had a material weakness as of ~~September 30~~ **December 31** , ~~2022~~ **2023 and in prior periods** because our ~~review~~ control over the evaluation of applicable ~~accounting standards~~ **indirect taxes in local jurisdictions** and assessment of **indirect tax accrued liabilities** ~~completeness and accuracy of valuation assumptions, related to non- routine transactions that include collaboration revenue,~~ was not appropriately designed **, ~~or operating effectively. While this improper design~~** and **as a ~~operation did not~~** result ~~in a material error in the annual or interim financial statements, there is a reasonable possibility that~~ a material misstatement in the **Prior** ~~annual or interim financial~~ **Financial** ~~statements~~ **Statements** ~~would~~ **was** not ~~have been~~ detected. A material weakness, as defined in Rule 12b- 2 under the Exchange Act, is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company' s annual or interim financial statements will not be prevented or detected on a timely basis. ~~This material weakness has been remediated as of December 31, 2022.~~ We ~~have amended our~~ **are in the** process ~~to add~~ **of implementing a remediation plan, which includes** additional ~~layers~~ **training** of ~~review by members~~ **existing staff, enhanced use** of **indirect tax consultants** ~~our management team regarding the evaluation of applicable accounting standards~~ and **experts, and designing controls over the** completeness and accuracy of ~~valuation assumptions~~ **the supporting evidence** related to **indirect tax liabilities** ~~non- routine transactions that include collaboration revenue. The effectiveness of our process changes and overall remediation efforts is being assessed by management on an ongoing basis~~ . The remediation actions are ~~also~~ being monitored by the Audit Committee ~~of our Board of Directors~~ . However, we cannot assure you that these efforts will remediate this material weakness in a timely manner, or at all, or that we will be able to maintain effective controls and procedures even if we remediate this material weakness. If we are unable to successfully remediate this material weakness, design or operate effective controls and procedures, or identify any future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and we may experience a loss of public confidence, which could have an adverse effect on our business, financial condition and the market price of our common stock. We are required to disclose changes made in our internal control procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are a " non- accelerated filer, " our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls could detect problems that our management' s assessment might not. **Any additional** ~~Undetected~~ **undetected** material weaknesses in our internal controls could lead to **further** financial statement restatements and require us to incur additional expenses of remediation. In addition, if we are unable to remediate this material weakness, or if we are otherwise unable to conclude that our internal control over financial reporting is effective, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our securities could decline, and we could be

subject to sanctions or investigations by The Nasdaq Capital Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. **reform** may lead to substantial new regulations and disclosure obligations,which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.We expect the rules and regulations applicable to public companies to continue to result in substantial legal and financial compliance costs and to make some activities more time- consuming and costly.If these requirements divert the attention of our management and personnel from other business concerns,they could have a material adverse effect on our business,financial condition and results of operations.These costs could decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services.For example,these rules and regulations could make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage.We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements.The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors,our board committees or as executive officers .–Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall. If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. We had ~~72~~ **90** , ~~470~~ **601** , ~~440~~ **999** shares of common stock outstanding as of December 31, ~~2022~~ **2023** . We are unable to predict the effect that sales may have on the prevailing market price of our common stock. Sales of our common stock by current stockholders may make it more difficult for us to sell equity or equity- related securities in the future at a time and price that we deem reasonable or appropriate and may make it more difficult for you to sell shares of our common stock. In addition, shares of common stock that are either issuable upon the exercise of outstanding options or warrants or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. We believe, based on our current business plan, that our existing cash and cash equivalents will not be sufficient to fund our obligations for the twelve months following the filing of this report. Significant additional capital will be needed to continue our operations as currently planned, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating as a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, new investors could gain rights, preferences and privileges senior to our existing stockholders and our existing stockholders may be materially diluted by such subsequent sales. Pursuant to our 2015 Equity Incentive Plan, or the 2015 EIP, our management is authorized to grant stock options to our employees, directors and consultants. The number of shares of our common stock reserved for issuance under the 2015 EIP will automatically increase on January 1 of each year through and including January 1, 2025, by 4 % of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year or a lesser number of shares determined by our board of directors. Additionally, the number of shares of our common stock reserved for issuance under our 2015 Employee Stock Purchase Plan, or the ESPP, will automatically increase on January 1 of each year through and including January 1, 2025, by the lesser of 1 % of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year or 490, 336 shares. Unless our board of directors elects not to increase the number of shares available for future grant each year under the 2015 EIP and the ESPP, our stockholders may experience additional dilution, which could cause our stock price to fall. We have broad discretion in the use of working capital and may not use it effectively. Our management has broad discretion in the application of our working capital. Because of the number and variability of factors that determine our use of our working capital, its ultimate use may vary substantially from its currently intended use. Our management might not apply our working capital in ways that ultimately increase the value of your investment. We expect to use our working capital to fund research and development activities and general operating expenses. The failure by our management to apply this working capital effectively could harm our business. Pending its use, we may invest our working capital in short- term, investment- grade, interest- bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply our working capital in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline. Anti- takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management. Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include: • a board of directors divided into three classes serving staggered three- year terms, such that not all members of the board will be elected at one time; • a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders; • a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer or by a majority of the total number of authorized directors; • advance notice requirements for

stockholder proposals and nominations for election to our board of directors; • a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two- thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors; • a requirement of approval of not less than two- thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and • the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15 % or more of our outstanding voting stock. These anti- takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then- current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline. Our amended and restated bylaws provide 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 obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: 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 bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This choice of forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. The choice of forum provision 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. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could adversely affect our business and financial condition. While the Delaware courts have determined that exclusive choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline. Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited. Under current law, unused U. S. federal net operating losses generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited to 80 % of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an " ownership change " (generally defined as a greater than 50 % change (by value) in its equity ownership over a three- year period), the corporation' s ability to use its pre- change net operating loss carryforwards and other pre- change tax attributes to offset its post- change income or taxes may be limited. As a result of capital raising and other transactions that have occurred since our inception in 2012, we have identified several ownership changes that will impact our ability to utilize our net operating losses and credit carryforwards. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, ~~2022~~ **2023**, we had U. S. federal net operating loss carryforwards of approximately $ ~~185~~ **153**. ~~3~~ **8** million ~~, after adjustments for Section 382 limitations to date~~, portions of which will begin to expire in 2035, and which could be limited if we experience an " ownership change. " In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows. Uncertainties in the interpretation and application of existing, new and proposed tax laws and regulations could materially affect our tax obligations and effective tax rate. The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws or regulations proposed or implemented by the current or a future U. S. presidential administration, Congress, or taxing authorities in other jurisdictions, including jurisdictions outside of the ~~United States~~ **U. S.**, could materially affect our tax obligations and effective tax rate. To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes may

adversely impact our business, financial condition, results of operations, and cash flows. The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the ~~United States~~ **U. S.** , to our international business activities, tax rates, new or revised tax laws, or interpretations of tax laws and policies, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a challenge or disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest, and penalties, which could result in one- time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a " permanent establishment " under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. Effective January 1, 2022, the Tax Act eliminated the option to deduct research and development expenses for tax purposes in the year incurred and requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the ~~United States~~ **U. S.** and over 15 years for research activities conducted outside the ~~United States~~ **U. S** . Although there have been legislative proposals to repeal or defer the capitalization requirement to later years, there can be no assurance that the provision will be repealed or otherwise modified. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. Our business and operations would suffer in the event of system failures. Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and we may incur substantial costs to attempt to recover or reproduce the data. If any disruption or security breach resulted in a loss of or damage to our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and / or the further development of our product candidates could be delayed. Our operations are vulnerable to interruption by natural disasters, power loss, terrorist activity, public health crisis, pandemic diseases and other events beyond our control, the occurrence of which could materially harm our business. Businesses located in California have, in the past, been subject to electrical blackouts as a result of a shortage of available electrical power and any future blackouts could disrupt our operations. We are also vulnerable to a major earthquake, wildfire, inclement weather and other natural and man- made disasters and public health crisis and pandemic diseases, such as coronavirus, and we have not undertaken a systematic analysis of the potential consequences to our business as a result of any such natural disaster, public health crisis or pandemic diseases and do not have an applicable recovery plan in place. In addition, if any of our third- party contract manufacturers are affected by natural disasters, such as earthquakes, power shortages or outages, floods, wildfire, public health crises, such as pandemics and epidemics, terrorism or other events outside of our control, our business and operating results could suffer. For example, as a result of the COVID- 19 pandemic, we ~~have~~ experienced significant disruptions in the conduct of our clinical trials and our general business operations as the result of various federal, state and local stay- at- home, shelter- in- place and quarantine measures. We carry only limited business interruption insurance that would compensate us for actual losses from interruption of our business that may occur and any losses or damages incurred by us in excess of insured amounts could cause our business to materially suffer.