Risk Factors Comparison 2024-03-21 to 2023-03-23 Form: 10-K

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SUMMARY OF RISK FACTORS • We have a limited operating history, have not completed ~~Set forth below are the risks that we believe are material to our investors and they should be carefully considered. If~~ any ~~of the following risks~~ **late- stage clinical trials** and ~~uncertainties actually occurs~~ **have no products approved for commercial sale** , **which may make it difficult for you to evaluate** our **current** business ~~, prospects, financial condition~~ and ~~results~~ **likelihood** of **success** ~~operations could be materially~~ and **viability; •** ~~adversely affected. The risks described below are not intended to be exhaustive and other factors not presently known to us or that we currently believe are immaterial may affect our business, prospects, financial condition and results of operations if they occur. This section contains forward- looking statements. You should refer to the explanation of the qualifications and limitations on forward- looking statements beginning on page three of this Annual Report on Form 10- K. Risks Related to the Strategic Alternative Process and Potential Strategic Transaction~~ We ~~may not be successful in identifying and implementing any strategic transaction, and any strategic transactions that we may consummate in the future could have negative consequences. We are continuing to evaluate all potential strategic options for the company, including a merger, reverse merger, sale, wind- down, liquidation and dissolution or other strategic transaction. We are also exploring strategic transactions regarding our product candidates and related assets, including, without limitation, licensing transactions and asset sales. There can be no assurance, however, that we will be able to successfully consummate any particular strategic transaction or that any transaction, if pursued, will be completed on attractive terms, within the anticipated timing, or at all. The process of continuing to evaluate these strategic options may be very costly, time- consuming and complex and we have incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business. In addition, any strategic business combination or other transactions that we may consummate in the future could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affects our business and decreases the remaining cash available for use in our business or the execution of our strategic plan. There can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve the anticipated results. Any potential transaction would be dependent on a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, the interest of third parties in a potential transaction with us, obtaining stockholder approval and the availability of financing to third parties in a potential transaction with us on reasonable terms. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly diminish or delay any future distributions to our stockholders. If we are not successful in setting forth a new strategic path for Magenta, or if our plans are not executed in a timely fashion, this may cause reputational harm with our stockholders and the value of our securities may be adversely impacted. In addition, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to the future of Magenta could cause our stock price to fluctuate significantly. We may not realize any additional value in a strategic transaction. Potential counterparties in a strategic transaction involving our company may place minimal or no value on our assets and our public listing. Further, should we resume development of our product candidates, the development and any potential commercialization of our product candidates~~ will require substantial additional ~~cash~~ **capital** to ~~fund~~ **finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate clinical trials, product development programs or future commercialization efforts; • We have incurred significant losses since inception, and we expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have no products for sale, have not generated any product revenue and may never generate product revenue or become profitable; • We face competition from entities that have developed or may develop programs for the diseases we plan to address with DNTH103 or other product candidates; • DNTH103 and our other programs are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we or our current or future collaborators are unable to complete development of, or commercialize, our product candidates, or experience significant delays in doing so, our business will be materially harmed; • We are substantially dependent on the success of our most advanced product candidate, DNTH103, and our anticipated clinical trials of such candidate may not be successful; • If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of DNTH103 or any other product candidates may be delayed and our expenses may increase and our stock price may decline; • Our approach to the discovery and development of product candidates is unproven, and we may not be successful in our efforts to build a pipeline of product candidates with commercial value; • Preclinical and clinical development involves a lengthy and expensive process that is subject to delays and with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate; • If we encounter difficulties enrolling patients in our future clinical trials, our clinical development activities could be delayed or otherwise adversely affected;**

• We have collaborations with third parties, including our existing license and development collaboration with Zenas BioPharma. If we are unable to maintain these collaborations, or if these collaborations are not successful, our business could be adversely affected; • We have identified material weaknesses in our internal control over financial reporting which, if not corrected, could affect the reliability of our financial statements and have other adverse consequences; • In order to successfully implement our plans and strategies, we will need to grow the size of our organization and we may experience difficulties in managing this growth; • Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage; • The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time- consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, such product candidates, and our ability to generate revenue will be materially impaired; • We may not be able to meet requirements for the chemistry, manufacturing and control of our product candidates; • Our product candidates for which we intend to seek approval as biologics may face competition sooner than anticipated; • The market price of our common stock is expected to be volatile, the market price of our common stock may drop, and an active trading market for our common stock may not be sustained and our stockholders may not be able to sell their shares of common stock for a profit, if at all; • Provisions in our certificate of incorporation and bylaws and under Delaware law could make an acquisition of us more difficult and may discourage any takeover attempts which stockholders may consider favorable, and may lead to entrenchment of management; and • We will incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies. Risks Related to Our Limited Operating History, Financial Position and Capital Requirements We have a limited operating history, have not completed any late- stage clinical trials and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability. We are a clinical- stage biotechnology company with limited operating history that have incurred significant operating losses and has utilized substantially all of our resources to conduct research and development activities (including with respect to our DNTH103 program) and undertake preclinical studies of product candidates, conducting a clinical trial of our most advanced product candidate and the manufacturing of the product candidates, business planning, developing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these activities. We have limited experience as a company in initiating, conducting or completing clinical trials. In part because of this lack of experience, we cannot be certain that our current and planned clinical trials will begin or be completed on time, if at all. In addition, while we initiated a Phase 2 clinical trial of DNTH103 in patients with gMG in the first quarter of 2024, we have not completed a late- stage clinical trial for any product candidate, have no products approved for commercial sale and have not yet demonstrated our ability to successfully complete late- stage clinical trials (including Phase 3 or other pivotal clinical trials), obtain regulatory or marketing approvals, manufacture a commercial- scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, any predictions made about our future success or viability may not be as accurate as ~~the~~ they could be if we had a longer operating history. In addition, as our business grows, we may encounter unforeseen expenses, restrictions, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with an early research and development focus to a company capable of supporting larger scale clinical trials and eventually commercial activities. We may not be successful in such a transition. We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate clinical trials, product development programs or future commercialization efforts. Developing biotechnology products is a very long, time- consuming, expensive and uncertain process that takes years to complete. Since our inception in 2019, we have funded our operations primarily through private financings and have incurred significant recurring losses, including net losses of $ 43. 6 million and $ 28. 5 million for the years ended December 31, 2023 and 2022, respectively. We expect our expenses to increase in connection with our ongoing activities, particularly as we prepare to conduct multiple Phase 2 clinical trials, prepare for additional IND and other regulatory filings, potentially initiate additional clinical trials, and continue to research, develop and conduct preclinical studies of our other potential product candidates. In addition, if we obtain regulatory approval for any product candidate for commercial sale, including DNTH103, we anticipate incurring significant commercialization expenses related to product manufacturing, marketing, sales and distribution activities to launch any such product. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to perform preclinical studies or clinical trials in addition to those that we currently anticipate. Because the design and outcome of our current, planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. Our future capital requirements depend on many factors, including factors that are not within our control. We will also incur additional costs associated with **operating as** ~~conducting the necessary preclinical and clinical testing and obtaining regulatory approval. Consequently, any potential counterparty in~~ a **public** ~~strategic transaction involving our~~ company ~~may choose~~ **that Former Dianthus did** not **incur as** ~~to spend additional resources and continue development of our product candidates and may attribute little or no value, in such~~ a **private company** ~~transaction, to those product candidates~~ . **Accordingly** ~~If we are successful in completing a strategic transaction~~ , we ~~may be exposed to other operational and financial risks. Although there can be no assurance that a strategic transaction will result from the process we have undertaken to identify and evaluate strategic~~

~~alternatives, the negotiation and consummation of any such transaction~~ will require ~~significant time~~ **substantial additional funding to continue our operations. Based** on ~~the part of our management, and the diversion of management' s attention may disrupt our business. The negotiation and consummation of any such transaction may also require more time or~~ **our** ~~greater~~ **current operating plan, we believe that our existing** cash **, cash equivalents and short- term investments, together with the proceeds from our private placement consummated in January 2024, should be sufficient to fund our operations into the second half of 2027. This estimate is based on assumptions that may prove to be materially wrong, and we could use our available capital** resources **sooner** than we ~~anticipate and expose us to other operational and financial risks~~ **currently expect. Our future capital requirements will depend on many factors** , including: • **the timing** ~~increased near- term~~ and ~~long- term expenditures~~ **progress of preclinical and clinical development activities** ; • ~~exposure to unknown liabilities~~ **the number and scope of preclinical and clinical programs we pursue** ; • ~~higher than expected acquisition or~~ **our ability to establish an acceptable safety profile with IND- enabling toxicology studies to enable clinical trials; • successful patient enrollment in, and the** ~~integration~~ **initiation and completion of, larger and later- stage clinical trials; • per subject trial** costs; • ~~incurrence~~ **the number and extent** of ~~substantial debt~~ **trials required** ~~or~~ **for regulatory approval** ~~dilutive issuances of equity securities to fund future operations~~ ; • ~~write- downs of assets or goodwill or incurrence of non- recurring, impairment or other~~ -- **the** ~~charges~~ **countries in which the trials are conducted** ; • ~~increased amortization expenses~~ **the length of time required to enroll eligible subjects in clinical trials** ; • ~~difficulty and cost in combining~~ the **number** ~~operations and personnel~~ of **subjects that participate in the trials; • the drop- out and discontinuation rate of subjects; • potential additional safety monitoring requested by regulatory agencies; • the duration of subject participation in the trials and follow- up; • the extent to which we encounter** any ~~acquired business~~ **serious adverse events in our clinical trials; • the timing of receipt of regulatory approvals from applicable regulatory authorities; • the timing, receipt and terms of any marketing approvals and post- marketing approval commitments from applicable regulatory authorities; • the extent to which we establish collaborations, strategic partnerships, or other strategic arrangements** with ~~our operations~~ **third parties, if any,** and **the performance of any such third party; • hiring and retaining research and development** personnel; • **our arrangements** ~~impairment of relationships~~ with ~~key suppliers or~~ **our contract development** ~~customers of any acquired business due to changes in management~~ and ~~ownership~~ **manufacturing organizations (" CDMOs "), and contract research organizations (" CROs ")** ; • **development and timely delivery** ~~inability to retain key employees~~ of ~~our company~~ **commercial- grade drug formulations that can be used in** ~~or~~ **our planned clinical trials and for commercial launch; • the impact of** any ~~acquired~~ business **interruptions to our operations or to those of the third parties with whom we work** ; and • ~~possibility~~ **obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights. We do not have any committed external sources** of **funds and adequate additional financing may not be available to us on acceptable terms, or at all. We may be required to seek additional funds sooner than planned through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Such financing may dilute our stockholders or the failure to obtain such financing may restrict our operating activities. Any additional fundraising efforts may divert our management from their day- to- day activities, which may adversely affect our business. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences and anti- dilution protections that adversely affect your rights as a stockholder. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. For example, on January 24, 2024, we completed the 2024 Private Placement in which we issued 14, 500, 500 shares of Common Stock and the 2024 Pre- Funded Warrants to purchase up to 4, 666, 332 shares of Common Stock to certain institutional and accredited investors, which resulted in dilution to our stockholders that did not participate in the 2024 Private Placement, and, to the extent that the 2024 Pre- Funded Warrants are exercised, our stockholders' ownership interests will be further diluted. If we raise additional funds through upfront payments or milestone payments pursuant to** future **collaborations with third parties, we may** ~~litigation. Any of the foregoing risks could~~ have ~~a material adverse effect~~ **to relinquish valuable rights to product development programs, or grant licenses** on **terms that are not favorable to us. Our ability to raise additional capital may be adversely impacted by global macroeconomic conditions and volatility in the credit and financial markets in the United States and worldwide, over which we may have no** ~~our~~ - **or** ~~business,~~ **little control. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our** financial condition and ~~prospects. If a strategic transaction is not consummated,~~ our **ability** ~~board of directors may decide~~ to pursue ~~a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities. There can be no assurance that a strategic transaction will be completed. If a strategic transaction is not completed, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up. Our ability to consummate a strategic transaction depends on our ability to~~

~~retain our employees required to consummate such transaction. Our ability to consummate a strategic transaction depends upon our ability to retain our employees required to consummate such a transaction, the loss of whose services may adversely impact the ability to consummate such transaction. In April of 2022, and then again in February 2023, we undertook an organizational restructuring that significantly reduced our workforce in order to conserve our capital resources. Our cash conservation activities may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete a strategic transaction depends in large part on our ability to retain certain of our remaining personnel. If we are unable to successfully retain our remaining personnel, we are at risk of a disruption to our exploration and consummation of a strategic alternative as well as business operations. Our corporate restructuring and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business. In April 2022, and then again in February 2023, we undertook an organizational restructuring that significantly reduced our workforce, including the departure of our chief executive officer. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. Furthermore, our restructuring plan may be disruptive to our operations. For example, our headcount reductions could yield unanticipated consequences, such as increased difficulties in implementing~~ our business strategy, ~~including retention of our remaining employees. Employee litigation related to the headcount reduction could be costly~~ and ~~prevent management from fully concentrating on the business. Any future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Due to our limited resources,~~ we may **have** ~~not be able~~ to **delay** ~~effectively manage our operations or recruit and retain qualified personnel~~, ~~which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, and loss of employees and reduced~~ **reduce the scope** ~~productivity among remaining employees. The impact and results~~ of **, suspend** ~~our~~ **or eliminate** ~~ongoing strategic process are uncertain and may not be successful. Our board of directors remains dedicated to diligently deliberating upon, and making informed decisions that the directors believe are in the best interests of the company and its stockholders. There can be no assurance, however, that the company's current strategic direction, or the board's evaluation of strategic alternatives, will result in any initiatives, agreements, transactions or plans that will further enhance stockholder value. In addition, given the substantial restructuring of our operations over the past several years, it may be difficult to evaluate our current business and future prospects on~~ **one** ~~the basis of historical operating performance. We may become involved in litigation that could divert management's attention and harm the company's business, and insurance coverage may not be sufficient to cover all costs and damages. In the past, litigation has often followed certain significant business transactions, such as the sale of a company~~ or **more** ~~announcement of any other strategic transaction, or the announcement of negative events, such as negative results from~~ clinical trials ~~. We may be exposed to such litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management's attention and resources~~, **product development programs** ~~which could adversely affect our~~ **or future commercialization efforts** ~~business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction~~. ~~Risks Related to Our Financial Position and Need for Additional Capital~~ We have incurred ~~net~~ **significant** losses ~~in every year~~ since ~~our~~ inception **,** and ~~anticipate that~~ we **expect** ~~will continue~~ to incur ~~net~~ **significant** losses ~~in~~ **for** the **foreseeable** future **and may not be able to achieve or sustain profitability in the future**. We ~~are a~~ **have no products for sale, have not generated any product revenue and may never generate product revenue or become profitable. Investment in** biotechnology ~~company focused on improving stem cell transplantation, and we have a limited operating history. Investment in biopharmaceutical~~ product development is **a** highly speculative ~~because it~~ **undertaking and** entails substantial upfront ~~capital~~ expenditures and significant ~~risk~~ **risks** that any **program** ~~potential product candidate~~ will fail to demonstrate adequate ~~effect~~ **efficacy** or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale ~~and~~ **, we** have not generated any revenue from product sales to date, and we continue to incur **significant research and development, and other** expenses related to our ongoing operations. ~~To date, we have invested substantially all of~~ **We do not expect to generate product revenue unless** ~~our~~ **or until we successfully complete clinical** ~~efforts and financial resources in the research and~~ development **and obtains regulatory approval** of ~~our~~ **, and then successfully commercialize, at least one** product ~~candidates~~ **candidate**. ~~In December 2022~~ **We may never succeed in these activities and** , **even if** we ~~announced~~ **do, may never generate product revenue or revenues** that **are significant** ~~we had stopped dosing in Cohort 4 (dose level 0. 13 mg / kg) of the Phase 1 / 2 clinical trial for~~ **or large enough** ~~MGTA- 117 in patients with relapsed / refractory acute myeloid leukemia, or R / R AML, and myelodysplastic syndromes, or MDS, pursuant to the clinical trial protocol, due to the observance of dose- limiting toxicities, or DLTs, in two~~ **to achieve profitability** ~~of the participants dosed in Cohort 4~~. ~~As a result of~~ **If we are unable to generate sufficient revenue through** ~~these~~ **the sale of any approved products, we may be unable to continue** ~~observations~~ **operations without additional funding** , ~~two SUSARs were reported to the U. S. Food and Drug Administration, or FDA. In January 2023, we announced that the last participant dosed in Cohort 3 (dose level 0. 08 mg / kg) in the Phase 1 / 2 clinical trial experienced a Grade 5 serious adverse event, or SAE, (respiratory failure and cardiac arrest resulting in death) deemed to be possibly related to MGTA- 117, and this was reported to the FDA as a SUSAR. After consultation with the trial's safety Cohort Review Committee, and with the highest regard for patient safety, we voluntarily paused dosing in the clinical trial. The FDA subsequently placed the trial on partial clinical hold in February 2023. In February of 2023, after a review of our business, programs, resources and capabilities, we announced the decision to halt further development of our programs and to conduct a comprehensive review of strategic alternatives. As a result of that decision, we discontinued the MGTA- 117 Phase 1 / 2 clinical trial in patients with R / R AML and MDS~~. We ~~discontinued the MGTA- 145 Phase 2 stem cell mobilization clinical trial in~~

~~patients with sickle cell disease, or SCD. Lastly, we stopped incurring certain costs relating to MGTA- 45, including manufacturing and costs relating to certain other activities that were intended to support an investigative new drug application, or IND, for MGTA- 45 (previously named CD45- ADC). As a result, we are not profitable and~~ have incurred **significant net** losses in each period since ~~our~~ inception ~~in June 2015~~ . ~~For~~ **Our net losses were $ 43. 6 million and $ 28. 5 million for** the years ended December 31, **2023 and** 2022 ~~and 2021~~ , ~~we reported~~ **respectively. We expect to continue to incur significant losses for the foreseeable future. Our operating expenses and** net losses **may fluctuate significantly from quarter to quarter** ~~of $ 76. 5 million and $ 71. 1 million, respectively. As of December 31, 2022, we had an~~ **and year to year** ~~accumulated deficit of $ 402~~ . ~~0 million. If~~ **We anticipate that our expenses will increase substantially if and as** we ~~resume~~ **: • advance our existing and future programs through preclinical and clinical** development ~~of our~~ **, including expansion into additional indications; • seek to identify additional programs and additional** product candidates **; • maintain** , **expand, enforce, defend and protect our intellectual property portfolio; • seek regulatory and marketing approvals for product candidates; • seek to identify, establish and maintain additional collaborations and license agreements; • ultimately establish a sales, marketing and distribution infrastructure to commercialize any drug products for which** we ~~will not~~ **may obtain marketing approval, either by ourselves or in collaboration with others; •** generate revenue from **commercial sales of products for which we receive marketing approval; • hire additional personnel including research and development, clinical and commercial personnel; • add operational, financial and management information systems and personnel, including personnel to support** product **development; • acquire or in- license products, intellectual property and technologies; and • establish commercial-** ~~sales~~ **scale** ~~unless and until~~ **cGMP capabilities through third- parties or our own manufacturing facility. In addition, our expenses will increase if, among other things,** we ~~successfully~~ **are required by the FDA or other regulatory authorities to perform trials or studies in addition to, or different than, those that we currently anticipate, there are any delays in** ~~complete~~ **completing our** clinical **trials or the** development ~~and~~ **of any product candidates, or there are any third- party challenges to our intellectual property or we need to defend against any intellectual property- related claim. Even if we** obtain ~~regulatory~~ **marketing** approval for **, and are successful in commercializing, one** ~~our~~ **or more** product candidates **, we expect to incur substantial additional research and development and other expenditures to develop and market additional programs and / or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our failure to become profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business and / or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment. Future reports on our financial statements may include an explanatory paragraph with respect to our ability to continue as a going concern. There is no assurance that adequate additional financing needed to allow us to continue as a going concern will be available to us on acceptable terms, or at all. The perception that we may not be able to continue as a going concern may cause others to choose not to do business with us due to concerns about our ability to meet our contractual obligations. Risks Related to Discovery, Development and Commercialization We face competition from entities that have developed or may develop programs for the diseases we plan to address with DNTH103 or other product candidates. The development and commercialization of drugs is highly competitive** . If **approved, DNTH103 or other product candidates will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. We compete with a variety of multinational biopharmaceutical companies, specialized biotechnology companies and emerging biotechnology companies, as well as academic institutions, governmental agencies, and public and private research institutions, among others. Many of the companies with which** we **are currently competing or will compete against in the future have significantly greater 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 industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, DNTH103 or other product candidates. Our competitors have developed, are developing or may develop programs and processes competitive with DNTH103 or other product candidates and processes. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments. Our success will depend partially on our ability to develop and commercialize products that have a competitive safety, efficacy, dosing and / or presentation profile. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective, have a more attractive dosing profile or presentation or are less expensive than any products we may develop, if any, or if competitors develop competing products or if biosimilars enter the market more quickly than we are able to, if at all, and are able to gain market acceptance. See the section titled " Business — Competition " for a more detailed description of our competitors and the factors that may affect the success of the products that we develop. DNTH103 and our other programs are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we or our current or future collaborators are unable to complete development of, or commercialize, our product candidates, or experience significant delays in doing so, our business will be materially harmed. We have no products on the market and DNTH103 and our other programs are in the early stages of development. As a result, we expect it will be many years before we**

commercialize any product candidate, if any. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for, and successfully commercializing, DNTH103 or other product candidates either alone or with third parties, and we cannot guarantee that we will ever obtain regulatory approval for any ~~of our~~ product candidates ~~, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing and distribution~~ . **We have limited experience** ~~Further, we expect to incur additional costs associated with operating~~ as a ~~public~~ company ~~. We expect to continue to incur costs and expenditures~~ in ~~connection with the process of evaluating our strategic alternatives. Should we resume development of our product candidates, we will incur substantial research and development costs and other expenditures to develop such product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Should we resume development of our product candidates, we will require additional capital to fund our operations. If we fail to obtain necessary financing, we will not be able to complete the development and commercialization of our product candidates. Our operations have consumed substantial amounts of cash since our inception. Should we resume development of our product candidates, we would expect to continue to spend substantial amounts of cash (including the net proceeds from our initial public offering, or IPO, and our subsequent public and private equity offerings) to conduct~~ **conducting** ~~further research~~ and **managing the** ~~development and preclinical testing and~~ clinical trials **necessary** ~~of our product candidates,~~ to ~~seek~~ **obtain** regulatory approvals **, including** ~~for our product candidates and to launch and commercialize any product candidates for which we receive regulatory~~ approval ~~, including potentially building our own commercial organization to address the U. S., the European Union and certain other markets. As of December 31, 2022, we had approximately $ 112. 0 million in cash, cash equivalents and marketable securities. Should we resume development of our product candidates, our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with successful development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future expenses and future funding requirements, both near and long- term, will depend on many factors, including but not limited to: • the timing and outcome of our exploration of potential strategic alternatives; • the initiation, progress, timing, costs and results of research, preclinical studies and clinical trials for our product candidates; • the costs to develop, maintain, and enhance a sustainable, scalable, reproducible and transferable manufacturing process for our product candidates; • the clinical development plans we establish for these product candidates; • the number and characteristics of product candidates that we develop or may in- license; • the cost of milestone or other payments under any license, acquisition, collaboration or other strategic transaction agreements; • the outcome, timing and cost of meeting regulatory requirements established~~ by the FDA **or** ~~, the EMA and other~~ comparable foreign regulatory authorities ~~; • the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights; • the cost of defending material intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates; • the effect of competing technological and market developments; • the cost and timing of completion of commercial- scale outsourced manufacturing activities; • the cost of seeking to attract, hire and retain skilled personnel; • the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own; and • the cost of, and ability to maintain on reasonable commercial and economic terms, sufficient office and laboratory space to support our operations~~ . We ~~cannot be certain that additional funding will be available on acceptable terms, or at all, and such funding may become even more difficult to obtain due to rising interest rates and the current downturn in the U. S. capital markets and the biotechnology sector in general. Competition for additional capital among biotechnology companies may be particularly intense during this present economic downturn. We may be unable to raise capital through public offerings of our common stock and may need to turn to alternative financing arrangements. Such arrangements, if we pursue them, could involve issuances of one or more types of securities, including common stock, preferred stock, convertible debt, warrants to acquire common stock or other securities. These securities could be issued at or below the then prevailing market price for our common stock. In addition, if we issue debt securities, the holders of the debt would~~ have ~~a claim to our assets that would be superior to the rights of stockholders until the principal, accrued and unpaid interest and any premium or make- whole has been paid. Interest on any newly- issued debt securities and / or newly- incurred borrowings would increase our operating costs and reduce our net income, and these impacts may be material. If the issuance of new securities results in diminished rights to holders of our common stock, the market price of our common stock could be materially and adversely affected. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives, and we may~~ also ~~be forced to reduce or terminate our operations. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. As part of our strategic review process, we began exploring potential strategic alternatives that include, without limitation, an acquisition, merger, business~~

~~combination or other transaction. We are also exploring strategic transactions regarding our product candidates and related assets, including, without limitation, licensing transactions and asset sales. In such transactions, we may relinquish valuable rights to, sell or otherwise dispose of our technologies, product candidates or other assets at unfavorable prices or on terms unfavorable to us. In particular, given the current downturn in the U. S. capital markets and the biotechnology sector in general, we may enter into such transactions on terms and at prices less favorable to us than would otherwise occur. We also could be required to seek collaborators for one or more of our product candidates at an earlier stage than otherwise would be desirable. We may also be required to relinquish or license on unfavorable terms our rights to technologies or product candidates. As a result, we may fail to realize the full potential of our product candidates. Any of the foregoing events could have a material adverse effect upon our business and future prospects. Our company has a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability. We were founded and commenced operations in June 2015. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential product candidates, and undertaking preclinical studies and clinical trials. Although we have conducted clinical trials for certain of our product candidates, we have~~ not yet demonstrated ~~an~~ **our** ability to ~~successfully complete certain clinical trials of our~~ **obtain regulatory approvals, manufacture a commercial scale** product ~~candidates, obtain marketing approvals, manufacture a commercial- scale medicine,~~ or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful **product** commercialization. ~~Typically~~ **Before obtaining regulatory approval for the commercial distribution of product candidates** , ~~it takes treatment follow- up 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,or may deviate from the clinical trial protocol or drop out of the trial,which may require that we add new clinical trial sites or investigators;• we may elect to,or regulators,IRBs or ethics committees may require **,** that we or our investigators,suspend or terminate clinical research or trials for various reasons,including noncompliance with regulatory requirements or a finding that the participants ~~in our trials~~ are being exposed to unacceptable health risks;• the cost of **preclinical studies and** clinical trials of any ~~of our~~ product candidates may be greater than we anticipate **,and / or greater than we have budgeted for** ;• the **supply or** quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be **insufficient or** inadequate ~~to initiate~~ **;and • ~~or~~ our** ~~complete a given clinical~~ **product candidates may have undesirable side effects or other unexpected characteristics,causing us or our investigators,regulators,IRBs or ethics committees to suspend or terminate the** ~~trial~~ **trials , ;**~~• our~~ **or** ~~inability to manufacture sufficient quantities of our product candidates for use in clinical trials,or delays in manufacturing or distribution;•~~ reports **may arise** from **preclinical or** clinical testing of other **blood and immune reset and cell- based** therapies ~~may~~ **that** raise safety or efficacy **concerns about our product candidates** about ~~10~~ **our product candidates; • our failure** to ~~15 years~~ **establish an appropriate safety profile for a product candidate based on clinical or preclinical data for such product candidate as well as data emerging from other therapies in the same class as our product candidates; and • the FDA or other regulatory authorities may require us** to **submit additional data such as additional toxicology studies, or impose other requirements before permitting us to initiate a clinical trial. Commencing clinical trials in the United States is subject to acceptance by the FDA of an IND, BLA or similar application and finalizing the trial design based on discussions with the FDA and other regulatory authorities. In the event that the FDA requires us to complete additional preclinical studies or we are required to satisfy other FDA requests prior to commencing clinical trials, the start of our clinical trials may be delayed. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials, delay the enrollment of our clinical trials or impose stricter approval conditions than we currently expect. There are equivalent processes and risks applicable to clinical trial applications in other countries, including countries in the European Union. We may not have the financial resources to continue** ~~develop~~ **development** ~~a~~ **of, or to modify existing or enter into** new **collaborations** ~~medicine from the time it is discovered to when it is available~~ for ~~treating patients. Consequently~~ , **a product candidate if we experience** any **issues that delay** ~~predictions we make about our~~ **or prevent regulatory approval of, or our ability to commercialize, DNTH103 or any other product candidates. We or our current or future collaborators' inability to complete development of, or commercialize, DNTH103 or any other product candidates or significant delays in doing so, could have a material and adverse effect on our business, financial condition, results of operations, cash flows, and prospects. We are substantially dependent on the success of our most advanced product candidate, DNTH103, and our anticipated clinical trials of such candidate may not be successful. Our** future success **is substantially dependent on** ~~or~~ **our** ~~viability~~ **ability** ~~may not be as accurate as~~ **to timely obtain marketing approval for, and then successfully commercialize, our most advanced product candidate, DNTH103. We are investing a majority of our efforts and financial resources into** ~~they~~ **the** ~~could be if we had~~ **research and development of this candidate. We initiated** a ~~longer operating history~~ **global Phase 2 clinical trial of DNTH103 in gMG in the first quarter of 2024, following receipt of FDA clearance of our IND application. We plan to submit a CTA in the European Union in the second quarter of 2024** . In addition, **pending clearance of INDs** ~~we may encounter unforeseen expenses, difficulties, complications, delays,~~ and **/ or CTAs that we plan to submit, we anticipate initiating Phase 2 clinical trials in MMN in the second quarter of 2024 and CIDP in the second half of 2024. The success of DNTH103 may depend on having a comparable safety and efficacy profile and a more favorable dosing schedule (i. e., less frequent dosing) and more patient- friendly administration (i. e., S. C. self- administration using a pen or** other ~~known and unknown factors.~~ **prefilled device) to products currently approved** ~~For~~ **or in development** ~~example, management may fail to undertake sufficient risk mitigation strategies~~ for **the indications** ~~elements of our business subject to heightened risk, and as a result our business may be harmed. We have never~~

~~generated revenue from product sales and may never be profitable. Should~~ we ~~resume~~ **plan to pursue. DNTH103 will require additional clinical** development ~~of our product candidates~~, ~~our ability to~~ **evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we** generate **any** ~~revenue from product sales and achieve profitability depends on our ability, alone or with collaborative partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, product candidates we may identify for development. We may not generate~~ revenues from product sales ~~for the next several years~~, if ~~ever~~ **any** . ~~Our ability~~ **We are not permitted** to ~~generate future revenues from~~ **market or promote this** product **candidate,** ~~sales would depend heavily on our~~ **or any other** ~~and or our collaborators' ability to successfully: • identify~~ product candidates **, before we receive marketing approval from the FDA** and **/ or comparable foreign regulatory authorities, and we may never receive such marketing approvals. The success of DNTH103 will depend on a variety of factors. We do not have** complete ~~research and preclinical and~~ **control over many of these factors, including certain aspects of** clinical development **and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts** of **any future collaborator. Accordingly, we cannot guarantee that we will ever be able to generate revenue through the sale of this product candidate, even if approved. If we are not successful in commercializing DNTH103, or we are significantly delayed in doing so, our business will be materially harmed. If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of DNTH103 or any other product candidates may be delayed and our expenses may increase and, as a result, our stock price may decline. From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies, preclinical studies and clinical trials and the submission of regulatory filings. We have publicly announced and may in the future publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of DNTH103 or any other product candidates may be delayed or never achieved and, as a result, our stock price may decline. Additionally, delays relative to our projected timelines are likely to cause overall expenses to increase, which may require us to raise additional capital sooner than expected and prior to achieving targeted development milestones. Our approach to the discovery and development of product candidates is unproven, and we may not be successful in our efforts to build a pipeline of product candidates with commercial value. Our approach to the discovery and development of DNTH103 leverages clinically validated mechanisms of action and incorporates advanced antibody engineering properties designed to overcome limitations of existing therapies. DNTH103 is purposefully designed to improve upon currently approved products and existing product candidates. However, the scientific research that forms the basis of our efforts to develop a product candidate using only the classical complement pathway and half- life extension technologies is ongoing and may not result in viable product candidates. The long- term safety and efficacy of these technologies and exposure profile of DNTH103 compared to currently approved products is unknown. We may ultimately discover that our technologies for our specific targets and indications and DNTH103 or** any product candidates **resulting therefrom do not possess certain properties required** ~~we may identify; • seek and obtain regulatory and marketing approvals~~ for ~~any of~~ **therapeutic effectiveness. We currently have only preclinical and topline data from** our **Phase 1 clinical trial regarding properties of DNTH103 and the same results may not be seen in patients in our later stage trials. In addition,** product candidates **using technologies may demonstrate different chemical** ~~for which we complete clinical trials; • launch~~ and **pharmacological properties in patients than** ~~commercialize any of our product candidates for which we obtain regulatory and marketing approval by establishing a sales force, marketing, and distribution infrastructure or, alternatively, collaborating with a commercialization partner; • qualify for adequate coverage and reimbursement by government and third- party payors for any of our product candidates for which we obtain regulatory and marketing approval; • develop, maintain, and enhance a sustainable, scalable, reproducible, and transferable manufacturing process for the~~ **they do** ~~product candidates we may develop; • establish and maintain supply and manufacturing relationships with third parties that can provide adequate,~~ in ~~both amount~~ **laboratory studies. This technology** and **DNTH103** ~~quality, products and services to support clinical development and the market demand for~~ **or** ~~any of our product candidates for which we obtain regulatory and marketing approval; • obtain market acceptance of~~ any product candidates ~~we~~ **resulting therefrom** may **not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective or harmful ways. In addition, we may in the future seek to discover and** develop ~~as~~ **product candidates that are based on novel targets and technologies that are unproven. If our discovery activities fail to identify novel targets or technologies for drug discovery, or such targets prove to be unsuitable for treating human disease, we may not be able to develop** viable **additional product candidates. We** ~~treatment options; • address competing technological~~ and **our existing or future collaborators may never receive approval to** market ~~developments; • implement internal systems~~ and **commercialize DNTH103 or** ~~infrastructure, as needed; • negotiate favorable terms in~~ any ~~collaboration, licensing, or~~ other **product candidates** ~~arrangements into which we may enter and perform our obligations in such collaborations; • maintain, protect, and expand our portfolio of intellectual property rights, including patents, trade secrets, and know- how; • avoid and defend against third- party interference or infringement claims; and • attract, hire, and retain qualified personnel~~ . Even if ~~one~~ **we or an existing or future collaborator obtains regulatory approval, the approval may be** ~~or~~ **for** ~~more of~~ **targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. If the products resulting from DNTH103 or any** ~~the~~ **other** product candidates ~~we may develop is approved~~ **prove to be ineffective, unsafe** ~~for~~ **or** ~~commercial~~ **commercially** ~~sale~~ **unviable** , ~~we anticipate incurring significant costs~~

associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, the EMA, or other regulatory authorities to perform clinical and other studies in addition to those that we anticipate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. Risks Related to Product Development and Regulatory Approval Should we resume development of our product candidates **and pipeline may have little** , if **any** we are unable to advance our product candidates through development , **value** obtain regulatory approval and commercialize them , **which may have a material and adverse effect on** or if we experience significant delays in doing so, our business will be materially harmed. As noted above , **financial condition** in December 2022 we announced that two study participants in Cohort 4 in the Phase 1 / 2 clinical trial for MGTA- 117 in patients with AML and MDS had experienced DLTs. In January 2023 , we announced that the last participant dosed in Cohort 3 in the clinical trial experienced a Grade 5 SAE (respiratory failure and cardiac arrest resulting in death) deemed to be possibly related to MGTA- 117 and that we voluntarily paused dosing in the clinical trial. The FDA subsequently placed the trial on partial clinical hold in February 2023. In February of 2023, after a review of our business, programs, resources and capabilities, we announced the decision to halt further development of our programs and to conduct a comprehensive review of strategic alternatives. As a result **results** of **operations** that decision , **cash flows** we discontinued the MGTA- 117 Phase 1 / 2 clinical trial in patients with R / R AML and MDS. We discontinued the MGTA- 145 Phase 2 stem cell mobilization clinical trial in patients with SCD. Lastly , we stopped incurring certain costs relating to MGTA- 45, including manufacturing and costs relating to certain other activities that were intended to support an **and prospects** investigative new drug application, or IND, for MGTA- 45 . Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development, regulatory approval and commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any product, and we may never be able to develop or commercialize a marketable product. Should we resume development of our product candidates, each of our product candidates will require additional preclinical **Preclinical** and clinical development **involves** , regulatory approval, potentially in multiple jurisdictions, obtaining manufacturing supply, capacity and expertise, building of a **lengthy** commercial organization, substantial investment and **expensive process that is subject to delays and with** significant marketing efforts before we generate any revenue from product sales. Our product candidates must be authorized for marketing by the FDA, or certain **uncertain outcomes** other foreign regulatory agencies , **and results** such as the EMA, before we may commercialize our product candidates in the U. S. or other countries. The success of **earlier** our product candidates will depend on several factors, including the following: • successful completion of preclinical studies and successful enrollment and completion of clinical trials **may not be predictive** , including toxicology studies, biodistribution studies and minimally efficacious dose studies in animals, where applicable, under the FDA' s current Good Clinical Practices, or cGCPs, and the FDA' s current Good Laboratory Practices, or cGLP; • effective IND applications or Clinical Trial Authorizations that allow commencement of our planned clinical trials or future clinical trials for our product candidates; • positive results from preclinical and clinical programs that support a finding of safety and effectiveness and an acceptable risk- benefit profile of our product candidates in the intended populations; • receipt of regulatory approvals from applicable regulatory authorities; • establishment of arrangements with third- party manufacturers for clinical supply and, where applicable, commercial manufacturing capabilities; • successful development of our internal or external manufacturing processes or transfer to larger- scale facilities operated by either a third- party contract development and manufacturing organization, or CDMO, or by us; • establishment and maintenance of patent and trade secret protection or regulatory exclusivity for our product candidates; • commercial launch of our product candidates, if and when approved, whether alone or in collaboration with others; • acceptance of our product candidates, if and when approved, by patients, the medical community and third- party payors; • effective competition against other therapies, including certain chemotherapies; • establishment and maintenance of healthcare coverage and adequate reimbursement; • enforcement and defense of intellectual property rights and claims; and • maintenance of a continued acceptable safety profile of our product candidates following approval. If we do not succeed in one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. The successful development of biopharmaceuticals and cell- based therapies is highly uncertain. Successful development of biopharmaceuticals and cell- based therapies is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Blood and immune reset and cell- based therapies that appear promising in the early phases of development may fail to reach the market for several reasons including: • preclinical study results may show the therapies to be less effective than desired or to have harmful or problematic side effects; • clinical trial results may show the therapies to be less effective than expected (e . **If** g., the trial failed to meet its primary endpoint or **our** the results are not competitive compared to other therapeutic alternatives) or to have unacceptable side effects or toxicities; • failure to receive the necessary regulatory approvals or a delay in receiving such approvals, which delays may be caused by, among other things, slow enrollment in clinical trials, delays due to investigations concerning safety, length of time to achieve study endpoints, additional requirements for data by regulatory agencies, additional time requirements for data analysis, or biologics license application, or BLA, new drug application, or NDA, preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data, or unexpected safety or manufacturing issues; • manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the therapy uneconomical; and • the proprietary rights of others and their competing products and technologies that may prevent the therapy from being commercialized. Success in preclinical studies and early clinical trials does not ensure that large- scale clinical trials will be successful. The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one therapy to the next and may be difficult to predict. Even if we are successful in getting market approval, third- party payers could require us to conduct additional studies, including post- marketing studies related to the cost effectiveness of a product, to qualify for

reimbursement, which could be costly and divert our resources. In addition, if one of our product candidates is approved for marketing, we will be subject to significant regulatory obligations regarding the submission of safety and other post- marketing information and reports and registration, and we will need to continue to comply (or ensure that our third- party providers comply) with the FDA's current Good Manufacturing Practices, or cGMP, and cGCP requirements for any clinical trials that we conduct post- approval. In addition, there is always the risk that we or a regulatory authority might identify previously unknown problems with a product post- approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates' post- market approval could have a material adverse effect on our business, financial condition and results of operations. Clinical trials may reveal significant adverse events not seen in preclinical or clinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates. Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never **not sufficient to support regulatory** approved **approval of** as products. It is impossible to predict when or if any product candidates we may develop will prove safe in humans. If any product candidates we develop are associated with serious adverse events, 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 serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective, any of which would have a material adverse effect on our business, financial condition, results of operations and prospects. It is possible that product candidates that initially showed promise in early- stage testing will later have been found to cause side effects that prevent further clinical development of the product candidates. As noted above, in December 2022 we announced that two study participants in Cohort 4 in the Phase 1 / 2 clinical trial for MGTA- 117 in patients with AML and MDS had experienced DLTs. In January 2023, we announced that the last participant dosed in Cohort 3 in the clinical trial experienced a Grade 5 SAE (respiratory failure and cardiac arrest resulting in death) deemed to be possibly related to MGTA- 117 and that we voluntarily paused dosing in the clinical trial. Ultimately, we reported three safety events that were deemed to be Suspected, Unexpected, Serious Adverse Reactions, or SUSARs, to the FDA and the FDA placed the clinical trial on partial clinical hold in February 2023. In February of 2023, after a review of our business, programs, resources and capabilities, we announced the decision to halt further development of our programs and to conduct a comprehensive review of strategic alternatives. As a result of that decision, we discontinued the MGTA- 117 Phase 1 / 2 clinical trial in patients with R / R AML and MDS. We discontinued the MGTA- 145 Phase 2 stem cell mobilization clinical trial in patients with SCD. Lastly, we stopped incurring certain costs relating to MGTA- 45, including manufacturing and costs relating to certain other activities that were intended to support an investigative new drug application, or IND, for MGTA- 45. If any other significant adverse events or side effects are observed in any of our future clinical trials, we may have difficulty recruiting patients to the clinical trial, patients may drop out of a trial, or we may be required to abandon the trial or our development efforts of that product candidate altogether. We, the FDA or other applicable regulatory authorities, or an institutional review board, or IRB, may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early- stage studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects. Stem cell transplant is a high- risk procedure with curative potential that may result in complications or adverse events for patients in clinical trials or for patients that use any of our product candidates, if approved. Stem cell transplant can cure patients across multiple diseases, but its use carries with it risks of toxicity, serious adverse events and death. Because many of our therapies are used to prepare or treat patients undergoing stem cell transplant, patients in clinical trials or patients that use any of our product candidates may be subject to many of the risks that are currently inherent to this procedure. In particular, stem cell transplant involves certain known potential post- procedure complications that may manifest several weeks or months after a transplant and which may be more common in certain patient populations. If serious adverse events, undesirable side effects, evidence of lower than expected efficacy, or unexpected characteristics are identified during the development of any of our product candidates, we may need to limit, delay or abandon our further clinical development of those product candidates, even if such events, effects or characteristics were the result of stem cell transplant or related procedures generally and were not directly or specifically caused or exacerbated by our product candidates. In the event we need to limit, delay or abandon the clinical development of any of our product candidates, our business will likely be materially adversely affected. In addition, patients who are in clinical studies or undergoing stem cell transplant typically have underlying disorders or compromised immune systems that make them vulnerable or fragile for undergoing additional clinical studies. This may cause negative outcomes for those patients that could slow down the trial, prevent the trial from moving to the next phase or even suspend the trial. As a result, the FDA could put the trial on clinical hold until any potential FDA concerns are satisfied. Should we resume development of our product candidates, if we are not

~~able to identify a safe and effective dose for any of our product candidates, we may need to delay, abandon or limit our development of any potential product candidates. Should we resume development of our product candidates, we may not be able to identify a safe and effective dose for our product candidates, and as a result we may need to delay, abandon or limit their development. Some of our product candidates may utilize ADCs, which utilize toxins to kill cells. ADCs, including those that have received marketing approval, have dose- dependent safety findings that can include liver toxicity, depending on the target of the ADC and the drug used in the conjugate. In addition, ADCs may have other adverse side effects including fatalities. For example, our CD117- ADC, which was designed to deplete hematopoietic stem cells, or HSCs, was generally well tolerated at efficacious doses in non- human primate studies, but three study participants in our Phase 1 / 2 clinical trial for MGTA- 117 in patients with AML and MDS experienced safety events, two in Cohort 4 (dose level 0. 13 mg / kg) and one in Cohort 3 (dose level 0. 08 mg / kg), that were ultimately reported to the FDA as SUSARs. The patient in Cohort 3 who experienced a safety event experienced a Grade 5 SAE (respiratory failure and cardiac arrest resulting in death) deemed to be possibly related to MGTA- 117, and we voluntarily paused dosing in the clinical trial in January 2023. The FDA placed the study on partial clinical hold in February 2023 and we subsequently discontinued the trial. Resuming development of MGTA- 117 would require among other things that we address and resolve the FDA' s partial clinical hold for MGTA- 117. The dose required for efficacy may differ for different populations, for example between adult and pediatric populations, between populations with diseases that involve bone marrow to different extents, or between uses of our product candidates as a monotherapy or as combination with other therapeutic agents. Additional trials to determine the safe and effective dose for different settings of use of any product candidates would be required. Clinical development involves a lengthy and expensive process, with an uncertain outcome. Should we resume development~~ of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development ~~and commercialization~~ of ~~our~~ **such** product ~~candidates~~ **candidate** ~~. Should we resume their development, our product candidates would be in the preclinical development and / or clinical trial stages, and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval~~ . Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical ~~development~~ **studies** and then conduct extensive clinical trials to demonstrate the safety and efficacy of **our product candidate in humans. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and failure can occur at** any **time during the** ~~of our future product candidates in humans. Preclinical~~ **preclinical study or** ~~and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a~~ clinical trial **process. For example, we depend on the availability of non- human primates (" NHPs ") to conduct certain preclinical studies that we are required to complete prior to submitting an IND or foreign equivalent and initiating clinical development. There is currently a global shortage of NHPs available for drug development. This could cause the cost of obtaining NHPs for our future preclinical studies to increase significantly and, if the shortage continues, could also result in delays to our development timelines. Furthermore, a failure of one or more clinical trials** can ~~fail~~ **occur** at any stage of testing. The outcome of preclinical studies and early **- stage** clinical trials may not be predictive of the success of later clinical trials ~~, and interim results of a clinical trial do not necessarily predict final results~~ . Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and 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~~ **product candidates** . ~~Additionally~~ **In addition** , ~~some of our past clinical trials utilized~~ **we expect to rely on patients to provide feedback on measures** , **which are subjective** and ~~any future~~ **inherently difficult to evaluate. These measures can be influenced by factors outside of our control and can vary widely from day to day for a particular patient, and from patient to patient and from site to site within a** clinical trial ~~we conduct may utilize, an " open- label " trial design~~ . **We cannot be sure** ~~An " open- label " clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open- label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open- label clinical trials are subject to various limitations~~ that ~~may exaggerate any therapeutic effect as patients in open- label clinical trials are aware when they are receiving treatment. Open- label clinical trials may be subject to a " patient bias " where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open- label clinical trials may be subject to an " investigator bias " where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open- label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open- label clinical trial when studied in a controlled environment with a placebo or active control. Successful completion of clinical trials is a prerequisite to submitting a BLA or NDA to~~ the FDA **or** ~~, a Marketing Authorization Application to the EMA and similar approval filings to~~ comparable foreign regulatory authorities **will agree with our clinical development plan** ~~, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates~~ . ~~Our~~ **We plan to use the data from our Phase 1 clinical trial of DNTH103 in healthy volunteers to support Phase 2** clinical trials **in gMG, MMN, CIDP and other indications. If the FDA or comparable regulatory authorities require us to conduct additional trials or enroll additional patients, our development timelines** may be delayed ~~or may not~~ **. We cannot** be ~~completed on schedule~~ **sure that submission of an IND, a CTA, or similar application will result in the FDA or comparable foreign regulatory authorities, as applicable, allowing clinical trials to begin in a timely manner** , if at all **. Moreover** , ~~and this~~ **even if these trials begin, issues** may ~~lead~~ **arise that could cause regulatory authorities** to **suspend or terminate such clinical trials. Events that may prevent successful or timely initiation or completion of clinical trials include: inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation or continuation of**

clinical trials; ~~delay~~ **delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials; delays or failure** in obtaining regulatory **authorization to commence a trial;** ~~approval for our product candidates. We may experience~~ delays in ~~completing preclinical studies and initiating or completing clinical trials. We also may experience numerous unforeseen events during, or as a result of, any clinical trials that we could conduct that may delay or prevent our ability to develop, receive marketing approval for or commercialize our product candidates, including: • regulators, IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; • we may experience delays in~~ reaching ~~, or fail to reach,~~ agreement on acceptable terms with prospective **CROs and clinical** trial sites ~~and prospective contract research organizations, or CROs~~, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and **clinical** trial sites; ~~•~~ **delays in identifying, recruiting and training suitable clinical investigators; delays in obtaining required IRB approval at each clinical trial site; difficulties in patient enrollment in our** clinical trials **for a variety** of ~~any~~ **reasons; delays in manufacturing, testing, releasing, validating or importing / exporting sufficient stable quantities of our** product candidates ~~may fail to show safety or~~ **for** ~~efficacy, produce negative or inconclusive results and we may decide, or regulators may require us~~ **use in** ~~, to conduct additional preclinical studies or~~ clinical trials or **the inability** ~~we may decide~~ to ~~abandon product development programs~~ **do any of the foregoing** ; ~~•~~ **failure by our CROs,** ~~the~~ **other third** ~~number of patients~~ -- **parties** ~~required for~~ - **or us to adhere to** clinical ~~trials~~ - **trial** ~~of~~ **protocols; failure to perform in accordance with the FDA' s or** any ~~product candidates may be~~ **other regulatory authority' s GCPs or regulations or applicable regulations or regulatory guidelines in other countries; changes to the clinical trial protocols; clinical sites deviating from trial protocol or dropping out of a trial; changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data; transfer of manufacturing processes to** larger ~~than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or fail to return for post~~ - **scale facilities operated by** ~~treatment follow- up at a higher rate than we anticipate; • our~~ third- party **CDMOs and delays or failure by** ~~contractors may fail to comply with regulatory requirements or~~ **our** ~~meet~~ **CDMOs or us to make any necessary changes to such manufacturing process; and third parties being unwilling or unable to satisfy** their contractual obligations to us in a timely manner, or at..... or efficacy concerns about our product candidates . We could also encounter delays if a ~~future~~ clinical trial is **placed on clinical hold,** suspended or terminated by us, the **FDA, the competent authorities of the European Union (" EU "), member states or other regulatory authorities or the** IRBs **or ethics committees** of the institutions in which such trials are being conducted, **if a clinical trial is recommended for suspension or termination by** the ~~Data~~ **data** ~~Safety~~ **safety** ~~Monitoring~~ **monitoring** ~~Board~~ **board or equivalent body** for such trial, or **on account** ~~the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number~~ of ~~factors~~ **changes to federal** , ~~including failure~~ **state, or local laws. If we are required** to conduct ~~the clinical trial in accordance with regulatory requirements or clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. As noted above, the FDA placed our MGTA- 117 Phase 1 / 2 clinical trial for MGTA- 117 in patients with R / R AML and MDS on partial clinical hold in February 2023, and we subsequently discontinued the study. In addition~~ **additional** ~~, many of the factors that cause, or lead to, a delay in the commencement or completion of~~ clinical trials ~~may also ultimately lead to the denial of regulatory approval of our~~ - **or other testing of DNTH103 or any other** product candidates **beyond** ~~. Further, the~~ **those that we contemplate, if we unable to successfully complete** ~~FDA or other regulatory authorities may disagree with a future clinical trial design and our interpretation of data from~~ clinical trials **of DNTH103** ~~or may change the requirements for~~ - **or** ~~approval even after~~ **any other product candidates, if** ~~they~~ - **the results of** ~~have reviewed and commented on the~~ **these** ~~design~~ **trials are not positive** ~~for~~ - **or are only moderately positive** ~~our~~ - **or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs. We may not be successful in our efforts to identify or discover additional product candidates in the future. A key part of our business strategy is to identify and develop additional product candidates. Our preclinical research and** clinical trials ~~. Our~~ **may initially show promise in identifying potential** product **candidates yet fail to yield product candidates for clinical** development ~~costs will increase if~~ **for a number of reasons. For example,** we ~~experience delays~~ **may be unable to identify or design additional product candidates with the pharmacological and pharmacokinetic drug properties that we desire, including, but not limited to, extended half- life, acceptable safety profile or the potential for the product candidate to be delivered** in **a convenient formulation. Research programs to identify new product candidates require substantial technical, financial, and human resources. If we are unable to identify suitable active selective complement targets for preclinical and** clinical **development, we may** ~~testing or marketing approvals. We do~~ not ~~know whether any preclinical studies~~ **be able to successfully implement** ~~or~~ **our business strategy, and may have to delay, reduce the scope of, suspend or eliminate one or more of our product candidates,** clinical trials ~~will begin as planned, will need to be restructured~~ or **future commercialization efforts** ~~will be completed on schedule~~ , ~~or at all. Significant preclinical or clinical trial delays also could shorten any periods during~~ which **would negatively impact** ~~we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in preclinical or~~ **our** ~~future clinical development programs may harm our business,~~ financial condition ~~and prospects significantly~~ . **If** ~~As noted, we have ceased development of our product candidates. There is an additive degree of risk to any development program that is paused because the time to restart the program and the associated expense may be longer and more costly than previously anticipated. It may also not be possible to restart the program altogether. Should we resume development of our product~~

~~candidates, if~~ we encounter ~~delays or~~ difficulties enrolling patients in our **future** clinical trials, our clinical development activities could be delayed or otherwise adversely affected. **We** ~~Should we resume development of our product candidates, we~~ may experience ~~delays or~~ difficulties in patient enrollment in our **future** clinical trials for a variety of reasons ~~, including impacts that have resulted, or may in the future result, from the COVID- 19 pandemic~~ . The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients **in future trials for DNTH103 or any other product candidates will** ~~depends~~ **depend** on many factors, including **if** ~~: • the patient eligibility criteria defined in the protocol; • the size of the patient population required for analysis of the trial' s primary endpoints; • the proximity of~~ patients **choose** to ~~trial sites; • the design of the trial; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • our ability to obtain and maintain patient consents; • the risk that patients enrolled~~ -- **enroll** in clinical trials **, rather than using approved products,** ~~will drop out of the trials before completion; and • adequate staffing at institutions running our~~ - **or if** ~~clinical trials to efficiently conduct such trials. In addition,~~ our **competitors have ongoing** ~~clinical trials may compete with other~~ clinical trials for product candidates that are ~~in~~ **under development for** the same **indications** ~~therapeutic areas~~ as our product candidates, and ~~this competition will reduce the number and types of~~ patients **instead** ~~available to us, because some patients who might have opted to~~ enroll in **such** ~~our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our~~ clinical trials **. Additionally** ~~at the same clinical trial sites that some of our competitors use~~ , ~~which would reduce~~ the number of patients **required** ~~who are available~~ for ~~our~~ clinical trials ~~in such clinical~~ **of DNTH103 or any other product candidates may be larger than we anticipate, especially if regulatory bodies require the completion of non- inferiority or superiority** ~~trial trials site~~ . ~~Delays in~~ **Even if we are able to enroll a sufficient number of** ~~patient~~ **patients** ~~enrollment may result in increased costs or~~ **for** ~~may affect the timing or~~ **our future** ~~outcome of the planned~~ clinical trials, ~~which could prevent completion~~ **we may have difficulty maintaining patients in** ~~or~~ **our clinical** ~~advancement of these~~ trials **. Our** ~~into the next phase and may adversely affect our ability~~ **inability** to ~~advance the~~ **enroll or maintain a sufficient number of patients would result in significant delays in completing clinical trials or receipt of marketing approvals and increased** development ~~of~~ **costs** ~~our~~ - **or may require us to abandon one** ~~product candidates. Should we resume development of our~~ - **or** ~~product candidates, interim, more clinical trials altogether.~~ ~~preliminary~~ **Preliminary** ~~and ,~~ " topline " **or interim** data from **our** clinical trials that we ~~may~~ announce or publish from time to time may change as more patient data ~~become~~ **becomes** available **and** ~~following the interim data. Preliminary data~~ are subject to audit and verification procedures ~~,~~ **. We have publicly disclosed** and **may in** ~~deeper analysis of~~ the ~~data beyond the~~ **future publicly disclose preliminary or** topline data ~~may provide~~ **from our preclinical studies and clinical trials, which are 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** ~~color and context to~~ the data **. We also make assumptions** , ~~all~~ **estimations, calculations and conclusions as part** of ~~which could~~ **our analyses of these data without the opportunity to fully and carefully evaluate complete data. As a** result **,** ~~in material or other~~ -- **the** ~~changes in~~ **preliminary or 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 or subsequently made subject to audit and verification procedures. Any preliminary or topline data should be viewed with caution until** the final data **is available** . **We have publicly disclosed and** ~~Should we resume development of our product candidates, we~~ may **in the future** disclose interim data from **our** preclinical studies and clinical trials ~~, which are based on an interim analysis of then- available data from ongoing studies or trials~~ . Interim data ~~from preclinical studies and clinical trials that we may complete~~ are subject to the risk that one or more of the clinical ~~observations~~ **outcomes** may materially change as patient enrollment continues and more patient data become available **or as patients** from ~~the particular study or~~ **our** ~~trial. As a result, interim data should be viewed with caution until final data are available. Adverse differences between interim data and final data could significantly harm the development of our product candidates and our business prospects with respect thereto. We may also announce or publish preliminary data from preclinical studies or~~ clinical trials ~~that~~ **continue other treatments. Further, others, including regulatory agencies, may not accept or** ~~are~~ **agree** ~~based on a preliminary~~ **with our assumptions, estimates, calculations, conclusions or** ~~analysis~~ **analyses or may interpret or weigh the importance** of ~~final~~ data **differently, which could impact** ~~. Preliminary data from preclinical studies and clinical trials are subject to change following a more comprehensive review of~~ the ~~data from~~ **value of** the **particular product candidate, the approvability or commercialization of a particular product candidate and us in general. In addition, the information we choose to publicly disclose regarding a** particular preclinical study or ~~trial. We also make assumptions, estimations, calculations and conclusions as part of our preliminary analyses of the data, and we may not have received, or had the opportunity to fully and carefully evaluate, all of the data at the time of making such assumptions, estimations, calculations and / or conclusions. As a result, preliminary data remain subject to audit and verification procedures that may result in the final data being different from the preliminary data we previously announced or published. We may also announce or publish topline data from preclinical studies and clinical trials, which are a subset of the total data and are intended to provide the important results from the study or trial. Deeper analysis of the data beyond the topline data may provide more color and context to the results. If the additional color or context shows, in retrospect, that the topline data was incomplete or adverse, it could significantly harm the development of our product candidate and our business prospects with respect thereto. Further, third parties, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses, or they 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 and our business prospects. In addition, the information we announce or publish regarding a particular preclinical study or~~ clinical trial ~~may represent only a portion of~~ **is based on what is typically** extensive information ~~generated from that study or trial~~ , and **you** ~~our~~ - **or** ~~stockholders or other~~ **others** ~~third parties~~ may not agree with what we determine is

material ~~, important~~ or otherwise appropriate information to include in our disclosure. If the **preliminary, topline or** interim ~~, preliminary, or topline~~ data that we report differ ~~materially~~ from ~~final~~ **actual** results, or if **others** ~~third parties~~, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, **DNTH103** ~~our~~ **or any other** product ~~candidates~~ **candidate** may be harmed, which could harm our business ~~prospects~~, ~~operating results or~~ financial condition **, results of operations, cash flows, and prospects. Our current or future clinical trials or those of our future collaborators may reveal significant adverse events or undesirable side effects not seen in our preclinical studies and may result in a safety profile that could halt clinical development, inhibit regulatory approval or limit commercial potential or market acceptance of DNTH103 or any other product candidates or result in potential product liability claims. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects, adverse events or unexpected characteristics. While our completed preclinical studies in NHPs and our Phase 1 clinical trial in humans have not shown any such characteristics, we cannot assure you that such characteristics will not be observed in our future clinical trials. If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to such trials, patients may drop out of our trials, patients may be harmed, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether, including DNTH103. We, the FDA, EU member states, or other applicable regulatory authorities, or an IRB or ethics committee, may suspend any clinical trials of DNTH103 or any other product candidates at any time for various reasons, including a belief that subjects or patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential products developed in the biotechnology industry that initially showed therapeutic promise in early- stage studies and trials have later been found to cause side effects that prevented their further development. Other potential products have shown side effects in preclinical studies that do not present themselves in clinical trials in humans. Even if the side effects do not preclude a product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of an approved product due to its tolerability versus other therapies. In addition, a half- life extension could prolong the duration of undesirable side effects, which could also inhibit market acceptance. Treatment- emergent adverse events could also affect patient recruitment or the ability of enrolled subjects to complete our clinical trials or could result in potential product liability claims. Potential side effects associated with DNTH103, or any other product candidates, may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from DNTH103, or any other product candidates, may not be normally encountered in the general patient population and by medical personnel. Any of these occurrences could harm our business, financial condition, results of operations, cash flows, and prospects significantly. In addition, even if we successfully advance DNTH103 or any other product candidates through clinical trials, such trials will only include a limited number of patients and limited duration of exposure to such product candidates. As a result, we cannot be assured that adverse effects of DNTH103 or any other product candidates will not be uncovered when a significantly larger number of patients are exposed to such product candidate after approval** . Further, ~~announcement~~ **any clinical trials may not be sufficient to determine the effect and safety consequences** of **using** ~~preliminary, interim or~~ **our** ~~topline data~~ **product candidate over a multi- year period. If any of the foregoing events occur or if DNTH103 or any other product candidates prove to be unsafe, our entire pipeline could be affected, which would have a material adverse effect on our business, financial condition, results of operations, cash flows, and prospects. We may expend our limited resources to pursue a particular product candidate, such as DNTH103, and fail to capitalize on candidates that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we intend to focus our research and development efforts on certain selected product candidates. For example, we are initially focused on our most advanced product candidate, DNTH103. As a result, we may forgo or delay pursuit of opportunities with other potential candidates that may later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that candidate 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 candidate. Even if regulatory approval is obtained, any approved products resulting from DNTH103 or any other product candidate may not achieve adequate market acceptance among clinicians, patients, healthcare third- party payors and others in the medical community necessary for commercial success and we may not generate any future revenue from the sale or licensing of such products. Even if regulatory approval is obtained for DNTH103 or any other product candidates, they may not gain market acceptance among physicians, patients, healthcare payors or the medical community. We may not generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive cost and whether it will otherwise be accepted in the market. There are several approved products and product candidates in later stages of development for the treatment of gMG, MMN and CIDP. Market participants with significant influence over acceptance of new treatments, such as clinicians and third- party payors, may not adopt a biologic with a target product profile such as that of DNTH103 or for its targeted indications, and we may not be able to convince the medical community and third- party payors to accept and use, or to provide favorable reimbursement for, any product candidates developed** by us ~~,~~ **or** ~~or~~ **our** ~~differences between~~ **existing or future collaborators. An extended half- life may make it more difficult for patients to change treatments and there is a perception** that **half- life extension** ~~data and the final data,~~ could **exacerbate side effects, each** ~~result in volatility in the price~~ of **which may adversely affect our ability to gain market acceptance. Market acceptance of DNTH103** ~~our~~ **or** ~~common stock~~ **any other product candidates will depend on many factors, including factors that are**

not within our control. Sales of products also depend on the willingness of clinicians to prescribe the treatment. We cannot predict whether clinicians, clinicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that any of our approved products are safe, therapeutically effective, cost effective or less burdensome as compared with competing treatments. If DNTH103 or any other product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product and may not become or remain profitable . We have **never commercialized a product candidate and may lack the necessary expertise, personnel and resources to successfully commercialize a product candidate on our own or together with suitable collaborators. We have never commercialized a product candidate, and we currently have** no ~~experience as~~ **sales force, marketing or distribution capabilities. To achieve commercial success for** a ~~company in~~ **product candidate, which we may license to others, we may rely on the assistance and guidance of those collaborators. For a product candidate for which we retain commercialization rights and marketing approval, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party. Factors that may affect our ability to commercialize a product candidate, if approved, on our own include recruiting and** ~~obtaining~~ **retaining adequate numbers of effective sales and marketing personnel, developing adequate educational and marketing programs to increase public acceptance of our approved product candidate, ensuring regulatory compliance of our employees and third parties under applicable healthcare laws and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time- consuming and could delay the launch of a product candidate upon approval. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of an approved product candidate, we may not generate revenues from them or be able to reach or sustain profitability. We have never completed any late- stage clinical trials and we may not be able to file an IND, a CTA or other applications for** regulatory approval **to commence additional clinical trials on the timelines we expect, and, even if we are able to, the FDA, EMA** ~~for~~ **or** ~~a drug~~ **comparable foreign regulatory authorities may not permit us to proceed and could also suspend / terminate the trial after it has been initiated. We are early in** ~~or~~ **our** ~~biologic. As a company, we have never~~ **development efforts and will need to successfully complete later- stage and pivotal clinical trials in order to** ~~obtained~~ **obtain FDA, EMA, or comparable foreign** regulatory approval **to market** ~~for, or commercialized, a drug or biologic. Should we resume development of~~ our product candidates **. Carrying out clinical trials and the submission of a successful IND or CTA is a complicated process. As an organization, we have limited experience in preparing, submitting and prosecuting regulatory filings. We initiated a global Phase 2 clinical trial of DNTH103 in gMG in the first quarter of 2024, following receipt of FDA clearance of our IND application. We plan to submit a CTA in the European Union in the second quarter of 2024. In addition, pending clearance of the INDs and / or the CTAs that we plan to submit, we anticipate initiating Phase 2 clinical trials of DNTH103 in patients with MMN in the second quarter of 2024 and CIDP in the second half of 2024. However, we may not be able to file the IND or CTA in accordance with our desired timelines. For example, we may experience manufacturing delays or other delays with IND- or CTA- enabling studies, including with suppliers, study sites, or third- party contractors and vendors on whom we depend. Moreover, we cannot be sure that submission of an IND or a CTA or submission of a trial to an IND or a CTA will result in the FDA or EMA or comparable foreign regulatory authorities allowing further clinical trials to begin, or that, once begun, issues will not arise that lead us to suspend or terminate clinical trials. For example, upon submission of an IND or CTA for a Phase 2 clinical trial of DNTH103, the FDA or EMA may recommend changes to our proposed study designs, including the number and size of registrational clinical trials required to be conducted in such Phase 2 programs. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of our product candidates. Additionally, even if regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or a CTA, such regulatory authorities may change their requirements in the future. The FDA, EMA or comparable foreign regulatory authorities may require the analysis of data from trials assessing different doses of the product candidate alone or in combination with other therapies to justify the selected dose prior to the initiation of large trials in a specific indication. Any delays or failure to file INDs or CTAs, initiate clinical trials, or obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all. We are subject to similar risks related to the review and authorization of our protocols and amendments by comparable foreign regulatory authorities. Risks Related to Our Reliance on Third Parties We currently rely and expect to rely in the future on the use of manufacturing suites in third- party facilities or on third parties to manufacture DNTH103 and any other product candidates, and we may rely on third parties to produce and process our products, if approved. Our business could be adversely affected if we are unable to use third- party manufacturing suites or if the third- party manufacturers encounter difficulties in production. We do not currently lease or own any facility that may be used as our clinical- scale manufacturing and processing facility and currently rely on a CDMO, WuXi Biologics (as defined below), to manufacture our product candidate used in our Phase 1 and planned Phase 2 clinical trials. We currently have a sole source relationship with WuXi Biologics for our supply of DNTH103 (see Item 1. " Business — Collaboration, License and Services Agreements " in this Annual Report on Form 10- K for additional information on Dianthus' relationship with WuXi Biologics). If there should be any disruption in such supply arrangement, including any adverse events affecting our sole supplier, Wuxi Biologics** , it ~~is possible~~ **could have a negative effect on the clinical development of our product candidates and other operations while we work to identify and qualify an alternate supply source. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partner for compliance with cGMP requirements and any other regulatory requirements of the FDA or comparable foreign regulatory**

authorities for the manufacture of a product candidate. We perform periodic audits of each CDMO facility that **supports our supply of DNTH103 and review / approve all DNTH103 cGMP- related documentation. We also have a quality agreement with WuXi Biologics that documents our mutual agreement on compliance with cGMPs and expectations on quality- required communications to us. Beyond this, we have no control over the ability of our CDMO to maintain adequate quality control, quality assurance and qualified personnel. If** the FDA ~~may refuse to accept~~ **or a comparable foreign regulatory authority does not approve these facilities and the associated Quality Management System for the manufacture of a product candidate or if it withdraws** any ~~or all~~ **approval in the** future ~~NDAs~~ **, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and materially and adversely affect** ~~or~~ **our ability** ~~BLAs for substantive review or may conclude after review of our data that our application is insufficient~~ to **develop,** obtain regulatory approval for **or market such product candidate, if approved. Similarly, our failure, or the failure of our CDMO, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of a product candidate or drug and harm our business and results of operations. In addition, we have not yet caused** any product candidates ~~. If the FDA does~~ **to be manufactured on a commercial scale and may** not ~~approve~~ **be able to do so for** any ~~future NDAs or BLAs, it may require that we conduct additional costly clinical, preclinical or manufacturing validation studies before it will reconsider our applications. Depending on the extent~~ of ~~these or any other FDA- required studies, approval of any NDA or BLA or other application that we submit may be significantly delayed, possibly for several years, or may require us to expend more resources than we have available. Any failure or delay in obtaining regulatory approvals would prevent us from commercializing~~ our product candidates, ~~generating revenues~~ **if approved. Moreover, our CDMO may experience manufacturing difficulties due to resource constraints, governmental restrictions or as a result of labor disputes or unstable political environments. Supply chain issues, including those resulting from the COVID- 19 pandemic** and ~~achieving~~ **the ongoing military conflicts between Russian** and ~~sustaining~~ **Ukraine and Israel and surrounding areas and the attacks on marine vessels traversing the Red Sea, may affect our third- party vendors and cause delays. Furthermore, since we have engaged WuXi Biologics, a manufacturer located in China, we are exposed to the** ~~profitability~~ ~~--~~ **possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments or political unrest or unstable economic conditions in China** . ~~It~~ **If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. For example, in the event that we need to transfer from WuXi Biologics, which** is ~~also possible~~ **our sole manufacturing source for DNTH103, we anticipate** that ~~additional studies~~ **the complexity of the manufacturing process may materially impact the amount of time it would take to secure a replacement manufacturer. The delays associated with the verification of a new manufacturer** , if ~~performed~~ **we are able to identify** ~~and~~ ~~-~~ **an** ~~completed~~ **alternative source** , **could negatively affect** ~~may not be considered sufficient by the FDA to approve any NDA, BLA or~~ **our** ~~other application that we submit~~ **ability to supply product candidates, including DNTH103, in a timely manner or within budget** . If any **CDMO on which** ~~of these outcomes occur,~~ we ~~may be forced~~ **will rely fails** to **manufacture quantities** ~~abandon the development~~ of ~~our~~ **a** product ~~candidates~~ ~~-~~ **candidate at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability** , ~~which~~ **our business, financial condition, cash flows, and prospects** ~~would~~ **could be materially and adversely affected. In addition, our CDMO and / or distribution partners are responsible for transporting temperature- controlled materials that can be inadvertently degraded during transport due to several factors, rendering certain batches unsuitable for trial use for failure to meet, among others, our integrity and purity specifications. We and our CDMO may also face product seizure or detention or refusal to permit the import or export of products. Our business could be materially adversely affected by business disruptions to our third- party providers that could** materially adversely affect our ~~business~~ **anticipated timelines, potential future revenue** and **financial condition and increase our costs and expenses. Each of these risks** could **delay** ~~potentially cause us to cease operations. We face similar risks for~~ ~~-~~ **or prevent the completion of our preclinical studies and clinical trials** ~~our~~ ~~-~~ **or the approval of any** ~~applications in foreign jurisdictions. Should we resume development~~ of our product candidates **by** ~~, because we may develop them for the treatment of diseases in which there is little clinical experience using new technologies, there is increased risk that~~ the FDA, ~~the EMA, or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results~~ ~~-~~ **result in higher costs** ~~, and these results may be difficult to analyze. Should we resume development of our~~ ~~-~~ **or adversely impact commercialization of our** ~~product~~ **products** ~~candidates, during the regulatory review process, we would need to identify clinical trial designs, success criteria, and endpoints such that the FDA, the EMA, or other regulatory authorities will be able to determine the clinical efficacy and safety profile of any product candidates we may develop. As our product candidates may seek to treat diseases in which there is little clinical experience using new technologies, there is heightened risk that the FDA, the EMA, or other regulatory authorities may not consider the clinical trial design or endpoints that we propose to provide clinically meaningful results (reflecting a tangible benefit to patients)~~ . In addition, ~~the resulting clinical data~~ **we currently rely on foreign CROs** and **CDMOs** ~~results may be difficult to analyze. The FDA~~ , ~~the EMA~~ **including WuXi Biologics** , ~~or~~ **and will likely continue to rely on foreign CROs and CDMOs in the future. Foreign CDMOs may be subject to U. S. legislation, including the proposed BIOSECURE Act, sanctions, trade restrictions and** other **foreign** regulatory ~~authorities may lack~~ **requirements, which could increase** the **cost** ~~specific subject matter knowledge~~ or **reduce** ~~guiding historical precedent to properly analyze~~ the ~~clinical data~~ **supply of material available to us, delay the procurement or supply of such material or have** ~~and~~ ~~-~~ **an** ~~results~~ **adverse effect on our ability to secure significant commitments** from **governments** ~~our clinical trials, which may adversely affect our ability~~ to **purchase** ~~obtain regulatory approval for~~ our ~~product~~

~~candidates~~ **potential therapies** . **For example** ~~Even if the FDA does find our success criteria to be sufficiently validated and clinically meaningful~~ , ~~we may not achieve the pre- specified endpoints to a degree of statistical significance. This may be a particularly significant risk for many of the genetically defined diseases for which we plan to develop product candidates because many of these~~ -- **the biopharmaceutical industry in China** ~~diseases have small patient populations, and designing and executing a rigorous clinical trial with appropriate statistical power~~ is **strictly regulated by** ~~more difficult than with diseases that have larger patient populations. Further, even if we do achieve~~ the ~~pre- specified criteria, we may produce results that~~ **Chinese government. Changes to Chinese regulations or government policies affecting biopharmaceutical companies** are unpredictable ~~or inconsistent with the results of the non- primary endpoints or other relevant data. The FDA also weighs the benefits of a product against its risks, and the FDA may view the efficacy results in the context of safety as not being supportive of regulatory approval. Other regulatory authorities in the European Union and other countries may make similar comments with respect to these endpoints and data. Any product candidates we may develop will be based on a novel technology that makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all. Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize a product candidate we may develop, and any such approval may be for a narrower indication than we seek. We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if any product candidates we may develop meet their safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an~~ **and** ~~FDA Advisory Committee or other regulatory authority recommends non- approval or restrictions on approval. In addition, we~~ may ~~experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials, and the review process. Regulatory authorities also may approve a product candidate for more limited indications than requested, or they may impose significant limitations in the form of narrow indications, warnings or distribution and use restrictions under a Risk Evaluation and Mitigation Strategy, or REMS. These regulatory authorities may require precautions or contra- indications with respect to conditions of use, or they may grant approval subject to the performance of costly post- marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of any product candidates we may develop. Any of the foregoing scenarios could materially harm the commercial prospects for any product candidates we may develop and materially adversely affect our business, financial condition, results of operations and prospects. Even if we obtain regulatory approval of any of our product candidates, the approved products may be subject to post- approval studies and will remain subject to ongoing regulatory requirements. If we fail to comply, or if concerns are identified in subsequent studies, our approval could be withdrawn, and our product sales could be suspended. If we are successful in obtaining regulatory approval for any of our product candidates, regulatory agencies in the U. S. and other countries where a product will be sold may require extensive additional clinical trials or post- approval clinical trials that are expensive and time- consuming to conduct. Alternatively, we may not be able to conduct such additional trials, which might force us to abandon our efforts to develop or commercialize certain product candidates. Even if post- approval studies are not requested or required, after our products are approved and on the market, there might be safety issues that emerge over time that require a change in product labeling, additional post market studies or clinical trials, imposition of distribution and use restrictions under a REMS, or withdrawal of the product from the market, which would cause our revenue to decline. Additionally, any products that we may successfully develop will be subject to ongoing regulatory requirements after they are approved. These requirements will govern the manufacturing, packaging, marketing, distribution, and use of our products. If we fail to comply with such regulatory requirements, approval for our products may be withdrawn, and product sales may be suspended. We may not be able to regain compliance, or we may only be able to regain compliance after a lengthy delay, significant expense, lost revenues and damage to our reputation. A breakthrough therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval. We may seek a breakthrough therapy designation for our product candidates if the clinical data support such a designation for one or more product candidates. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under non- expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification. The regenerative medicine advanced therapy, or RMAT, designation by the FDA for any of our product candidates may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval. We may seek an RMAT designation for our product candidates if the clinical data support such a designation for one or more product candidates. Designation as an RMAT is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a RMAT, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of RMAT designation for our product candidates may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify for RMAT designation, the FDA may later decide that the biological products no longer meet the conditions for qualification. Accelerated approval by the FDA, even if granted for our product candidates, may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive regulatory approval. We may seek accelerated approval of our~~

product candidates using the FDA's accelerated approval pathway. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of accelerated approval was granted. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the Agency, that all advertising and promotional materials intended for dissemination or publication be submitted to the Agency for review which can delay the commercialization of the product. There can be no assurance that the FDA would allow any of the product candidates we may develop to proceed on an accelerated approval pathway. Even if we do receive accelerated approval, however, we may not experience a faster development, regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate FDA approval for our product candidates. Our product candidates may not be eligible for Orphan drug status. We may seek Orphan drug designation for MGTA-145 in other indications or our product candidates if the clinical data support such a designation. For example, the FDA granted orphan designation to MGTA-145 for the mobilization of HSCs to the peripheral blood for collection and subsequent transplant in May 2020. The U. S. and European Union may designate drugs for relatively small patient populations as orphan drugs. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process, but does make the product eligible for orphan drug exclusivity, reduced filing fees and specific tax credits. Generally, if a company receives the first marketing approval for a product with an orphan designation in the clinical indication for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity means that the FDA (or EMA in the European Union) will not approve another application to market the same drug for the same indication, except in limited circumstances, for a period of seven years in the U. S. (the applicable period in the European Union is 10 years). This exclusivity, however, could block the approval of our proposed product candidates if a competitor obtains marketing approval before us. However, even if we obtain orphan drug exclusivity for any of our proposed product candidates, we may not be able to maintain it. For example, if a competitive product is shown to be clinically superior to our product candidates, any orphan drug exclusivity we have will not block the approval of such competitive product. On August 3, 2017, Congress passed the FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified the FDA's preexisting regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The law reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. Moreover, in the Consolidated Appropriations Act of 2021, Congress did not further change this interpretation when it clarified that the interpretation codified in FDARA would apply in cases where the FDA issued an orphan designation before the enactment of FDARA but where product approval came after the enactment of FDARA. The FDA may further reevaluate its regulations and policies under the Orphan Drug Act. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. A fast track designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development, regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval. The FDA has broad discretion whether or not to grant a fast track designation for a particular indication, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Receipt of fast track designation may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not guarantee qualification for the FDA's priority review procedures. In addition, the FDA may withdraw any fast track designation at any time. We may seek fast track designation for our product candidates, but there is no assurance that the FDA will grant this status to any of our proposed product candidates. We may seek priority review designation for our product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process. We may request priority review for our product candidates, however, we cannot assume that our product candidates will meet the criteria for that designation. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster development or regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all. Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. 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 the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent

~~years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years 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 a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could~~ have a material adverse effect on our **collaborators in China which could have an adverse effect on our** business ~~. Further~~, **financial condition, results of operations and prospects. Evolving changes in China' s public health, economic, political, and social conditions and the uncertainty around China' s relationship with other governments, such as the United States and the U. K., could also negatively impact our ability to manufacture our product candidates for our planned clinical trials or have an adverse effect on our ability to secure government funding, which could adversely affect our financial condition and cause us to delay our clinical development programs. If our CDMO, WuXi Biologics, is unable to obtain sufficient raw and intermediate materials on a timely basis or if our CDMO experiences other supply difficulties, our business may be materially and adversely affected. We work closely with our CDMO, WuXi Biologics, to ensure their suppliers have continuity of supply of raw and intermediate materials but cannot guarantee these efforts will always be successful. Our CDMO has experienced, and may experience in the** 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. Separately~~, **raw** ~~since March 2020 when foreign~~ and **intermediate materials supply shortages** ~~domestic inspections of facilities were largely placed on hold, the FDA has been working to resume pre- pandemic inspection activities~~, including ~~routine surveillance, bioresearch monitoring and pre- approval inspections. Should the~~ **those resulting from** ~~FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. In the course of~~ the COVID- 19 pandemic, ~~a number of companies have announced receipt of complete response letters due to the FDA' s inability to complete required inspections for their applications. Regulatory authorities outside the U. S. may adopt similar restrictions or other policy measures in response to the ongoing COVID- 19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions,~~ which could ~~have a~~ **contribute to manufacturing delays and impact the progress of our clinical trials. Further, while we work with our CDMO to diversify their sources of raw and intermediate** ~~material~~ **materials , in certain instances they acquire raw and intermediate materials from a sole supplier, and there can be no assurance that they will be able to quickly establish additional or replacement sources for some materials. A reduction or interruption in supply, and an inability to develop alternative sources for such supply, could** ~~adverse~~ **adversely** ~~effect~~ **affect our ability to manufacture our product candidates in a timely or cost- effective manner and could delay completion of our clinical trials, product testing, and potential regulatory approval of our product candidates. We currently rely, and plan to rely in the future,** on ~~our business. Future shutdowns~~ **third parties to conduct and support** ~~or~~ **our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out** ~~other~~ **their** ~~disruptions could also affect other government agencies~~ **contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates. We utilize and plan to continue to utilize and depend upon independent investigators and collaborators** , such as ~~the SEC~~ **medical institutions** , **CROs** ~~which may also impact our business by delaying review of our public filings~~, ~~to the extent such review is necessary, and our ability to access the public markets. Risks Related to Reliance on Third Parties and Manufacturing We have been and may in the future be subject to many manufacturing risks, any of which could substantially increase our costs, delay clinical programs and limit supply of our product candidates. We have historically contracted~~ -- **contract** ~~with third party manufacturers~~ **testing labs and strategic partners,** to **conduct and** ~~make our product candidates to~~ support **our** preclinical **studies** and clinical trials **under agreements with us** . ~~Our CDMOs may not be able to adopt, adapt~~ **We will rely heavily on these third parties over the course of** ~~or~~ **our preclinical studies and** ~~scale up the manufacturing process in a timely manner to support our future~~ clinical trials ~~. The process of manufacturing our product candidates is complex~~, ~~highly regulated~~ and **we control only certain aspects of** ~~subject to several risks, including: • the~~ **their activities** ~~manufacturing processes are susceptible to product loss due to contamination by adventitious microorganisms, equipment failure, improper installation or operation of equipment, vendor or operator error and improper storage conditions~~. **As a** ~~Even minor deviations from normal manufacturing processes could~~ result **, we** ~~in reduced production yields and quality as well~~ **will** ~~as other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, the manufacturing facilities may need to be closed for an extended period of time to investigate and eliminate the contamination; • the manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor and raw material shortages, financial difficulties of our CDMOs, natural disasters, power failures, local political unrest and numerous other factors; • any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our product candidates. We may also~~ have **less direct** ~~to record inventory write- offs and incur other charges and expenses for product candidates that fail to meet specifications, undertake costly remediation efforts or seek more expensive manufacturing alternatives. The manufacture of our product candidates requires significant~~

~~expertise and capital investment, including the development of advanced manufacturing techniques and process controls.~~ **control** ~~. Manufacturers~~ **over the conduct, timing and completion** of these ~~biopharmaceutical products sometimes encounter difficulties in production, especially during scale- up from the manufacturing process used for~~ preclinical **studies** and ~~early~~ clinical trials ~~to a validated process needed for pivotal clinical studies~~ and ~~commercial launch. These problems include failure to meet target production costs and yields, sub- par quality control testing, including stability of~~ the **management** ~~product, quality assurance system failures, operator error and shortages~~ of **data developed through** ~~qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We cannot assure you that any product quality issues relating to the manufacture of our product candidates will not occur in the future. We do not have and we do not currently plan to acquire or build the facilities or internal capabilities to manufacture bulk drug substance or filled drug product for use in~~ preclinical studies ~~,~~ **and** clinical trials **than would be the case if we were relying entirely upon** ~~or~~ **our** ~~commercialization~~ **own staff** . ~~To a~~ **Nevertheless, we** ~~large~~ ~~--~~ **are** ~~extent,~~ **responsible for ensuring** that ~~makes~~ **each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve** us ~~dependent on the goodwill~~ of ~~our contract manufacturing partners to quickly fix deviations that will inevitably occur during the manufacturing of our product. Any delay or~~ **our regulatory responsibilities** ~~interruption in the supply of clinical trial materials could delay the completion of preclinical studies or clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new pre- clinical studies or clinical trials at additional expense or terminate preclinical studies or clinical trials altogether~~ . We **and our** ~~have no manufacturing facility. As a result, we have been dependent on~~ third- party ~~manufacturers~~ **contractors and CROs are required to comply with GCP regulations** ~~, as well as on~~ **which are guidelines enforced by the FDA and comparable foreign regulatory authorities for any product candidate in clinical development. If we or any of these** third parties **fail to comply** ~~for our supply chain. If we experience problems~~ with **applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot provide assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that** any **of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product generated under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these** third parties ~~,~~ **violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. Any third parties conducting** ~~or~~ **our** ~~the actual demand~~ **clinical trials will not be with our employees and, except** for **remedies available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our product candidates. These third parties may be involved in mergers, acquisitions** ~~our~~ **or similar transactions and may have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could negatively affect their performance on our behalf and the timing thereof and could lead to products that compete directly or indirectly with our current or** future product candidates ~~, if any, exceed our forecasts, the manufacture of adequate supplies of our future product candidates or products could be delayed. We do not own or operate facilities for the manufacture of our future product candidates, if any. We currently have no plans to build our own manufacturing facilities for clinical or commercial operations. We have in the past relied on third party manufacturers for the chemical manufacture of active pharmaceutical ingredient and for the production of final product formulation and packaging for clinical trials, and we expect to rely on such third party manufacturers for any future product candidate we develop. Although alternative third- party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers should we resume clinical development of our product candidates. We may encounter technical difficulties or delays in the transfer of manufacturing on a commercial scale to third party manufacturers. We may be unable to enter into agreements for commercial supply with third party manufacturers or may be unable to do so on acceptable terms. If we are unable to arrange for alternative third- party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or obtain regulatory approval to market them. Reliance on third party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves. These risks include reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, including a failure to manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications, and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third- party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates and could cause us to incur higher costs and prevent us from commercializing our product candidates successfully. In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of products, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties. We have in the past relied on and, should we resume development of our product candidates, may continue to rely on third parties to conduct our preclinical and clinical trials and we may rely on them to perform other tasks for us as well~~ . If these third parties do not successfully carry out their contractual duties ~~, meet~~

~~expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed. We have in the past relied on and, should we resume development of our product candidates, we may continue to rely upon medical institutions, clinical investigators, contract laboratories, our CROs and other third parties to conduct future preclinical studies and clinical trials for our product candidates. We expect to rely heavily on these parties for execution of preclinical and future clinical trials for our product candidates, and we control only certain aspects of their activities. Nevertheless, we will be responsible for ensuring that each of our preclinical and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution. We and any CROs we engage will be required to comply with regulations, including cGCPs and cGLPs for conducting, monitoring, recording and reporting the results of preclinical and clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA and comparable foreign regulatory authorities for any drugs in clinical development. The FDA enforces cGCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs or cGLP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials will comply with cGCPs or cGLPs. In addition, our clinical trials must be conducted with product candidates produced in accordance with the requirements in the FDA's cGMP requirements. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action. If we rely on CROs to conduct future clinical trials of our product candidates, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future preclinical studies and clinical trials will also result in less day- to- day control over the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. If any of our relationships with these third- party CROs terminate, we may not be able to enter into arrangements with alternative CROs. If CROs do not successfully carry out their contractual duties~~ or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols ~~,~~ **or** regulatory requirements or for other reasons, ~~any preclinical studies or~~ **our** clinical trials ~~with which such CROs are associated with~~ may be extended, delayed or terminated **and** ~~. In such cases,~~ we may not be able to **complete development of,** obtain regulatory approval ~~for~~ **of** or successfully commercialize **DNTH103** ~~our~~ **or other** product candidates. ~~As a result~~ **We have collaborations with third parties , including our existing license and development collaboration with Zenas BioPharma. If we are unable to maintain these collaborations,** ~~our~~ **or if** ~~financial results and the~~ **these** ~~commercial prospects~~ **collaborations are not successful, our business could be adversely affected. We have various collaboration and license arrangements, including with Zenas BioPharma** for ~~our~~ **the development and commercialization of DNTH103 in the greater area of China, and we currently hold an exclusive license for worldwide (excluding the greater area of China) development and commercialization rights for certain potential** product candidates **. Further** ~~in the subject indication could be harmed~~ **, we may in the future form** ~~our~~ **or** ~~costs could increase and~~ **seek strategic alliances, create joint ventures** ~~our~~ **or collaborations,** ~~ability to generate revenue could be delayed. Any significant disruption in our~~ **or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates. Collaborations or licensing arrangements that we enter into may not be successful, and any success will depend heavily on the efforts and activities of such collaborators or licensors. If any of our collaborators, licensors or licensees experience delays in performance of, or fail to perform their obligations under, their applicable agreements with us, disagree with our interpretation of the terms of such agreement or terminate their agreement with us, our pipeline of product candidates would be adversely affected. If we fail to comply with any of the obligations under our collaborations or license agreements, including payment terms and diligence terms, our collaborators, licensors or licensees may have the right to terminate our agreements, in which event we may lose intellectual property rights and may not be able to develop,** ~~manufacturer~~ **manufacture, market or sell the products covered by such agreements or may face other penalties under** ~~or~~ **our** ~~supplier relationships~~ **agreements. Our collaborators, licensors or licensees may also fail to properly maintain or defend the intellectual property we have licensed from, if required by our agreement with them, or even infringe upon our intellectual property rights, leading to the potential invalidation of our intellectual property or subjecting us to litigation or arbitration, any of which would be time- consuming and expensive and** could harm our **ability to commercialize our product candidates. Further, any of these relationships may require us to increase our near and long- term expenditures, issue securities that dilute our existing stockholders or disrupt our management and** business. **In addition, collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours. As part of our strategy, we plan to evaluate additional opportunities to enhance our capabilities and expand our development pipeline or provide development or commercialization capabilities that complement our own. We may not realize the benefits of such collaborations, alliances or licensing arrangements.** Any **of these relationships may require us to incur non- recurring and other charges, increase our near and long- term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. We may face** significant ~~delay~~ **competition** in **attracting**

appropriate collaborators, and more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we consider attractive. These companies may have a competitive advantage over us due to ~~the~~ their ~~supply of~~ size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a **competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of 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. Collaborations are complex and time- consuming to negotiate, document and execute. In addition, consolidation among large pharmaceutical and biotechnology companies has reduced the number of potential future collaborators. We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our** product ~~candidate~~ **candidates or bring them to market. Risks Related to Our Business and Operations In order to successfully implement ~~or~~ our ~~its~~ plans and strategies, we will need to increase the size of our organization and we may experience difficulties in managing this growth. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of preclinical and clinical drug development, technical operations, clinical operations, regulatory affairs and, potentially, sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial personnel and systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team working together in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. We are highly dependent on our** key ~~materials~~ **personnel, and we anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our managerial, scientific and medical personnel, including our Chief Executive Officer, Chief Medical Officer, Chief Financial Officer, General Counsel, Chief Accounting Officer and other members of our leadership team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain " key person " insurance** for ~~a clinical trial~~ **any of our executives or other employees. The loss of the services of our executive officers or other key employees** could ~~considerably delay completion~~ **impede the achievement** of ~~clinical trials~~ **our research** , **development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key personnel may be difficult and may take an extended period of time. If we do not succeed in attracting and retaining qualified personnel, it could materially and adversely affect our business, financial condition, cash flows, and results of operations. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources on our employee recruitment and retention efforts. Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties. Our future growth may depend, in part, on our ability to develop and commercialize DNTH103 or other** product ~~testing, potential~~ **candidates in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote any product candidates before we receive** regulatory approval ~~of our product candidates and the commercial launch of our product candidates, if approved, which would impair our ability to generate revenues~~ from the **applicable foreign regulatory authority** ~~sale of our product candidates. Risks Related to Commercialization~~ , ~~Government Regulation~~ and **we** ~~Competition We~~ may never ~~obtain FDA~~ **receive such regulatory** approval for any ~~of our~~ product candidates ~~in the U~~ . **To** ~~S., and even if we do, we may never~~ obtain **separate regulatory** approval ~~for or~~ **in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and** ~~commercialize~~ --- **commercial** ~~any~~ **sales, pricing and distribution** of **DNTH103** ~~our~~ - **or other** product candidates **, and we cannot predict success** in **these** ~~any other jurisdiction~~ **jurisdictions . If we fail to comply with the regulatory requirements in international markets or to receive applicable marketing approvals** , ~~which would limit~~ **our target market will be reduced and** our ability to realize ~~their~~ -- **the** full market potential **of DNTH103 or other product candidates will be harmed, and our business will be adversely affected. Moreover, even if we obtain approval of DNTH103 or other product candidates and ultimately commercialize such product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries. Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CDMOs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CDMOs, suppliers and vendors acting for or on our behalf may engage in misconduct or other improper activities. It is not always possible to identify and deter misconduct by these parties and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Our internal information technology systems, or those of any of our CROs, CDMOs, other contractors, third party service providers or consultants or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper**

access to, use of, or destruction of proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations. In the ordinary course of our business, we and the third parties upon which we rely collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) proprietary, confidential, and sensitive data, including personal data, intellectual property, trade secrets, and other sensitive data (collectively, sensitive information). Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and those of our third- party CROs, CDMOs, other contractors (including sites performing our clinical trials), third party service providers and supply chain companies, and consultants, as well as other partners, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by employees, contractors, consultants, business partners and / or other third parties, or from cyber- attacks by malicious third parties, which may compromise system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, data. Some actors now engage and are expected to continue to engage in cyber- attacks, 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 cyber- attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. 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. To the extent that any disruption or security breach were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of DNTH103, or other product candidates could be delayed. Further, our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third- party systems where information important to our business operations or commercial development is stored. As our employees work remotely and utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations, there are risks to our information technology systems and data. Additionally, 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. 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 be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. 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 of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. We rely on third- party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts. 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. 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 government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); increased investigation and compliance costs; financial loss; and other similar harms. Security incidents and attendant consequences may cause stakeholders (including investors and potential customers) to stop supporting our platform, deter new customers from products, and 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 or from disruptions in, or failure or security breach of, our systems or third- party systems where information important to our business operations or commercial development is stored, or that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. We are subject to stringent and changing laws, regulations and standards, and contractual obligations relating to

privacy, data protection, and data security. The actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), fines and sanctions, private litigation and / or adverse publicity and could negatively affect our operating results and business. We, and third parties with whom we work, are or may become subject to numerous domestic and foreign laws, regulations, and standards relating to privacy, data protection, and data security, the scope of which are changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules. We are or may become subject to the terms of contractual obligations related to privacy, data protection, and data security. Our obligations may also change or expand as our business grows. The actual or perceived failure by us or third parties related to us to comply with such laws, regulations and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, result in litigation and liability, and otherwise cause a material adverse effect on our business, financial condition, cash flows, and results of operations. See the sections titled " Business — Government Regulation — Data Privacy and Security " and " — Other Government Regulation Outside of the United States " located elsewhere in this Annual Report on Form 10- K for a more detailed description of the laws that may affect our ability to operate. 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 have a material adverse effect on the success of 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 may involve the use of hazardous and flammable materials, including chemicals and biological and 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 commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. We may acquire businesses or products, or form strategic alliances, in the future, and may not realize the benefits of such acquisitions. We may acquire additional businesses or products, form strategic alliances, or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new product candidates or products resulting from a strategic alliance or acquisition that delay or prevent us from realizing the expected benefits or enhancing our business. There is no assurance that, following any such acquisition, we will achieve the synergies expected in order to justify the transaction, which could result in a material adverse effect on our business and prospects. We maintain our cash at financial institutions, at times in balances that exceed federally- insured limits. The failure of financial institutions could adversely affect our ability to pay our operational expenses or make other payments. Our cash held in non- interest- bearing and interest- bearing accounts can at times exceed the Federal Deposit Insurance Corporation (" FDIC ") insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank on March 10, 2023. The Federal Reserve subsequently announced that account holders would be made whole. However, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders' access to their accounts and assets held in their accounts may be substantially delayed. For example, Former Dianthus could not access its assets held in its account with Silicon Valley Bank for a period in March 2023, which required Former Dianthus to obtain a short- term loan to fund its operations. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business. We have identified material weaknesses in our internal control over financial reporting which, if not corrected, could affect the reliability of our financial statements and have other adverse consequences. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the financial statements would not be prevented or detected on a timely basis. We have identified material weaknesses in our internal control over financial reporting that we are currently working to remediate, which relate to: (a) general segregation of duties, including the review and approval of journal entries as well as system access that has not been designed to allow for effective segregation of duties; and (b) our accounting software system has certain system limitations that do not allow for an effective control environment. Our management has concluded that these material weaknesses in our internal control over financial reporting are due to the fact that we have limited resources and do not have the necessary business processes and related internal controls formally designed and implemented coupled with the appropriate resources to oversee our business processes and controls. Our management is in the process of developing a remediation plan. The material weaknesses will be considered remediated when our management designs and implements effective controls that operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. Our management will monitor the effectiveness of our remediation plans and will make changes management determines to be appropriate. If not remediated, these material weaknesses could result in material misstatements to our annual or interim financial statements that might not be prevented or detected on a timely basis, or in delayed filing of required periodic reports. If we are unable to assert that our internal control over financial reporting is effective under Section 404 (a) of the Sarbanes- Oxley Act, or, if we become subject to Section 404 (b) of the Sarbanes- Oxley Act and our independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of the internal control over financial reporting, investors

may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be adversely affected and we could become subject to litigation or investigations by Nasdaq, the SEC, or other regulatory authorities, all of which could require additional financial and management resources. Risks Related to Intellectual Property Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage. We rely or may rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates and technologies and to prevent third parties from competing with us. Our success depends in large part on our ability to obtain and maintain patent protection for platform technologies, product candidates and their uses, as well as the ability to operate without infringing on or violating the proprietary rights of others. We own six pending patent applications, and we expect to continue to file patent applications in the United States and abroad related to discoveries and technologies that are important to our business. However, we may not be able to protect our intellectual property rights throughout the world and the legal systems in certain countries may not favor enforcement or protection of patents, trade secrets and other intellectual property. Filing, prosecuting and defending patents on product candidates worldwide would be prohibitively expensive and our intellectual property rights in some foreign jurisdictions may be less extensive than those in the United States. As such, we do not have patents in all countries or all major markets and may not be able to obtain patents in all jurisdictions even if we apply for them. Competitors may operate in countries where we do not have patent protection and could then freely use our technologies and discoveries in such countries to the extent such technologies and discoveries are publicly known or disclosed in countries where patent protection has not been requested. Our intellectual property portfolio is at an early stage, and we do not currently own or in- license any issued patents. Our pending and future patent applications may not result in patents being issued. Any issued patents may not afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or product candidates. Even if these patents are granted, they may be difficult to enforce. Further, any issued patents that we may license or own covering our product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the United States Patent and Trademark Office (" USPTO "). Further, if we encounter delays in any clinical trials or delays in obtaining regulatory approval, the period of time during which we could market product candidates under patent protection would be reduced. Thus, the patents that we may own or license may not afford any meaningful competitive advantage. In addition to seeking patents for some of our technology and product candidates, we may also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share facilities or third- party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in the market . In order to ~~eventually market~~ **protect our proprietary technology and processes, we rely in part on confidentiality agreements with collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors and those affiliated with or controlled by state actors. In addition, while we undertake efforts to protect our trade secrets and other confidential information from disclosure, others may independently discover trade secrets and proprietary information, and, in such cases, we may not be able to assert** any **trade secret rights against such party. Costly and time- consuming litigation could be necessary to enforce and determine the scope** of **our proprietary rights and failure to obtain** ~~our~~ **or maintain trade secret protection could adversely affect our competitive business position. Lastly, if our trademarks and trade names are not registered or adequately protected, then we may not be able to build name recognition in markets of interest and our business may be adversely affected. We may not be successful in obtaining or maintaining necessary rights to** product candidates **through acquisitions and** in **- licenses. Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in- license, or use these third- party proprietary rights. We may be unable to acquire or in- license** any **compositions, methods of use, processes or other third- party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third- party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third- party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third- party intellectual property rights on terms that would allow us to make an appropriate return on investment or at all. If we are unable to successfully obtain rights to required third- party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant product candidate, which could have a material adverse effect on our business, financial condition, results of operations, cash flows, and prospects. While we will normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to a**

product candidate, there may be times when the filing and prosecution activities for patents and patent applications relating to a product candidate are controlled by future licensors or collaboration partners. If any of these future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering a product candidate, we could lose rights to the intellectual property or exclusivity with respect to those rights, our ability to develop and commercialize such candidate may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution and patent applications which may be licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of licensees, future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution. Our future licensors may rely on third- party consultants or collaborators or on funds from third parties such that future licensors are not the sole and exclusive owners of the patents we in- license. If other third parties have ownership rights to future in- licensed patents, they may be able to license such patents to our competitors, and the competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, cash flows, and prospects. It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non- exclusive, thereby giving competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing the same, or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, cash flows, and prospects significantly. We cannot provide any assurances that third- party patents do not exist which might be enforced against our current technology or manufacturing methods, our product candidates, or future methods or product candidates, resulting in either an injunction prohibiting manufacture or future sales, or, with respect to future sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties, which could be significant. For example, we are aware of a certain U. S. patent owned by a third party with claims that are directed to a method of inhibiting complement C1s activity in an individual with an antibody that selectively binds active form of complement component C1s compared to inactive C1s and inhibits complement C1s activity by at least 60 % in a protease assay. Although we do not believe that this is a valid patent, this patent could be construed to cover our anti- C1s antibodies. Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including: the scope of rights granted under the license agreement and other interpretation- related issues; whether and to what extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; our right to sublicense patents and other rights to third parties; our right to transfer or assign the license; the inventorship and ownership of inventions and know- how resulting from the joint creations or use of intellectual property by future licensors and us and / or our partners; and the priority date of an invention of patented technology. We may be subject to patent infringement claims or may need to file claims to protect our intellectual property, which could result in substantial costs and liability and prevent us from commercializing potential products. Because the intellectual property landscape in the biotechnology industry is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our freedom to operate and guarantee that we can operate without infringing on or violating third party rights. If certain of our product candidates are ultimately granted regulatory approval, patent rights held by third parties, if found to be valid and enforceable, could be alleged to render one or more of such product candidates infringing. If a third party successfully brings a claim against us, we may be required to pay substantial damages, be forced to abandon any affected product candidate and / or seek a license from the patent holder. In addition, any intellectual property claims (e. g., patent infringement or trade secret theft) brought against us, whether or not successful, may cause us to incur significant legal expenses and divert the attention of our management and key personnel from other business concerns. We cannot be certain that patents owned or licensed by us will not be challenged by others in the course of litigation. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise funds and on the market price of our Common Stock. Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time- consuming. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that it infringes their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court or administrative body may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent' s claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court or administrative body may determine that the marks asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy received may not be commercially valuable. Further, we may be required to protect our patents through procedures created to attack the validity of a patent at the USPTO. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO

proceedings compared to the evidentiary standard in U. S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. In addition, if our product candidates are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our future licensees and other parties with whom we had business relationships and we may be required to indemnify those parties for any damages they suffer as a result of these claims, which may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of such claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. We may be subject to claims that we have wrongfully hired an employee from a competitor or that employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. As is common in the biotechnology industry, in addition to our employees, we engage and may engage in the services of consultants to assist in the development of our product candidates. Many of these consultants, and many of our employees, were or may have been previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology or pharmaceutical companies including our competitors or potential competitors. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know- how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non- solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations, financial condition and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy- Smith America Invents Act (the " Leahy- Smith Act ") could increase the uncertainties and costs surrounding the prosecution of our owned and any future in- licensed patent applications and the maintenance, enforcement or defense of our owned and any future in- licensed issued patents. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost- effective avenues for competitors to challenge the validity of patents, and enable third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO- administered post- grant proceedings, including post- grant review, inter partes review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 16, 2013, under the Leahy- Smith Act, the United States transitioned to a first- to- file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, 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, results of operations, cash flows, and prospects. In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. U. S. Supreme Court and U. S. Court of Appeals for the Federal Circuit rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations, including in the antibody arts. For example, the United States Supreme Court in Amgen, Inc. v. Sanofi (Amgen) recently held that Amgen' s patent claims to a class of antibodies functionally defined by their ability to bind a particular antigen were invalid for lack of enablement where the patent specification provided twenty- six exemplary antibodies, but the claimed class of antibodies covered a " vast number " of additional antibodies not disclosed in the specification. The Court stated that if patent claims are directed to an entire class of compositions of matter, then the patent specification must enable a person skilled in the art to make and use the entire class of compositions. This decision makes it unlikely that we will be granted U. S. patents with composition of matter claims directed to antibodies functionally defined by their ability to bind a particular antigen. Even if we are granted claims directed to functionally defined antibodies, it is possible that a third party may challenge our patents, when issued, relying on the reasoning in Amgen or other recent precedential court decisions.

Additionally, there have been proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U. S. Congress, the federal courts, the USPTO, and the relevant law- making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and weaken our ability to protect, defend and enforce our patent rights in the future. Geopolitical actions in the United States and in foreign **countries could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement or defense of issued patents. For example, the United States and foreign government actions related to Russia' s invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit- making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations, cash flows, and prospects may be adversely affected. In addition, a European Unified Patent Court (the " UPC ") came into force June 1, 2023. The UPC is a common patent court to hear patent infringement and revocation proceedings effective for member states of the European Union. This enables third parties to seek revocation of a European patent in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Although we do not currently own any European patents or applications, if we obtain such patents and applications in the future, any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce or defend the validity of any European patents we may obtain. We may decide to opt out from the UPC for any future European patent applications that we may file and any patents we may obtain. If certain formalities and requirements are not met, however, such European patents and patent applications could be challenged for non-compliance and brought under the** jurisdiction **of the UPC. We cannot be certain that future European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC. Obtaining and maintaining patent protection depends on compliance with various procedural, document submissions, 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, annuities fees and various other governmental fees on patents and / or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and / or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, 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. Non- compliance 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. If we fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, which might adversely affect our ability to develop and market our products. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third- party patent or may incorrectly predict whether a third party' s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products. In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our pending applications or any future issued patents, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. We may become subject to**

claims challenging the inventorship or ownership of our patents and other intellectual property. We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co- inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co- ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and / or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Our current or future licensors may have relied on third- party consultants or collaborators or on funds from third parties, such as the U. S. government or academic institutions, such that our licensors are not the sole and exclusive owners of the patents we in- licensed. If other third parties have ownership rights or other rights to our in- licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, cash flows, and prospects. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and future licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Our technology licensed from various third parties may be subject to retained rights. Our future licensors may retain certain rights under the relevant agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to the licensed technology in the event of misuse. In addition, the U. S. federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (the " Bayh- Dole Act "). The federal government retains a " nonexclusive, nontransferable, irrevocable, paid- up license " for its own benefit. The Bayh- Dole Act also provides federal agencies with " march- in rights. " March- in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a " nonexclusive, partially exclusive, or exclusive license " to a " responsible applicant or applicants. " If the patent owner refuses to do so, the government may grant the license itself. We may in the future collaborate with academic institutions to accelerate our preclinical research or development. While it is our policy to avoid engaging university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co- developed intellectual property will be free from government rights pursuant to the Bayh- Dole Act. If, in the future, we co- own or license in- technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh- Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected. Risks Related to Government Regulation The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time- consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, such product candidates, and our ability to generate revenue will be materially impaired. The process of obtaining regulatory approvals, both in the United States and abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. We cannot commercialize product candidates in the United States without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidates, including our most advanced product candidate, DNTH103 , we must ~~establish and~~ **demonstrate through lengthy,** ~~comply~~ **complex and expensive preclinical and clinical trials that such product candidates are both safe and effective for each targeted indication. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, a product candidate 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. The FDA and comparable foreign regulatory authorities 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, clinical or other data. A product candidate could be delayed in receiving, or fail to receive,**

regulatory approval for many reasons, including: the FDA or comparable foreign regulatory authorities may disagree with ~~numerous~~ **the design or implementation of our clinical trials; we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe** and ~~varying~~ **effective for its proposed indication; the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; serious and unexpected drug- related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to a product candidate; we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; the data collected from clinical trials of a product candidate may not be acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials; the FDA or the applicable foreign regulatory authority may disagree regarding the formulation, labeling and / or the specifications of a product candidate; the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; and the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in us failing to obtain regulatory approval to market DNTH103 or other product candidates, which would significantly harm our business, results of operations and prospects. If we were to obtain approval, regulatory authorities may approve any such product candidate for fewer or more limited indications than we request, including failing to approve the most commercially promising indications, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for a product candidate, we will not be able to commercialize, or will be delayed in commercializing, such product candidate and our ability to generate revenue will be materially impaired. Disruptions at the FDA and other government agencies could negatively affect the review of our regulatory submissions, which could negatively impact our business. The ability of the FDA to review and approve regulatory submissions can be affected by a variety of factors, including disruptions caused by government shutdowns and public health crises. Such disruptions could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. We may not be able to meet requirements for the chemistry, manufacturing and control of our product candidates. In order to receive approval of our products by the FDA and comparable foreign regulatory authorities, we must show that we and our contract manufacturing partners are able to characterize, control and manufacture our drug products safely and in accordance with** regulatory requirements **. This includes synthesizing the active ingredient, developing** ~~on a jurisdiction- by- jurisdiction basis regarding safety and~~ **an** ~~efficacy~~ **acceptable formulation, performing tests to adequately characterize the formulated product, documenting a repeatable manufacturing process, meeting facility, process and testing validation requirements, and demonstrating that our drug products meet stability requirements . Meeting these CMC requirements is a complex task that requires specialized expertise. If we are not able to meet the CMC requirements, we may not be successful in getting our products approved. We intend to deliver our product candidates via a drug delivery device that will have its own regulatory, development, supply and other risks. We intend to deliver our product candidates via a drug delivery device, such as an injector or other delivery system. There may be unforeseen technical complications related to the development activities required to bring such a product to market, including primary container compatibility and / or dose volume requirements. Our product candidates may not be approved or may be substantially delayed in receiving** ~~Approval~~ **approval** ~~by the FDA in the U. S.,~~ if ~~obtained, does~~ **the devices do** not ~~ensure~~ **gain and / or maintain their own regulatory approvals or clearances. Where** approval **of** ~~by regulatory authorities in other~~ **the** ~~countries or jurisdictions~~ **drug product and device is sought under a single application, the increased complexity of the review process may delay approval** . In addition, **some drug delivery devices are provided by single- source unaffiliated third- party companies. We may be dependent on the sustained cooperation and effort of those third- party companies both to supply the devices and, in some cases, to conduct the studies required for approval or other regulatory clearance of the devices. Even if approval is obtained, we may also be dependent on those third- party companies continuing to maintain such approvals or clearances once they have been received. Failure of third- party companies to supply the devices, to successfully complete studies on the devices in a timely manner, or to obtain or maintain required approvals or clearances of the devices could result in increased development costs, delays in or failure to obtain regulatory approval and delays in product candidates reaching the market or in gaining approval or clearance for expanded labels for new indications. We have and may in the future conduct clinical trials for our product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations. We conducted our Phase 1 clinical trial for DNTH103 in New Zealand, and we may in the future choose to conduct more of our clinical trials outside the United States. We currently intend to conduct our Phase 2 clinical trials for DNTH103 in the United States and outside the United States. Although the FDA may accept data from** clinical trials conducted **outside the United States,** ~~in one country may not be accepted~~ **acceptance of this data is subject to conditions imposed** by ~~regulatory authorities in other~~ **the** ~~countries~~ **FDA. For example , the clinical trial must be well designed** and ~~regulatory approval~~ **conducted and performed by qualified investigators** in **accordance with ethical principles. The trial population must also adequately represent the U. S. population, and the data must be**

applicable to the U. S. population and U. S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend ~~one-~~ on ~~country~~ its determination that the trials also complied with all applicable U. S. laws and regulations. If the FDA does not ~~guarantee regulatory approval in~~ accept the data from any trial that we conduct outside ~~other --~~ the ~~country. Approval processes vary among countries and can involve~~ United States, it would likely result in the need for additional ~~product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical~~ trials , which ~~could~~ would be costly and time- consuming ~~. Regulatory requirements can vary widely from country to country~~ and would delay or permanently halt our development of the applicable product candidates. Even if the FDA accepted such data, it could ~~delay~~ require us to modify ~~or our prevent~~ planned clinical trials to receive clearance to initiate such trials in the ~~introduction of~~ United States ~~our -~~ or ~~products in those countries~~ to continue such trials once initiated . ~~The~~ Other risks inherent in conducting international clinical trials include: foreign regulatory ~~approval process involves all~~ requirements, differences in healthcare services, and differences in cultural customs that could restrict or limit our ability to conduct our clinical trials; administrative burdens of ~~the~~ conducting clinical trials under multiple sets of foreign regulations; foreign exchange fluctuations; diminished protection of intellectual property in some countries; and political and economic risks ~~associated with FDA approval~~ relevant to foreign countries . Our ~~We do not have any~~ product candidates for which we intend to seek approval as biologics may face competition sooner than anticipated. The ACA, includes a subtitle called the BPCIA which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA- licensed reference biological product. Under the BPCIA, an application for a highly similar or " biosimilar " product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12- year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for ~~sale in~~ the competing product containing the sponsor' s own preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity and potency of their product. Our investigational biological products, if approved, could be considered reference products entitled to the 12- year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider a product candidate to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any ~~jurisdiction, including international markets, and we do~~ reference products in a way that is similar to traditional generic substitution for non- biological products is not ~~have experience in obtaining~~ yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. Even if we receive regulatory approval of DNTH103 or other product candidates, we will be subject to extensive ongoing regulatory obligations and continued regulatory review, which may result in ~~international markets. If~~ significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements ~~in international markets~~ or experience unanticipated problems with ~~or~~ our product candidates. Any ~~to obtain and maintain required approvals, or if~~ regulatory approvals ~~in international markets are delayed,~~ that we may receive for DNTH103 ~~our -~~ or ~~target market will be reduced and our ability to realize the~~ other ~~full market potential of our products will be unrealized. Failure to obtain marketing approval in foreign jurisdictions would prevent any~~ product candidates ~~we may develop from being marketed in~~ will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of such ~~jurisdictions, which, in turn, would materially impair our ability to generate revenue. In order to market and sell any~~ product candidates , ~~we may develop in the European Union and many -~~ may ~~other foreign jurisdictions, we or our third- party collaborators must obtain~~ contain significant limitations related ~~separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required~~ to use restrictions ~~obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U. S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U. S., it is required that the product be approved~~ for ~~reimbursement before the product can be approved~~ specified age groups, warnings, precautions ~~for -~~ or contraindications ~~sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the U. S. on a timely basis , if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions,~~ and ~~approval by one regulatory authority outside the U. S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We~~ may include burdensome ~~not be able to file for marketing approvals and may not receive necessary approvals to commercialize our medicines in any jurisdiction, which would materially impair our ability to generate revenue. Even if we obtain marketing approvals for any product candidates we develop, the terms of approvals and ongoing regulation of our products could require the substantial expenditure of resources and may limit how we manufacture and market our products, which could materially impair our ability to generate revenue. Any product candidate for which we obtain marketing approval, along with the manufacturing processes,~~ post- approval ~~clinical data~~ study or risk management requirements. For example, the FDA may require a REMS in order to approve a product candidate, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or comparable foreign regulatory authorities approve a product candidate, the products and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping , labeling, storage, approval, advertising, ~~and promotional --~~ promotion ~~activities for such medicine -~~ , sale, distribution, import

and export will be subject to **comprehensive regulation** ~~continual requirements of and review~~ by the FDA and other **regulatory agencies in the United States and by comparable foreign** regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration **, as well as ongoing compliance with current cGMPs** and ~~listing~~ **GCPs for any clinical trials that we conduct following approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials, restrictions on the manufacturing process, warning or untitled letters, civil and criminal penalties, injunctions, product seizures, detentions or import bans, voluntary or mandatory publicity** requirements **and imposition of restrictions on operations** , ~~cGMP~~ **including costly new manufacturing** requirements ~~relating to quality control, applicable product tracking and tracing requirements, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping~~ . **The occurrence** ~~Even if marketing approval~~ of ~~a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the medicine 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. Accordingly, assuming we, or~~ any **event** ~~collaborators we may have, receive marketing approval for~~ **or** ~~one~~ **penalty described above may inhibit** ~~or~~ **our** ~~more~~ **ability to commercialize DNTH103 or other** product candidates ~~we develop, we,~~ and **generate revenue** ~~such collaborators,~~ and **could require us** ~~our and their contract manufacturers will continue~~ to expend **significant** time ~~, money,~~ and ~~effort~~ **resources** in ~~all areas of~~ **response and could generate negative publicity. We may face difficulties from healthcare legislative reform measures. Existing** regulatory ~~compliance~~ **policies may change** , ~~including manufacturing~~ **and additional government regulations may be enacted that could prevent** , ~~production,~~ **limit or delay regulatory approval of DNTH103 or other** product ~~surveillance~~ **candidates. We cannot predict the likelihood** , ~~and quality control~~ **nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad** . If we ~~and such collaborators~~ **are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we** are not able to ~~comply with post-~~ **maintain regulatory compliance, we may lose any marketing** approval **that** ~~regulatory requirements,~~ we **may** ~~and such collaborators could~~ have **obtained** ~~the marketing approvals for our products withdrawn by regulatory authorities~~ and **we may not** ~~our, or such collaborators', ability to market any future products could be limited, which could adversely affect our ability to~~ achieve or sustain profitability. **See** ~~Further,~~ the ~~cost of compliance with post~~ **section titled " Business — Government Regulation — Healthcare Reform " located elsewhere in this Annual Report on Form 10** - **K for** ~~approval regulations may have~~ a ~~negative effect on~~ **more detailed description of healthcare reforms measures that may prevent us from being able to generate revenue, attain profitability,** ~~our~~ - **or commercialize** ~~business, operating results, financial condition and prospects. Even if our~~ product candidates ~~are approved by government regulators~~ **. Our business operations and current and future arrangements with investigators** , **healthcare professionals** ~~the commercial success of any of our product candidates will depend upon the degree of market acceptance by physicians~~ , ~~patients~~ **consultants** , third- party payors **, patient organizations** and ~~others in the medical community~~ **customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties** . ~~Even~~ **Our business operations and current and future arrangements** with **investigators** ~~the requisite approvals from the FDA in the U. S.~~ , ~~the EMA in the European Union and other regulatory authorities internationally, the commercial success of our product candidates will depend, in part, on the acceptance of physicians, patients and health~~ **healthcare professionals** ~~care payors of our product candidates as medically necessary~~ , **consultants** ~~cost- effective and safe. Even before receiving any potential regulatory approval for a product candidate~~ , ~~we may determine that the clinical trial results for a product candidate suggest that it does not have a product profile that would be competitive compared to other therapeutic options. Any product that we develop or commercialize may not have or gain acceptance by physicians, patients, health care payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. Efforts to educate the medical community and~~ third- party payors ~~on~~ **, patient organizations and customers may expose us to broadly- applicable fraud and abuse and** ~~the~~ **other** ~~benefits of~~ **healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute** our product candidates **abuse or other** ~~comply with applicable healthcare~~ laws and regulations ~~will involve substantial costs~~ **governing the processing of data by healthcare entities** .If our operations are found to be in violation of any of these laws or any other governmental ~~laws and~~ regulations that may apply to us,we may be subject to significant ~~penalties,including~~ civil,criminal and administrative penalties,damages,fines, **imprisonment,** exclusion **of drugs** from government ~~-~~ funded healthcare programs, ~~integrity oversight~~ **such as Medicare** and **Medicaid** ~~reporting obligations to resolve allegations of non- compliance~~ , ~~disgorgement,individual imprisonment,contractual damages,reputational harm,diminished profits~~ and the curtailment or restructuring of our operations. **If** ~~Further,defending against~~ any **of the physicians or other healthcare providers or entities with whom we expect to do business is found to not be in** may require significant **personnel** resources **. Therefore** , **even if we are** ~~including management time and financial resources, and may not be~~ successful **in defending against any such actions that may be brought against us, our business may be impaired** . ~~The degree of market acceptance of~~ **Even if we are able to commercialize DNTH103** ~~our~~ - **or other** product candidates, ~~if~~ **due to unfavorable pricing regulations and / or third- party coverage and reimbursement policies, we may not be able to offer such products at competitive prices which would seriously harm our business. We intend to seek** ~~approved~~ **approval to**

market DNTH103 and other product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for ~~commercial sale, will depend on several factors, including: • the efficacy, durability and safety of~~ such product candidates ~~as demonstrated~~ **, we will be subject to rules and regulations** in ~~clinical trials; • the~~ **those jurisdictions. Our** ~~potential and perceived advantages of product candidates over alternative treatments; • the cost of treatment relative to alternative treatments; • our~~ ability to ~~offer the product for sale at competitive prices; • the clinical indications for which the product candidate is approved by the FDA or the EMA; • the product's convenience and ease of administration compared to alternative treatments; • the willingness of physicians to prescribe new therapies; • the willingness of the target patient population to try new therapies; • the prevalence and severity of any side effects; • product labeling or product insert requirements of the FDA, EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling; • relative convenience and ease of administration; • the strength of marketing and distribution support; • the timing of market introduction of competitive products; • publicity concerning our products or competing products and treatments; • changes in the standard of care for the targeted indications for the product; and • sufficient third- party payor coverage and adequate reimbursement. In addition, we analyze these factors with respect to our product candidates before they are approved by conducting market research. Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched. Further, we may determine not to commercialize a product candidate based on that analysis or based on unfavorable pricing and reimbursement terms. Any product candidate of ours that does not have a competitive product profile compared to other therapeutic options, including those that obtain regulatory approval but fail to achieve market acceptance or commercial success, would adversely affect our business prospects. We currently have no marketing and sales organization and have no experience in marketing products. Should we resume development of our product candidates, if we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue. We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. Should we resume development of our product candidates, we would intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful** **successfully** **. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. There can be no assurance that we will be able to develop in- house sales and distribution capabilities or establish or maintain relationships with third- party collaborators to commercialize any product in the U. S. or overseas. Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates or therapies profitably. Even if we are able to** commercialize any product candidates ~~, such products may become subject to unfavorable pricing regulations, third- party reimbursement practices, or healthcare reform initiatives, which would harm our business. Should we resume development of our product candidates, their success, if approved, depends on the availability of adequate coverage and reimbursement from third- party payors. Because our product candidates represent new approaches to blood and immune reset, we cannot be sure~~ that ~~coverage and reimbursement will be available for, or accurately estimate the potential revenue from our product candidates or assure that coverage and reimbursement will be available for any product that~~ we may develop ~~. In addition, we plan to develop certain of our product candidates to be used in conjunction with gene therapy treatments that have encountered challenges in obtaining coverage and reimbursement, and such challenges may also affect the coverage and reimbursement we may obtain for our product candidates, or may indirectly impact the commercial potential for our product candidates if the gene therapy treatment which with our product candidate would be used is not adequately covered or reimbursed. For additional information regarding laws and regulations related to reimbursement, see " Item 1. Business — Reimbursement. " Obtaining coverage and reimbursement approval of a product from a government or other third- party payor is a time- consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost- effectiveness data for the use of our products on a payor- by- payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to maintain pricing sufficient to achieve or sustain profitability or may require co- payments that patients find unacceptably high. Additionally, third- party payors may not cover, or provide adequate reimbursement for, long- term follow- up evaluations required following the use of product candidates. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. The regulations that govern marketing approvals, pricing, and reimbursement for new medicines vary widely from country to country. For example, some countries require approval of the sale price of a medicine before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a medicine in a particular country, but then be subject to price regulations that delay our commercial launch of the medicine, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the medicine in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval. There is significant uncertainty related to insurance**

~~coverage and reimbursement of newly approved products. Because our product candidates may have a higher cost of goods than conventional therapies, and may require long- term follow- up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. It is difficult to predict at this time what third- party payors will decide with respect to the coverage and reimbursement for our product candidates. There may be significant delays in obtaining reimbursement for newly approved medicines, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or similar regulatory authorities outside the U. S. Moreover, eligibility for reimbursement does not imply that any medicine 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 medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the medicine and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines and may be incorporated into existing payments for other services. We cannot be sure that reimbursement will be available for any medicine that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. Our ability to commercialize any medicines successfully also~~ will depend in part on the extent to which reimbursement for these ~~medicines~~ **products** and related treatments will be available from government health administration authorities, private health insurers ~~,~~ and other organizations. Government authorities and **other** third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. ~~A primary trend in the U. S. healthcare industry and elsewhere is cost containment.~~ Government authorities and **other** third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. **These entities may create preferential access policies for a competitor' s product, including a branded or generic / biosimilar product, over our products in an attempt to reduce their costs, which may reduce our commercial opportunity. Additionally, if any of our product candidates are approved and we are found to have improperly promoted off- label uses of those programs, we may become subject to significant liability, which would materially adversely affect our business and financial condition. See the sections titled " Business — Government Regulation — Coverage and Reimbursement " and " — Regulation in the** European Union ~~drug marketing and reimbursement~~ **" located elsewhere in this Annual Report on Form 10- K for a more detailed description of the government** regulations **and third- party payor practices that** may ~~materially~~ affect our ability to **commercialize** ~~market and receive coverage for our products in the European Member States. Should we resume development of~~ our product candidates ~~, we would intend~~ **. We are subject** to ~~seek approval to market our product candidates in both the~~ U. S. and **certain** ~~in selected~~ foreign ~~jurisdictions~~ **export and import controls, sanctions, embargoes, anti- corruption laws, and anti- money laundering laws and regulations** . ~~If~~ **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, 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 or from recipients in the public or private sector. We may engage third parties to sell products outside the United States, to conduct clinical trials, and / or to** obtain **necessary permits, licenses, patent registrations, and other regulatory** ~~approval~~ **approvals** ~~in one~~ **. We have direct** or ~~more foreign jurisdictions~~ **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** ~~our~~ **or** ~~product candidates~~ **other illegal activities of our employees** . **agents, contractors, and other collaborators, even if** we ~~will be subject to rules~~ **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,** ~~those~~ **the** ~~jurisdictions~~ **loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any** . In some ~~foreign~~ countries, particularly ~~those in~~ **member states of** the European Union, the pricing of ~~biologics~~ **prescription drugs** is subject to governmental control ~~and other market regulations which could put pressure on the pricing and usage of our product candidates~~ . In these countries, pricing negotiations with governmental authorities can take considerable time after ~~obtaining~~ **receipt of** marketing approval ~~of~~ **for** a **therapeutic** ~~product candidate~~ . In addition, ~~market acceptance~~ **there can be considerable pressure by governments** and ~~sales~~ **other stakeholders on prices and reimbursement levels, including as part** of **cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution,** ~~our~~ **or arbitrage between low- priced and high- priced member states, can further reduce prices. To obtain coverage and reimbursement or pricing approvals in some countries, we or current or future collaborators may be required to conduct a clinical trial or other studies that compare the cost- effectiveness of a** product **to** ~~candidates will depend significantly on the~~ **other** ~~availability~~ **available** ~~of adequate coverage and~~ **therapies in order to obtain or maintain** reimbursement ~~from third- party payors for~~ **or pricing approval** ~~our product candidates and may be affected by existing and future health care reform measures. Historically, products launched in the European Union do not follow price structures of the U. S. and generally prices tend to be significantly lower~~ .

Publication of discounts by third- party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If **reimbursement of any product approved for marketing is unavailable or limited in scope or amount, or if** pricing is set at unsatisfactory levels **,** ~~or~~ **our** ~~if reimbursement~~ **business, financial condition, results** of **operations, cash flows,** ~~our~~ **or** ~~products is unavailable or limited in scope or amount~~ **prospects could be materially and adversely affected. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations , including those related to the pricing of prescription pharmaceuticals, as the UK determines which EU laws to replicate** ~~our~~ **or** ~~revenues from sales~~ **replace. If the UK were to significantly alter its regulations affecting the pricing of prescription pharmaceuticals, we could face significant new costs. If we decide to pursue a Fast Track Designation or Orphan Drug Designation** by ~~us or~~ **the FDA, it may not lead to a faster development** ~~our~~ **or regulatory review** ~~strategic partners and the potential profitability of any of our~~ **or approval process. We may seek Fast Track Designation or Orphan Drug Designation for one or more** product candidates ~~in those countries would be negatively affected. Foreign governments often impose strict price controls on approved products, which may adversely affect our future profitability in those countries, and recent federal legislation and actions by federal, state and local governments may permit reimportation of drugs from foreign countries into the U. S., including foreign countries where the drugs are sold at lower prices than in the U. S., which could adversely affect our future profitability. Frequently foreign governments impose strict price controls on newly approved therapeutic products~~ . If ~~we obtain regulatory approval to sell products in foreign countries, we may be unable to obtain~~ a **drug is intended** ~~price that provides an adequate financial return on our investment. Furthermore, we may face competition in the U. S.~~ for **the treatment of a serious** ~~our~~ **or** ~~development candidates~~ **life- threatening condition** and ~~investigational medicines~~ **the drug demonstrates the potential to address unmet medical needs for this condition , the product sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant such designations, so even** if ~~approved, from therapies sourced from foreign countries that have placed price controls on pharmaceutical products. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability. Ongoing healthcare legislative and regulatory reform measures may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates, and may affect the prices we may set. 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 that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any products for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (1) changes to our manufacturing arrangements; (2) additions or modifications to product labeling; (3) the recall or discontinuation of our products; or (4) additional record- keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. For additional information regarding these regulations, statutes or their interpretations, see " Item 1. Business — Governmental Regulation — Current and Future Legislation. " The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect: • the demand for any of our product candidates, if approved; • the ability to set a price that~~ we believe **a particular** ~~is fair for any of our product candidates, if approved; • our ability to generate revenues and achieve or maintain profitability; • the level of taxes that we are required to pay; and • the availability of capital. Additional laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such~~ product candidate is ~~prescribed~~ **eligible** ~~or~~ **for** ~~used. We expect~~ **such designations, we cannot guarantee** that the ~~healthcare reform measures~~ **FDA would decide to grant it. Even if we do receive Fast Track Designation or Orphan Drug Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation or Orphan Drug Designation if it believes** that ~~have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other~~ **the designation** ~~government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Data collection~~ is ~~governed by complex and restrictive regulations governing the use, processing, and transfer of personal information, and compliance with these regulations could result in additional costs and limitations on our ability to collect and process data. Failure to comply with these regulations could subject us to significant penalties, which may adversely affect our business. In the event we decide to conduct clinical trials or enroll subjects in future clinical trials in the European Union or the U. K., we may be subject to additional privacy restrictions. The collection, use, storage, transfer, and other processing of personal data, including personal health data, regarding individuals in the European Economic Area is governed, as of May 2018, by the European Union' s General Data Protection Regulation, or EU GDPR. Following the U. K.' s withdrawal from the European Union, or Brexit, the EU GDPR has been incorporated into U. K.' s laws, or U. K. GDPR and together with the EU GDPR, the GDPR. Despite Brexit, the EU and U. K. GDPR remain largely aligned. Currently, the most impactful point of divergence relates to transfer mechanisms (i. e., the ability for companies in the European Union or the U. K. to transfer personal data to third countries, including the United States), because it requires us to implement a variety of different contractual clauses approved by European Union' s or U. K.' s regulators. This complexity and the additional contractual burden increases our overall risk exposure. There may be further divergence in the future, including with regard to administrative burdens. The U. K. has announced plans to reform the country' s data protection legal framework in its~~

~~Data Reform Bill, which will introduce significant changes from the EU GDPR. This and the subsequent separation of the data protection regimes of these territories mean we are required to comply with separate data protection laws in the European Union and the U. K., which may lead to additional compliance costs and could increase our overall risk exposure as we may~~ no longer **supported by** ~~be able to take a unified approach across the European Union and the U. K., and we will need to amend our processes and procedures to align with the new framework. The~~ data ~~protection obligations of the GDPR continue to apply to U. K.- related processing of personal data in substantially unvaried form~~ - **from** ~~under the U~~ **a clinical development program** . ~~K. General Data Protection~~ **See the section titled " Business — Government** Regulation **— Expedited Development** ~~, or U. K. GDPR. However, going forward, there is an~~ **and Review Programs** ~~increasing risk of divergence in application, interpretation and enforcement of the data protection laws as between the U. K. and the European Union. Achieving and maintaining compliance with the EU GDPR and the U. K. GDPR is a rigorous and time- intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any future European or U. K. activities. For additional information regarding EU GDPR and U. K. GDPR, see " Item 1. Business — Governmental Regulation~~ " **located elsewhere** in this Annual Report on Form 10- K ~~. In~~ **for a more detailed description of** the ~~U~~ **process for seeking Fast Track Designation or Orphan Drug Designation** . ~~S.~~ **General Risk Factors Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate** , **and even if** the ~~data protection landscape~~ **markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all. Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth** is ~~rapidly growing and evolving~~ **subject to many factors** , **including our success in implementing our business strategy, which is subject to many risks** and ~~achieving~~ **uncertainties. Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage** and ~~maintaining compliance with~~ **reimbursement and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. We may become exposed to costly and damaging liability claims, either when testing a product candidate in the clinical or at the commercial stage, and our product liability insurance may not cover all damages from such claims. We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the** current and future ~~U. S. state~~ **use of a product candidate in clinical trials,** and ~~federal privacy laws will be similarly onerous and~~ **the sale of any approved products in the future,** may **expose us to liability claims. These claims may be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such product. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially and** adversely affect ~~our business. For example, if we fail to comply with~~ the **market** ~~California Consumer Protection Act, or~~ **for our products or any prospects for commercialization** ~~CCPA, we could be subject to civil penalties. Further, if we experience a data breach that results in the loss~~ of **our products** ~~personal information of California residents, we may be subject to a private right of action under the CCPA~~ . ~~While there are~~ **Although we believe we** currently ~~exemptions under the CCPA~~ **maintain adequate product liability insurance** for **DNTH103** ~~protected health information that is subject to Health Insurance Portability and Accountability Act, or HIPAA, and for patient information subject to clinical trial regulations, the CCPA may still negatively impact our business activities. There continues to be uncertainty surrounding the enforcement and implementation of the CCPA, which exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. The California Privacy Rights Act, or CRPA, which became effective on January 1, 2023, significantly modifies the CCPA and imposes additional obligations on companies covered by the legislation, including by expanding consumers' rights with respect to certain sensitive personal information, and establishing a state agency vested with the authority to enforce the CCPA. In addition, we may become subject to or affected by new or additional data protection requirements and face increased scrutiny or attention from regulatory authorities. The effects of these laws are potentially significant and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an~~ **and** ~~effort to comply and increase our potential exposure to regulatory enforcement and / or litigation. The CCPA, as amended by the CPRA, has prompted the enactment of similar, comprehensive privacy and data protection legislation in~~ other **product candidates** ~~states. For example , in March 2021, Virginia enacted the Consumer Data Protection Act, or CDPA, which became effective on January 1, 2023. In July 2021, Colorado passed the Colorado Privacy Act, or CPA, which will become effective on July 1, 2023. Additionally, in March 2022, Utah enacted the Utah Consumer Privacy Act, or UCPA, which will become effective on December 31, 2023. Also, in May 2022, Connecticut signed the Connecticut Data Privacy Act, or CTDPA, into law, which will become effective on July 1, 2023. Furthermore, a number of other U. S. states have proposed similar privacy and data protection legislation, and~~ it is possible that ~~certain of~~ **our liabilities could exceed our insurance coverage or that in** ~~these~~ -- **the** ~~proposals~~ **future we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that** will ~~pass. Although~~ **be adequate to satisfy** ~~many~~ - **any liability that may arise. If a successful product liability claim or series** of **claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Litigation costs and** the ~~existing state privacy laws exempt clinical~~ **outcome of litigation could have a** ~~trial~~ **material adverse effect on our business. From time to time, we may be subject to litigation**

claims through the ordinary course of our business operations regarding, but not limited to, securities litigation, employment matters, security of patient and employee personal information **, contractual relations with collaborators** and ~~health information governed~~ **licensors and intellectual property rights. Litigation to defend ourselves against claims** by ~~HIPAA~~ **third parties** , **or to enforce any rights** ~~future privacy and data protection laws may be broader in scope. We also anticipate~~ that **we** ~~more states~~ may **have against third parties** ~~enact legislation similar to the CCPA , which has prompted a number of proposals for new federal and state- level privacy legislation. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and~~ could result in **substantial** ~~increased compliance~~ costs and ~~/~~ **diversion of** ~~or~~ **our** ~~changes in~~ **resources, causing a material adverse effect on our** business ~~practices and policies. Additionally~~ , ~~HIPAA~~ **financial condition** , **results of operations, cash flows, and prospects. Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises such** as ~~amended by~~ **the COVID- 19 pandemic, political crises, geopolitical events, such as the conflict between Russia and Ukraine, or** ~~the~~ **other macroeconomic conditions** ~~Health Information Technology and Clinical Health Act~~ , **which could have a material and adverse effect on** ~~or~~ **our results** ~~HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission~~ of ~~individually identifiable health information~~ **operations, cash flows, and financial condition** . **The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including,** ~~Among~~ **among** other things, ~~HITECH~~ **diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, and uncertainty about economic stability. For example, the COVID- 19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, rising tensions between China and Taiwan, the ongoing conflict in Israel and surrounding areas, the attacks on marine vessels traversing the Red Sea and the ongoing military conflict between Russia and Ukraine have created volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may** ~~makes~~ **make** ~~HIPAA~~ **any necessary debt or equity financing more costly, more dilutive, or more difficult to obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs. We may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in initiating or expanding clinical trials and manufacturing sufficient quantities of materials. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition. The market price of our common stock is expected to be volatile, and the market price of our common stock may drop. The market price of our common stock has been and is likely to continue to be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include: • results of clinical trials and preclinical studies of our product candidates, or those our competitors or our existing or future collaborators; • failure to meet or exceed financial and development projections we may provide to the public; • failure to meet or exceed financial and development projections of the investment community; • if we do not achieve the perceived benefits of the Reverse Merger as rapidly or to the extent anticipated by financial or industry analysts; • announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors; • actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms; • disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies; • additions or departures of key personnel; • significant lawsuits, including patent or stockholder litigation; • if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock; • changes in the market valuations of similar companies; • general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors; • sales of securities by us or our securityholders in the future; • if we fail to raise an adequate amount of capital to fund our operations or continued development of our product candidates; • trading volume of our common stock; • announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments; • adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets; • the introduction of technological innovations or new therapies that compete with our products and services; and • period- to- period fluctuations in our financial results. Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, a recession, depression or other sustained adverse market event could materially and adversely affect our business and the value of our common stock. In the past, following periods of volatility in the market price of a company** ' s ~~privacy and security~~ **securities** ~~standards directly applicable to " business associates , " those independent contractors or agents of covered entities~~ **stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation** that **activists believe is not reflective of** ~~create, receive, maintain, transmit or~~ **our** ~~obtain protected health information in connection~~ **intrinsic value. Activist campaigns that contest or conflict** with ~~providing a service~~ **our strategic direction or seek changes in the composition of our Board of Directors could have an**

adverse effect on ~~behalf of a covered entity~~ **our operating results, financial condition and cash flows** . ~~HITECH also increased~~ **We will incur significant legal, accounting and** ~~the~~ **other** ~~civil and criminal penalties~~ **expenses as a public company** that ~~may be imposed against covered entities~~ **Former Dianthus did not incur as a private company** , **including** ~~business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and~~ costs associated with **public company reporting obligations under** ~~pursuing federal civil actions. In addition, there~~ -- **the Securities** ~~may be additional federal, state~~ and **Exchange Act** ~~non- U. S. laws which govern the privacy and security~~ of ~~health~~ **1934, as amended (the " Exchange Act "). Our management team consists of the executive officers of Former Dianthus, some of whom have not previously managed and operated a public company. These executive officers** and other ~~personal~~ **personnel** ~~information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. In addition, there may be additional federal, state and non- U. S. laws which govern the privacy and security of health and other personal information in certain circumstances. These laws may differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities~~ will ~~conclude that our business practices may not~~ **need to devote substantial time to gaining expertise related to public** ~~comply~~ **company reporting requirements** ~~with current or future statutes, regulations or case law involving applicable fraud~~ and abuse or other laws and regulations governing..... business is found to not be in compliance with applicable laws **and regulations** ~~, they may be subject~~ to **ensure that we** ~~criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Ensuring business arrangements~~ comply with **all of these requirements. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the Board of Directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms. If we no longer qualify as a smaller reporting company or otherwise no longer qualify for** applicable **exemptions, we will be subject to additional** laws **and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results and cash flows. We are subject to the reporting requirements of the Exchange Act** , **which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition** as well as ~~responding to possible investigations by government authorities~~ **other disclosure and corporate governance requirements. However** , ~~can be time~~ **we expect to qualify as a " smaller reporting company, " as such term is defined in Rule 12b** - ~~and resource- consuming and can divert a company's attention away~~ **2 under the Exchange Act, in at least the near term, which will allow us to take advantage of many of the same exemptions** from **disclosure requirements** ~~the business. Laws and regulations governing international operations may preclude us from developing~~ , **including not being** ~~manufacturing and selling certain products outside of the U. S. and require~~ **required** ~~us to develop, implement and maintain costly compliance programs. If we expand our operations outside of the U. S., we must dedicate additional resources~~ to comply with **the auditor attestation requirements of Section 404 of the Sarbanes- Oxley** ~~numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices~~ Act ~~,~~ **and reduced disclosure obligations regarding executive compensation in** ~~or~~ **our** ~~FCPA, prohibits any U~~ **periodic reports and proxy statements** . ~~S. individual~~ **Once we are no longer a smaller reporting company** or **otherwise no longer qualify** ~~business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate~~ for ~~the~~ **these exemptions, we will be required** ~~purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U. S.~~ to comply with ~~certain~~ **additional legal and regulatory requirements applicable to public companies and will incur significant legal,** accounting ~~provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an~~ **and** ~~adequate system of internal accounting controls for international operations. Compliance with the~~ **other** ~~FCPA is expensive~~ -- **expenses to do so** ~~and difficult, particularly in countries in which corruption is a recognized problem~~ . **If we** ~~In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals~~ are **not able** ~~operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Various laws, regulations and executive orders also restrict the use and dissemination outside of the U. S., or the sharing with certain non- U. S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the U. S., it will require us to dedicate additional resources~~ to comply with ~~these~~ -- **the** ~~laws~~ **requirements in a timely manner or at all** , ~~and these laws may preclude us from developing, manufacturing, or~~ **our** ~~selling certain products~~ **financial condition or the market price of our common stock may be harmed. If we fail to maintain proper** and **effective internal controls, our ability to** ~~product~~ **produce accurate financial statements on a timely basis** ~~candidates outside of the U. S., which~~ could **be impaired** ~~limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA's accounting provisions. If~~

~~we or our third- party manufacturers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business~~ . We are subject to ~~numerous environmental~~ **the reporting requirements of the Exchange Act** , ~~health~~ **the Sarbanes- Oxley Act** and ~~safety laws~~ **the rules** and regulations ~~, including those governing laboratory procedures and the handling, use, storage, treatment and disposal~~ of **Nasdaq** ~~hazardous materials and wastes~~ . **The Sarbanes** ~~In the past, our operations have involved the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also have produced hazardous waste products. We generally contracted with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our business operations, environmental damage resulting in costly clean- ~~ **Oxley Act** ~~up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third- party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and / or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. 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 do not currently carry biological or hazardous waste insurance coverage. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work- related injuries, this insurance may not provide adequate coverage against potential liabilities. We are competing against numerous large, established companies that have substantially greater financial, technical, research, manufacturing, marketing, distribution and other resources than us, and our operating results will suffer if we fail to compete effectively. The pharmaceutical and biopharmaceutical industry is characterized by intense competition and rapid and significant technological changes and advancements. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many companies, research institutions and universities are doing research and development work in a number of areas similar to those that we focus on that could lead to the development of new products which could compete with and be superior to our product candidates. We expect technological developments in the pharmaceutical and biopharmaceutical and related fields to occur at a rapid rate, and we believe competition will intensify as advances in these fields are made. Accordingly, we will be required to continue to devote substantial resources and efforts to research and development activities in order to potentially achieve and maintain a competitive position in this field. Products that we develop may become obsolete before we are able to market them or to recover all or any portion of our research and development expenses. Most of the companies with which we compete have substantially greater financial, technical, research, manufacturing, marketing, distribution and other resources than we do, including staff, experienced marketing and manufacturing organizations, and well- established sales forces. In addition, smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. We will be competing with respect to our products with companies that have significantly more experience and expertise in undertaking preclinical testing and human clinical trials with new or improved therapeutic products and obtaining regulatory approvals of such products. A number of these companies already market and may be in advanced phases of clinical testing of various drugs that will or may compete with our product candidates or other future potential product candidates. Our competitors may develop or commercialize products more rapidly than we do or with significant advantages over any products we develop. Our competitors may therefore be more successful in commercializing their products than we are, which could adversely affect our competitive position and business. In addition to larger pharmaceutical or biopharmaceutical companies that may develop different competing technologies or technologies, we will be competing with a number of smaller biotechnology companies. We are aware that collaborations between smaller companies and larger established companies may compete with our programs. Colleges, universities, governmental agencies and other public and private research organizations are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technologies that they have developed, some of which may be directly competitive with our programs and product candidates. In addition, certain gene therapy companies are also developing their own conditioning programs to be used in connection with their therapies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates. Such competitors may also develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement. Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. Our competitors also include companies focused on developing~~

~~technologies to improve the distinct steps of stem cell transplant. Risks Related to Intellectual Property We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business. In November 2016, we entered into a license agreement with Harvard University, or Harvard, pursuant to which we were granted a worldwide license to research, develop and commercialize one or more therapeutic products under certain conditioning- and mobilization- related patents and patent applications owned or controlled by Harvard. Certain of our product candidates are dependent on the patents, know- how and proprietary technology licensed from Harvard. In addition, in March 2018, we entered into an exclusive research, development option and license agreement with Heidelberg Pharma Research GmbH, or Heidelberg Pharma, pursuant to which we intend to combine our proprietary antibodies and Heidelberg Pharma' s amanitin conjugates platform, including our MGTA- 117 product candidate. If we commercialize any products utilizing Heidelberg Pharma' s amanitin conjugates platform, we will be dependent on the intellectual property rights we license from Heidelberg Pharma. On August 1, 2022 we entered into an amendment to the exclusive research, development option and license agreement with Heidelberg Pharma mutually clarifying certain performance obligations. Any material disputes with these licensors or termination of these licenses, or a finding that such intellectual property lacks legal effect, could result in the loss of significant intellectual property rights and could harm our ability to commercialize our product candidates, should we resume development of our product candidates. Certain of our license agreements, including our agreements with Harvard and Heidelberg Pharma, require~~ **requires** ~~us to use diligent efforts or meet development thresholds, to maintain the license, including establishing a set timeline for developing and commercializing products. If we fail to comply with any of the obligations under our license agreements, including payment terms and diligence terms, our licensors may have the right to terminate our agreements, in which event we may lose intellectual property rights and may not be able to develop, manufacture, market or sell the products covered by our agreements or may face other penalties under our agreements. In addition, such a termination could result in the licensor reacquiring the intellectual property rights and subsequently enabling a competitor to access the technology. Any such occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of our license agreements or reduction or elimination of our rights under them may result in our having to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all, which may mean we are unable to develop or commercialize the affected product candidate or cause us to lose our rights under the agreement. Further, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. Accordingly, material disputes may arise between us and our licensor, or our licensor and its licensors, regarding intellectual property subject to a license agreement, including those relating to: • the scope of rights, if any, granted under the license agreement and other interpretation- related issues; • whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement; • whether our licensor or its licensor had the right to grant the license agreement; • whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property without their authorization; • our right to sublicense patent and other rights to third parties under collaborative development relationships; • whether we are complying with our obligations with respect to the use of the licensed technology in relation to our development and commercialization of product candidates; • our involvement in the prosecution of the licensed patents and our licensors' overall patent enforcement strategy; • the allocation of ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and by us and our partners; and • the amounts of royalties, milestones or other payments due under the license agreement. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, increase what we believe to be our financial or other obligations under the relevant agreement, or decrease the financial or other benefits we might otherwise receive under the relevant agreement. On August 1, 2022 we entered into an amendment to the exclusive research, development option and license agreement with Heidelberg Pharma mutually clarifying certain performance obligations. If material disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, or are insufficient to provide us the necessary rights to use the intellectual property, we may be unable to successfully develop and commercialize the affected product candidates. If we or any such licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer. Any material disputes with our licensors or any termination of the licenses on which we depend could have a material adverse effect on our business, financial condition, results of operations and prospects. Should we resume development of our product candidates, our commercial success depends on our ability to obtain, maintain and protect our intellectual property and proprietary technology. Should we resume development of our product candidates, our commercial success would depend in large part on our ability to obtain, maintain and protect intellectual property protection through patents, trademarks, and trade secrets in the U. S. and other countries with respect to our proprietary product candidates. If we do not adequately protect our intellectual property rights, competitors may be able to erode, negate or preempt any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we own and have in- licensed certain issued patents and have filed and may file provisional and non- provisional patent applications in the U. S. or abroad related to our product candidates that are important to our business. Provisional patent applications are not eligible to become issued patents until~~ , among other things, ~~we file a non- provisional patent application within 12 months of the filing of one or more of our related provisional patent applications. If we do not timely file non- provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non- provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents~~ that ~~provide us with any competitive advantage. Moreover, the patent application and approval process is expensive and time- consuming. We may not be able to file and prosecute all necessary or desirable patent~~

applications at a reasonable cost or in a timely manner. In some instances, agreements through which we license patent rights may not give us **maintain effective disclosure controls and procedures and internal** control over **financial reporting** patent prosecution or maintenance, so that we may not be able to control which claims or arguments are presented, how claims are amended, and may not be able to secure, maintain, or successfully enforce necessary or desirable patent protection from those patent rights. We have not had **must perform system** and do not have primary **process evaluation and testing of our internal** control over **financial reporting** patent prosecution and maintenance for certain of the patents and patent applications we license, and therefore cannot guarantee that these patents and applications will be prosecuted or maintained in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. Moreover, some of our in- licensed patents and patent applications are, and our future owned and licensed patents may be, co- owned with third parties. If we are unable to **allow** obtain an exclusive license to any such third- party co- owners' interest in such patents or patent applications, such co- owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co- owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. If the scope of the patent protection we or our licensors obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. **our management** . The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our licensed patents have, or that any of our pending owned or licensed patent applications that mature into issued patents will include, claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage, nor can we assure you that our licenses will remain in force. Other parties have developed or may develop technologies that may be related or competitive with our approach, and may have filed or may file patent applications and may have been issued or may be issued patents with claims that overlap or conflict with our patent applications, either by claiming the same compounds, formulations or methods or by claiming subject matter that could dominate our patent position. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U. S. Furthermore, patents have a limited lifespan. In the U. S., the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to our product candidates. In addition, the patent portfolio licensed to us is, or may be, licensed to third parties, such as outside our field, and such third parties may have certain enforcement rights. Thus, our owned and licensed patents and any patents we own or license in the future could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against another licensee or in administrative proceedings brought by or against another licensee in response to such litigation or for other reasons. The patent protection we obtain for our product candidates may not be sufficient to provide us with any competitive advantage, or our patents may be challenged. Our owned and licensed patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or therapeutics in a non- infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but falls outside the scope of our patent protection or license rights. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business. Currently, a significant portion of our patents and patent applications are in- licensed, though similar risks would apply to any patents or patent applications that we now own or may own or in- license in the future. We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too **to report** late to obtain patent protection on them **the effectiveness** . Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or **our** filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our partners, collaborators, licensees, or licensors, whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees, or licensors, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and / or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. The patent position of biotechnology and pharmaceutical companies carries uncertainty. In addition, the determination of patent rights with respect to pharmaceutical compounds commonly involves complex legal and factual questions, which are dependent upon the current legal and intellectual property context, extant legal precedent and interpretations of the law by individuals. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are characterized by uncertainty. Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the U. S., the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent

applications in the U. S. and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, we cannot be certain that parties from whom we do or may license or purchase patent rights were the first to make relevant claimed inventions, or were the first to file for patent protection for them. If third parties have filed prior patent applications on inventions claimed in our patents or applications that were filed on or before March 15, 2013, an interference proceeding in the U. S. can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such prior applications after March 15, 2013, a derivation proceeding in the U. S. can be initiated by such third parties to determine whether our invention was derived from theirs. Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our owned and licensed patents or pending patent applications may be challenged in the courts or patent offices in the U. S. and abroad. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third- party submission of prior art to the U. S. Patent and Trademark Office, or USPTO, or to other patent offices around the world. Alternately or additionally, we may become involved in post- grant review procedures, oppositions, derivation proceedings, ex parte reexaminations, inter **internal controls over** partes review, supplemental examinations, or interference proceedings or challenges in district court, in the U. S. or in various foreign patent offices, including both national and regional, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. An adverse determination in any such challenges may result in loss of the patent or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, or in denial of the patent application or loss or reduction in the scope of one or more claims of the patent application, any of which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Pending and future patent applications may not result in patents being issued that protect our business, in whole or in part, or which effectively prevent others from commercializing competitive products. Competitors may also be able to design around our patents. Changes in either the patent laws or interpretation of the patent laws in the U. S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the U. S. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than U. S. law does. Any of these outcomes could have a material adverse effect on our ability to generate revenue. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following: • the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case; • patent applications may not result in any patents being issued; • patents that may be issued or in- licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage; • our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates; • there may be significant pressure on the U. S. government and international governmental bodies to limit the scope of patent protection both inside and outside the U. S. for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and • countries other than the U. S. may have patent laws less favorable to patentees than those upheld by U. S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates. Issued patents that we have, may obtain or license may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non- infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors may seek to market generic versions of any approved products by submitting Abbreviated New Drug Applications to the FDA in which they claim that patents owned or licensed by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non- infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed. In addition to the protection afforded by patents, we rely upon trade secret protection, know- how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our contractors, collaborators, scientific advisors, employees and consultants and invention assignment agreements with our consultants and employees. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property

rights under these agreements may not be self- executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. In addition, we may not be able to prevent the unauthorized disclosure or use of our technical know- how or other trade secrets by the parties to these agreements despite the existence of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the contractors, collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation. As a result, we could lose our trade secrets. Enforcing a claim against a third party that illegally obtained and is using our trade secrets, like patent litigation, is expensive and time- consuming and the outcome is unpredictable. In addition, courts outside the U. S. are sometimes less willing or unwilling to protect trade secrets. Moreover, our trade secrets could otherwise become known or be independently discovered by our competitors or other third parties. Competitors and other third parties could purchase our product candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected or sufficient to provide an advantage over our competitors, our competitive position could be adversely affected, as could our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, 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, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects. Third- party claims of intellectual property infringement, misappropriation or other violations may prevent or delay our product discovery and development efforts and have a material adverse effect on our business. Our commercial success depends in part on our avoiding infringement, misappropriation and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Recently, under U. S. patent reform, new procedures including inter partes review and post grant review have been implemented. As stated above, this reform will bring uncertainty to the possibility of challenge to our patents in the future. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Third parties may assert that we are employing their proprietary technology without authorization. For example, we are aware of patents and a patent application owned by a third party with claims that could be construed to cover MGTA- 117. The third- party owner of these patents and patent application may seek to allege that our development and commercialization of MGTA- 117 infringes their patent rights and file a patent infringement lawsuit against us in the future. While we believe we would have valid defenses against any such allegation or lawsuit, such defenses may be unsuccessful. In this regard, patents issued in the U. S. by law enjoy a presumption of validity that can be rebutted only with evidence that is " clear and convincing, " a heightened standard of proof. There may also be third- party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third- party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third- party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be

available on commercially reasonable terms or at all. Even if we obtained such a license, it may only be non- exclusive, which would permit third parties to use the same intellectual property and compete with us. If we are unable to obtain a necessary license to a third- party patent on commercially reasonable terms, or at all, we may be unable to commercialize our product candidates or such efforts may be impaired or delayed, which could in turn significantly harm our business. Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We may not have sufficient resources to bring these actions to a successful conclusion. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses and access to intellectual property owned or controlled by third parties in order to advance our research or allow commercialization of our product candidates. We may fail to obtain these licenses and / or access to such intellectual property at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations and prospects. 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 on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. 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. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, 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. In such an event, our competitors might be able to enter the market earlier than would otherwise have been the case, which would have a material adverse effect on our business. Some intellectual property that we have in- licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as " march- in " rights, certain reporting requirements and a preference for U. S.- based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non- U. S. manufacturers. Many of the intellectual property rights we have licensed are generated through the use of U. S. government funding and are therefore subject to certain federal regulations. As a result, the U. S. government may have certain rights to intellectual property embodied in our product candidates pursuant to the Bayh- Dole Act of 1980, or Bayh- Dole Act. These U. S. government rights in certain inventions developed under a government- funded program include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U. S. government has the right to require us to grant exclusive, partially exclusive, or non- exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as " march- in rights "). The U. S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U. S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the U. S. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the U. S. or that under the circumstances domestic manufacture is not commercially feasible. This preference for U. S. manufacturers may limit our ability to contract with non- U. S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U. S. government funding, the provisions of the Bayh- Dole Act may similarly apply. We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time- consuming and unsuccessful. Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours - **our** is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent' s claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding

involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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 litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations and prospects. Changes to the patent law in the U. S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time- consuming and inherently uncertain. In addition, the U. S. has recently enacted and is currently implementing wide-ranging patent reform legislation. 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 Congress, the federal courts, and the USPTO, 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 the case, Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U. S. Supreme Court held that certain claims to DNA molecules are not patentable. In addition, the case Amgen Inc. v. Sanofi affects the way antibody claims are examined and litigated. We cannot predict how future decisions by the courts, the Congress or the USPTO may impact the value of our patents. In addition, a European Unified Patent Court, or UPC, is scheduled to come into force during 2023. The UPC will be a common patent court to hear patent infringement and revocation proceedings effective for member states of the European Union. This could enable third parties to seek revocation of any of our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time and may adversely affect our ability to enforce or defend the validity of our European patents. We may decide to opt out our European patents and patent applications from the UPC. If certain formalities and requirements are not met, however, our European patents and patent applications could be challenged for non- compliance and brought under the jurisdiction of the UPC. We cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, maintaining, defending and enforcing patents on our 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 of some foreign countries do not protect intellectual property rights 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 patent protection to develop their own drugs and may export otherwise infringing drugs to territories where we have patent protection, but enforcement rights are not as strong as those in the U. S. These drugs may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents 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 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. Many countries have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if 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, which could adversely affect our business, financial condition, results of operations, and prospects. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the U. S., if all

maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest filing date of a non-provisional application to which the patent claims priority. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments, and similar legislation in the European Union. The Hatch- Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations and prospects could be materially harmed. Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets. We employ individuals who were previously employed at universities or other biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may be subject to claims that former employees, collaborators or other third parties have an interest in our owned patent rights, trade secrets or other intellectual property as an inventor or co- inventor. For example, a third party may assert claims against us arising out of conflicting obligations of employees, consultants or others who are involved in developing our product candidates or other technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our owned patent rights, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates and other technologies. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. Intellectual property rights do not necessarily address all potential threats. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we license or own; • we, or our current or future licensors might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own; • we, or our current or future licensors might not have been the first to file patent applications covering certain of our or their inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights; • it is possible that our pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents; • issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; • the patents of others may harm our business; and • we may choose not to file a patent in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent covering such intellectual property. Should any of these events occur, they could harm our business, financial condition, results of operations, and prospects. Risks Related to Our Collaborations with Third Parties Should we resume development of our product candidates, we may depend on collaborations with third parties for the research, development, and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates and our business may be adversely affected. Should we resume development of our product candidates, we may depend on collaborations with third parties for the research, development, and commercialization of certain of the product candidates we may develop. For example, we had collaboration agreements with bluebird bio, Inc. for our Phase 2

trial of MGTA- 145 plus plerixafor for mobilization and collection of stem cells in patients with sickle cell disease, AVROBIO, Inc., or AVROBIO, to evaluate the potential utility of MGTA- 117 for conditioning patients before they receive one of AVROBIO' s investigational lentiviral gene therapies, and Beam Therapeutics, or Beam, to evaluate the potential utility of MGTA- 117 for conditioning of patients with sickle cell disease and beta- thalassemia receiving Beam' s base editing therapies. Each of these collaborations were terminated after our decision in February 2023 to halt further development of our programs. In any collaboration agreements that we may enter into in the future, we have or will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. Our ability to develop our product candidates and generate revenues from our collaborations will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements, as well as the success of the collaborators' underlying therapies. We cannot predict the success of any collaboration that we enter into. Collaborations involving our research programs or any product candidates we may develop pose certain risks to us, including the following: • Collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations. • Collaborators may not pursue development and commercialization of any product candidates we may develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator' s strategic focus, available funding or external factors such as an acquisition that diverts resources or creates competing priorities. • Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing. • A collaborator' s product candidate may have a safety or efficacy profile that would impact the collaborator' s ability to continue to pursue the development and commercialization of its product candidate which in turn would negatively impact our ability to continue to pursue the development and commercialization of our product candidate. • Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our medicines or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours. • Collaborators with marketing and distribution rights to one or more medicines may not commit sufficient resources to the marketing and distribution of such medicine or medicines. • Collaborators may not properly obtain, maintain, enforce, or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation. • Material disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of our medicines or product candidates or that result in costly litigation or arbitration that diverts management attention and resources. • We may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control. • Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. • Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished, or terminated. • Collaborators, including in the gene therapy space, may be unable to financially partner with us to develop our product candidates due to the current challenging conditions in the financial markets and their limited ability to raise capital. • Collaborators may be unable to survive in the current challenging economic environment, and as a result they may be forced to terminate their business operations, including termination of the performance of their collaboration agreements with us. If such collaborations do not result in the successful development and commercialization of products, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed, and we may need additional resources to develop product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval, and commercialization described in this Annual Report on Form 10- K **filing** apply to the activities of our collaborators. We have in the past and may in the future decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of any product candidates we may develop. These relationships, or those like them, may require us to incur non- recurring and other charges, increase our near- and long- term expenditures, issue securities that **year** dilute our existing stockholders , or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators, and the negotiation process is time- consuming and complex. Our ability to reach a definitive collaboration agreement will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator' s evaluation of several factors. If we license rights to any product candidates we or our collaborators may develop, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. Should we resume development of our product candidates, we may not be successful in finding strategic collaborators for continuing development of certain of our product candidates or successfully commercializing or competing in the market for certain indications. Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. 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. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential

~~or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through 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. The collaborator may also consider alternative product candidates or technologies 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. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us. We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time- consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue. In addition, any collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has~~ **as required** ~~final decision- making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire~~ by ~~the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation. Should we resume development of our product candidates, if we are not able to establish collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans. Should we resume development of our product candidates, our product development and research programs and the potential commercialization of any product candidates we may develop will require substantial additional cash to fund expenses. For some of the product candidates we may develop, we may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of 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 clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the U. S., the potential market for the subject product candidate, 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 or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us. Should we resume development of our product candidates, if any party to which we have outsourced certain functions fails to perform its obligations under agreements with us, the development and commercialization of our product candidates and any future product candidates could be delayed or terminated. Should we resume development of our product candidates, to the extent that we rely on third party individuals or other companies to manage the day- to- day conduct of our clinical trials or to manufacture, sell or market our product candidates or any future product candidates, we will be dependent on the timeliness and effectiveness of their efforts. If a clinical research management organization that we might utilize is unable to allocate sufficient qualified personnel to our trials or if the work performed by it does not fully satisfy the rigorous requirements of the FDA, we may encounter substantial delays and increased costs in completing our clinical trials. If a firm producing humanized forms of our molecular antibody product candidates or a manufacturer of the raw material or finished product for our clinical trials is unable to meet our time schedules or cost parameters, the timing of our clinical trials and development of our product candidates may be adversely affected. Any manufacturer that we select may encounter difficulties in scaling- up the manufacture of new products in commercial quantities, including problems involving product yields, product stability or shelf life, quality control, adequacy of control procedures and policies, compliance with FDA regulations and the need for further FDA approval of any new manufacturing processes and facilities. The manufacture of clinical supplies for trials and commercial quantities of our product candidates and any future product candidates are likely to be inherently more difficult and costly than typical chemical pharmaceuticals. This could delay commercialization of any of our product candidates, if approved, or reduce the profitability of these candidates for us. If any of these occur, the development and commercialization of our product candidates could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue such development and commercialization on our own. Risks Related to Employee Matters, Managing Growth and Other Risks Related to Our Business The COVID- 19 pandemic or any future pandemic, epidemic or outbreak of any other highly infectious disease could have a material adverse effect on our business, financial condition and results of operations. The extent to which the COVID- 19 pandemic, or any future pandemic, epidemic or outbreak of any highly infectious disease, impacts our business, financial condition and results of operations will depend on future developments, which are uncertain and cannot be predicted with confidence, including the scope, severity and duration of such pandemic, the emergence and characteristics of new variants, the actions taken to contain~~

the pandemic or mitigate its impact, including the adoption, administration and effectiveness of available vaccines, and the direct and indirect economic effects of the pandemic and containment measures, among others. For example, the COVID- 19 pandemic, including the emergence of various variants, has caused, and could continue to cause, widespread disruptions to the U. S. and global economy and has contributed to significant volatility and negative pressure in financial markets. The rapid development and fluidity of this situation precludes any prediction as to the full adverse impact of the COVID- 19 pandemic. Nevertheless, the COVID- 19 pandemic has affected, and may continue to adversely affect, our business, financial condition and results of operations, and it has had, and may continue to have, the effect of heightening many of the risks described in this Annual Report on Form 10- K. Should we resume development of our product candidates, the COVID- 19 pandemic may have an adverse impact on various aspects of our clinical trials and preclinical studies. These risks include but are not limited to the following: • Impacts on patient dosing and study monitoring, which may be paused or delayed due to changes in policies at various clinical sites, and interruption or delays in the operations of the FDA, among other reasons related to the COVID- 19 pandemic. If the COVID- 19 pandemic continues, other aspects of our future clinical trials will likely be adversely affected, delayed or interrupted, including, for example, site initiation, patient recruitment and enrollment, availability of clinical trial materials and data analysis. Some patients and clinical investigators may not be able to comply with clinical trial protocols and patients may choose to withdraw from our studies or we may choose to, or be required to, pause enrollment and or patient dosing in clinical trials in order to preserve health resources and protect trial participants. It is unknown how long these pauses or disruptions could continue. • We will rely on third parties, including CROs, CDMOs, and other contractors and consultants to, among other things, conduct preclinical and clinical trials, manufacture raw materials, manufacture and supply our product candidates, ship investigational drugs and clinical trial samples, perform quality testing and supply other goods and services to run our business. If any such third party is adversely impacted by restrictions resulting from the COVID- 19 pandemic, including staffing shortages, production slowdowns and disruptions in delivery systems, our supply chain may be disrupted, which could limit our ability to manufacture our future product candidates for our clinical trials and conduct our research and development operations. • We have established a hybrid work- from- home policy for all employees, as well as safety measures for those using our offices and laboratory facilities that are designed to comply with applicable federal, state and local guidelines instituted in response to the COVID- 19 pandemic. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cyber security risk, create data accessibility concerns and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors. • Our employees and contractors conducting non- business critical research and development activities may not be able to access our laboratory for an extended period of time as a result of the COVID- 19 pandemic and the possibility that governmental authorities further modify current restrictions. This could delay timely completion of preclinical activities, including completing investigational new drug, or IND, enabling studies or our ability to select future development candidates, and initiation of additional clinical trials for our other product candidates. • Certain government agencies, such as health regulatory agencies and patent offices, within the U. S. or internationally have experienced, and may continue to experience, disruptions in their operations as a result of the COVID- 19 pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under- resourced to continue to monitor our clinical trials and, as a result, review, inspection and other timelines may be materially delayed. It is unknown how long these disruptions could continue. Any elongation or de- prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates. For example, regulatory authorities may require that we not distribute a product candidate lot until the relevant agency authorizes its release. Such release authorization may be delayed as a result of the COVID- 19 pandemic, which would likely result in delays to our ongoing clinical trials. • The trading prices for our common stock and those of other biopharmaceutical companies have been highly volatile, partly due to the COVID- 19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the COVID- 19 pandemic could materially and adversely affect our business and the value of our common stock. Should we resume development of our product candidates, we will need to grow the size of our organization, and we may experience difficulties in managing this growth. As of December 31, 2022, we had 67 full- time employees. If we resume development of our product candidates, as our development, manufacturing and commercialization plans and strategies develop, and as we continue to operate as a public company, we would expect to need additional managerial, technical, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including: • identifying, recruiting, integrating, maintaining and motivating additional employees; • managing our internal development efforts effectively, including the clinical, FDA and international regulatory review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and • improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to develop, manufacture and commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of their attention away from day- to- day activities in order to devote a substantial amount of time, to managing these growth activities. We may rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including core aspects of regulatory approval, clinical management and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. We may also overextend consultants in certain roles. If we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or

terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. Should we resume development of our product candidates, if we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals. Should we resume development of our product candidates, if we lose key personnel, or if we fail to recruit additional highly skilled personnel, our ability to develop our product candidates will be impaired and our business may be harmed. Should we resume development of our product candidates, our ability to compete in the highly competitive biotechnology and pharmaceutical industries will depend upon our ability to attract and retain highly qualified managerial, scientific and medical personnel with particular subject matter expertise. We are highly dependent on our management team. The loss of the services of such key personnel, and our inability to find suitable replacements, could result in delays in the development of our product candidates and harm our business. Further, unless we are able to replace departed employees effectively, we may require current employees to fill additional roles, and this could overextend their responsibilities. As a result, we may experience increased turnover due to employees being overworked. Employees also may be unable to perform these multiple roles effectively due to time and resource constraints. Additionally, if we are unable to retain key personnel, we may be required to cover the roles previously performed by such employees with consultants. These consultants may lack the same skills and performance of departed employees and, as a result, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. We conduct our operations at our facility in Cambridge, Massachusetts. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we may grant equity awards that vest over time or vest upon the achievement of certain pre- established milestones. The value to employees of equity awards has been, and may continue to be, significantly affected by movements in our stock price that are beyond our control, and these equity awards may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, they may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these agreements provide for at- will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain " key man " insurance policies on the lives of these individuals or the lives of any of our other employees. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit the development and commercialization of our product candidates. We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: • decreased demand for our products; • injury to our reputation; • withdrawal of clinical trial participants and inability to continue clinical trials; • initiation of investigations by regulators; • costs to defend the related litigation; • a diversion of management' s time and our resources; • substantial monetary awards to trial participants or patients; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • loss of revenue; • exhaustion of any available insurance and our capital resources; • the inability to commercialize any product candidate; and • a decline in our share price. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. Although we currently carry clinical trial insurance, the amount of such insurance coverage may not be adequate, we may be unable to maintain such insurance, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. Our internal computer and information technology systems and infrastructure, or those of our collaborators, other contractors or consultants, may fail or suffer security compromises or breaches, which could result in a material disruption of our product development programs. Our internal computer and information technology systems and infrastructure and those of our current and any future collaborators and other contractors or consultants are vulnerable to breakdown or damage or interruption or otherwise may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, system malfunction, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We could also be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems, infrastructure and networks of our company and our vendors, including personal information of our employees and study subjects, and company and vendor confidential or proprietary data, whether stored on our systems or on those of third parties. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and / or systems. We may

experience threats to our data and systems, including malicious codes and viruses, phishing and other cyber- attacks. Cyber- attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber- attacks could include wrongful conduct by insider employees, vendors or other third parties, hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud or cyber- attacks, including the deployment of harmful malware, ransomware, denial- of- service attacks, unauthorized access to or deletion of files, phishing attacks and social engineering and business email compromises, and other means to affect service reliability and threaten or compromise systems, infrastructure, or the security, confidentiality, integrity and availability of information. Because the techniques used by threat actors who may attempt to penetrate and sabotage our computer systems or those of our collaborators or other contractors or consultants change frequently and may not be recognized until launched against a target, we may be unable to anticipate these techniques. Accordingly, if our cybersecurity measures or those of our service providers fail, the market perception of the effectiveness of our security measures could be harmed and our reputation, credibility, customer trust, business, results of operations and financial condition could be damaged. While we have not experienced any such material system failure, accident, cyber- attack or security compromise or breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security compromise or breach were to result in a loss of, damage to, unauthorized access or acquisition, or misuse of our data, systems, infrastructure or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability (including in connection with or resulting from litigation or governmental investigations and enforcement actions), our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed and our business could be otherwise adversely affected. We could be required to expend significant amounts of money and other resources to repair or replace information systems, infrastructure or networks, and we may need to devote significant resources to defend against, respond to and recover from cybersecurity incidents, diverting resources from the growth and expansion of our business. In addition, we could be subject to regulatory actions, regulatory inquiry or investigation and / or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud- based information systems, the related security risks will increase, and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our third- party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security compromise or breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm. We and the third parties with whom we work are increasingly utilizing social media tools as a means of communication both internally and externally, and noncompliance with applicable requirements, policies or contracts due to social media use or negative posts or comments could have an adverse effect on our business. Social media is increasingly being used to communicate about clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates, if any. Social media practices in the biopharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. In addition, our employees or third parties with whom we contract or may contract, such as CROs or CDMOs, may knowingly or inadvertently make use of social media in ways that may not comply with legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property or result in public exposure of personal information of our employees, clinical trial patients and others or information regarding our product candidates or clinical trials along with the potential for litigation related to off- label marketing or other prohibited activities. For example, clinical trial patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that trial enrollment may be adversely impacted, we fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public' s legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. Furthermore, negative posts or comments about us or our product candidates on social media could seriously damage our reputation, brand image and goodwill. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business. Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited. As of December 31, 2022, we had net operating loss carryforwards for federal income tax purposes of $ 272. 9 million, of which $ 17. 5 million begin to expire in 2035 and $ 255. 4 million can be carried forward indefinitely. As of December 31, 2022, we had net operating loss carryforwards for state income tax purposes of $ 272. 6 million, which begin to expire in 2035. As of December 31, 2022, we also had available research and orphan drug tax credit carryforwards for federal and state income tax purposes of $ 12. 3 million and $ 3. 4 million, respectively, which begin to expire in 2035 and 2030,

respectively. Under current law, federal net operating losses generated in taxable years ending after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses may be limited to 80 % of our taxable income annually for tax years beginning after December 31, 2020. Net operating losses generated prior to December 31, 2017, however, have a 20- year carryforward period, but are not subject to the 80 % limitation. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an " ownership change " is subject to limitations on its ability to utilize its pre- change net operating losses or tax credits to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who own at least 5 % of a corporation' s stock increases its ownership by more than 50 percentage points over its lowest ownership percentage (by value) within a rolling three- year period. Utilization of our net operating loss carryforwards and research and orphan drug tax credit carryforwards may be subject to a substantial annual limitation under Section 382 and 383 of the Code due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. The Company has not conducted a formal study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If an ownership change has occurred or does occur in the future, the amount of net operating loss and tax credit carryforwards presented in our financial statements could be limited or expire unutilized. There is also a risk that due to regulatory changes, such as suspensions on the use of net operating losses by federal or state taxing authorities or other unforeseen reasons, our existing net operating losses could expire or otherwise be unavailable to reduce future income tax liabilities. For these reasons, we may not be able to utilize a material portion of the net operating losses and research and orphan drug tax credit carryforwards reflected on our balance sheet, even if we attain profitability, which could potentially result in increased future tax liability to us and could adversely affect our operating results and financial condition. Risks Related to Our Common Stock An active trading market for our common stock may not be sustained. In June 2018, we closed our IPO. Prior to our IPO, there was no public market for our common stock. Although we have completed our IPO and shares of our common stock are listed and trading on the Nasdaq Global Market, an active trading market for our shares may not be sustained. If an active market for our common stock does not continue, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares, sell their shares at or above the prices at which they acquired their shares or sell their shares at the time they would like to sell. Any inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration. Our failure to meet Nasdaq' s continued listing requirements could result in a delisting of our common stock. If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the requirement to maintain a minimum bid price of $ 1. 00 per share of our common stock pursuant to Nasdaq Listing Rule 5450 (a) (1), or the Minimum Bid Price Requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. Any such delisting could also adversely impact our ability to raise additional capital or enter into strategic transactions. On January 31, 2023, we received a written notice from the staff, or the Staff, of Nasdaq' s Listing Qualifications Department, notifying us that, for the 30 consecutive business day period between December 15, 2022 through January 30, 2023, our common stock had not complied with the Minimum Bid Price Requirement. Nasdaq' s written notice does not result in the immediate delisting of our common stock from Nasdaq. In accordance with Nasdaq Listing Rule 5810 (c) (3) (A), the Company has 180 calendar days, or until July 31, 2023, or the Compliance Date, to regain compliance with the Minimum Bid Price Requirement. According to the written notice, if, at any time during this 180- day period, the closing bid price for our common stock is at least $ 1. 00 per share for a minimum of ten consecutive business days, the Staff will provide written confirmation of compliance and the common stock will remain listed on The Nasdaq Global Market. If we do not regain compliance with the Minimum Bid Price Requirement by the Compliance Date, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would be required to transfer our listing to The Nasdaq Capital Market and meet the continued listing requirement for the market value of publicly held shares and all other applicable initial listing standards for The Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and would need to provide written notice to Nasdaq of our intention to cure the deficiency during the additional 180- day compliance period, such as by effecting a reverse stock split, if necessary. As part of its review process, the Staff will make a determination of whether it believes we will be able to cure this deficiency. If the Staff determines that we will not be able to cure the deficiency, then the Staff will provide us written notice that our common stock will be subject to delisting. At that time, we may appeal the Staff' s delisting determination to a Nasdaq Hearing Panel. There can no assurance that, if we receive a delisting notice and appeal the delisting determination by the Staff to the Nasdaq Hearing Panel, such appeal would be successful. We intend to monitor the closing bid price of our common stock and may, if appropriate, consider available options to regain compliance with the Minimum Bid Price Requirement. However, we can provide no assurance that actions taken or not taken by us will restore compliance with Nasdaq' s listing requirements, stabilize the market price of our common stock, improve the liquidity of our common stock or prevent future non- compliance with Nasdaq' s listing requirements. Additionally, if our common stock is not listed on, or becomes delisted from, Nasdaq for any reason, trading our common stock could be conducted only in the over- the- counter, or OTC, market or on an electronic bulletin board established for unlisted securities such as the OTC Bulletin Board, an inter- dealer automated quotation system for equity securities that is not a national securities exchange, and the liquidity and price of our common stock may be more limited than if we were quoted or listed on Nasdaq or another national securities exchange. In such circumstances, you may be unable to sell your common stock unless a market can be established or sustained. The trading price of our common stock has been, and will likely continue to be, highly volatile. The trading price of our common stock may be highly volatile. The stock market in general, and the market for smaller pharmaceutical and biotechnology companies in

particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the purchase price, and you may lose some or all of your investment. The market price for our common stock may be, and has been, influenced by many factors, including but not limited to: • the status of our review of strategic alternatives, including an acquisition, merger, business combination or other transaction; • whether we are able to pursue or consummate a strategic transaction, or whether we pursue a dissolution and liquidation; • the success of existing or new competitive products or technologies; • regulatory actions with respect to our product candidates or our competitors' products and product candidates; • announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments; • the timing and results of preclinical studies for any of our product candidates; • the timing and results of clinical trials of our product candidates; • commencement or termination of collaborations for any of our programs and product candidates; • failure or discontinuation of any of our development programs; • results of clinical trials of product candidates of our competitors; • regulatory or legal developments in the U. S. and other countries; • developments or material disputes concerning patent applications, issued patents or other proprietary rights; • the recruitment or departure of key personnel; • the level of expenses related to any of our product candidates or clinical development programs; • the results of our efforts to develop additional product candidates or products; • actual or anticipated changes in estimates as to financial results or development timelines; • announcement or expectation of additional financing efforts; • sales of our common stock by us, our insiders or other stockholders; • variations in our financial results or those of companies that are perceived to be similar to us; • changes in estimates or recommendations by securities analysts, if any, that cover us; • changes in the structure of healthcare payment systems; • market conditions in the pharmaceutical and biotechnology sectors; • disruptions to political, governmental or regulatory systems, including shutdowns of the government and its agencies; • general economic, industry and market conditions; and • the other factors described in this " Risk Factors " section. We are an " emerging growth company " and a " smaller reporting company, " and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors. We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act **. As a private company** , reduced disclosure obligations regarding executive compensation in our **Former Dianthus has never been required to test its internal controls within a specified** periodic -- **period** reports **. This will require that we incur substantial professional fees** and proxy statements **internal costs to expand our accounting** and exemptions from **finance functions and that we expend significant management efforts. We may experience difficulty in meeting** the **these reporting** requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we completed our IPO, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a **timely manner**) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenue of at least $ 1. 235 billion or **For additional information related** (c) in which we are deemed to be a large accelerated filer, as defined in Rule 12b- 2 under the Exchange Act, and (2) the date on which we have issued more than $ 1. 0 billion in non- convertible debt during the prior three -- **the risks** - year period. Even after we no longer qualify as an **and uncertainties** emerging growth company, we may still qualify as a " smaller reporting company " which would allow us to take advantage of **our compliance** many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act **, see** and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these -- **the section above titled " Risks Related** exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to **Our Business and Operations —** private companies. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected **identified material weaknesses in our internal control over financial reporting which, if** not to " opt out **corrected, could affect the reliability of our financial statements and have other adverse consequences.** " of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (1) irrevocably elect to " opt out " of such extended transition period or (2) no longer qualify as an emerging growth company. We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Accordingly, stockholders must rely on capital appreciation, if any, for any return on their investment. We have never declared nor paid cash dividends on our capital stock. We currently plan to retain all of our future earnings, if any, to finance the operation, development and growth of our business. In addition , **to** the terms of any future debt **material weaknesses described above, we may discover additional weaknesses in** or **our** credit agreements may preclude us from paying dividends. As a **system of internal financial and accounting controls and procedures that could** result **in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system** , capital appreciation **no matter how well designed and operated** , **can provide only reasonable, not absolute, assurance that the control system' s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we are not able to comply with the requirements of Section 404**

of the Sarbanes- Oxley Act, or if ~~any~~ **we are unable to maintain proper and effective internal controls** , **we may not be able to produce timely and accurate financial statements. If that were to happen, the market price** of our ~~common~~ **Common** ~~stock~~ **Stock** ~~will~~ **could decline and we could** be **subject to sanctions** ~~the sole source of gain for~~ **or investigations by Nasdaq, the SEC** ~~our~~ **or** ~~stockholders for the~~ **other regulatory authorities** ~~foreseeable future. Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions~~ . Our **certificate** ~~executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned approximately 43 %~~ of **incorporation and bylaws** ~~our capital stock as of December 31, 2022. This concentration of ownership control could delay, defer or prevent a change in control, entrench our management or the board of directors, or impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire. Provisions in our corporate charter documents~~ and provisions under Delaware law **could make an acquisition of us more difficult and** may prevent ~~or frustrate~~ attempts by our stockholders to ~~change~~ **replace or remove** our management ~~or hinder efforts to acquire a controlling interest in us~~ . Provisions ~~in~~ **of** our ~~corporate charter~~ **certificate of incorporation** and ~~our by- laws~~ **bylaws** may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our **common** stockholders might otherwise receive a premium **price** for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our ~~common~~ **Common** ~~stock~~ **Stock** , thereby depressing the market price of our ~~common~~ **Common** ~~stock~~ **Stock** . In addition, because our ~~board~~ **Board** of ~~directors~~ **Directors** ~~is~~ **will be** responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our ~~board~~ **Board** of ~~directors~~ **Directors** . Among other things, these provisions: • establish a classified board of directors such that all members of the board are not elected at one time; • allow the authorized number of our directors to be changed only by resolution of our ~~board~~ **Board** of ~~directors~~ **Directors** ; • limit the manner in which stockholders can remove directors from the ~~board~~ **Board of Directors** ; • establish advance notice requirements for nominations for election to the ~~board~~ **Board** of ~~directors~~ **Directors** or for proposing matters that can be acted on at stockholder meetings; • require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent; • limit who may call a special meeting of stockholders; • authorize our ~~board~~ **Board** of ~~directors~~ **Directors** to issue preferred stock without stockholder approval, which could be used to institute a " poison pill " that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our ~~board~~ **Board** of ~~directors~~ **Directors** ; and • require the approval of the holders of at least 66. 67 % of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or ~~by- laws~~ **bylaws** . Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the **DGCL** ~~Delaware General Corporation Law~~ , which prohibits ~~a person who owns~~ **stockholders owning in excess of** 15 % ~~or more~~ of our outstanding voting stock from merging or combining with us **. Although we believe these provisions collectively will provide** for ~~a period~~ **an opportunity to receive higher bids by requiring potential acquirors to negotiate with our Board** of **Directors,** ~~three years after the~~ **they** ~~date of~~ **would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove** ~~the~~ **then** ~~transaction in~~ **current management by making it more difficult for stockholders to replace members of the Board of Directors,** which ~~the person acquired 15 % or more of our outstanding voting stock, unless the merger or combination~~ is **responsible** ~~approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders. This could also have the effect of discouraging others from making tender offers~~ for **appointing** ~~our common stock, including transactions that may be in~~ the **members** ~~best interest~~ of ~~our stockholders. These provisions may also prevent changes in our~~ management ~~or limit the price that investors are willing to pay for our stock~~ . Our ~~by- laws~~ **bylaws** provide that, unless we consent in writing to the selection of an alternative forum, certain designated courts will be the sole and exclusive forum for certain legal actions 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, employees or agents. Our ~~by- laws~~ **bylaws** provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of or based on a breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the **DGCL** ~~Delaware General Corporation Law~~ , our charter or our ~~by- laws~~ **bylaws** , or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, which ~~we~~ **for purposes of this risk factor** ~~refer~~ **refers** to herein as the " Delaware Forum Provision. " The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act **of 1933, as amended (the " Securities Act ")** and the Exchange Act. Our ~~by- laws~~ **bylaws** further provide that, unless we consent in writing to an alternative forum, federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, which ~~we~~ **for purposes of this risk factor** ~~refer~~ **refers** to herein as the " Federal Forum Provision. " In addition, our ~~by- laws~~ **bylaws** provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the foregoing Delaware Forum Provision and Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived ~~our~~ **its** compliance with the U. S. federal securities laws and the rules and regulations thereunder. **The** ~~We recognize that the~~ Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on **our** stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, the forum selection clauses in our ~~by- laws~~ **bylaws** may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our

directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. ~~General Risk Factors Adverse developments affecting~~ **We do not anticipate paying any cash dividends in the foreseeable future. The current expectation is that we will retain our future earnings, if any, to fund the growth of our business as opposed to paying dividends. As a result, capital appreciation, if any, of our Common Stock will be your sole source of gain, if any, for the foreseeable future. An active trading market for our Common Stock may not be sustained and our stockholders may not be able to sell their shares of Common Stock for a profit, if at all. An active trading market for our shares of Common Stock may not be sustained. If an active market for our Common Stock is not sustained, it may be difficult for our stockholders to sell their shares at an attractive price or at all. Future sales of shares by existing stockholders could cause our stock price to decline. If securityholders 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. In addition, shares of Common Stock that are subject to outstanding options or warrants of Dianthus are eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If any of the foregoing shares of Common Stock are sold, the trading price of our Common Stock could decline. Our executive officers, directors and principal stockholders will have the ability to control or significantly influence all matters submitted to our stockholders for approval. Our executive officers, directors and principal stockholders, in the aggregate, beneficially own approximately 66 % of our outstanding shares of Common Stock as of March 14, 2024. As a result, if these stockholders were to choose to act together,** ~~the~~ **they** ~~financial services industry~~ **would be able to control or significantly influence all matters submitted to our stockholders for approval** , **as well as our management and affairs. For example, these stockholders, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of us on terms that other stockholders may desire. If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline. The trading market for our Common Stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect to not provide research coverage of our Common Stock, and** such **lack of research coverage may** ~~as actual events or concerns involving liquidity, defaults, or non- performance by financial institutions or transactional counterparties, could~~ adversely affect **the market price** ~~our current and projected business operations, financial condition and results~~ of ~~operations~~ **our Common Stock** . ~~Actual~~ **In the** ~~events~~ - **event** ~~involving limited liquidity~~ **we do have equity research analyst coverage** , ~~defaults, non- performance~~ **we will not have any control over the analysts or the content and opinions included in their reports. The price of** ~~or~~ **our Common Stock could decline if one or more equity research analysts downgrade our stock or issue** other ~~adverse developments~~ **unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our Common Stock could decrease, which in turn could cause our stock price or trading volume to decline. We have broad discretion in the use of our cash and cash equivalents and the proceeds from the 2024 Private Placement and may invest or spend the proceeds in ways with which you do not agree and in ways** that ~~affect financial institutions, transactional counterparties~~ **may not increase the value of your investment. We have broad discretion over the use of** ~~or~~ **our cash and cash equivalents and** ~~other~~ -- **the** ~~companies in~~ **proceeds from** the ~~financial services industry~~ **2024 Private Placement. You may not agree with** ~~or~~ **our decisions** ~~the financial services industry generally~~ , **and** ~~or~~ **our** ~~concerns or rumors about~~ **use of the proceeds may not yield** any ~~events of~~ **return on your investment. Our failure to apply** these **resources effectively** ~~kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. We currently have a deposit account and a collateral account supporting a letter of credit with SVB related to our sublease with Novartis Institutes for Biomedical Research, Inc., or Novartis, and we are currently evaluating our banking relationships. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would~~ **could compromise** ~~have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements and certain other financial instruments with SVB, Signature Bank or~~ **our ability to pursue our growth strategy and we might not** ~~any other financial institution that is placed into receivership by the FDIC may~~ be ~~unable~~ -- **able** to **yield a significant return** ~~access undrawn amounts thereunder. In addition~~ , if any **, on** ~~of the parties with whom we conduct business are unable to access funds pursuant to credit agreements or~~ **our** ~~certain other financial instruments~~ --- **investment of** ~~or lending arrangements, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, and third parties may experience direct impacts from the~~ **these net proceeds** ~~closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry~~ . ~~Similar impacts~~ **You will not** have ~~occurred in~~ the **opportunity** ~~past, such as during the 2008- 2010 financial crisis. Inflation and rapid increases in interest rates have led~~ to **influence our decisions** ~~a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U. S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $ 25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses~~ on **how to use** ~~the sale of such instruments, widespread demands for customer withdrawals or~~ **our cash** ~~other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks~~

~~or financial institutions, or that they would do so in a timely fashion. Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources~~ **resources** ~~and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have such arrangements directly, or the financial services industry or economy in general~~ . **We may be subject** ~~These factors could include, among others, events such as liquidity constraints or failures, the ability~~ to ~~perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships but could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and~~ adverse **legislative** ~~impacts on our~~ -- **or regulatory tax changes** ~~current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following: • Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; • Delayed or lost access to, or reductions in borrowings available under revolving existing credit facilities or other working capital sources and / or delays, inability or reductions in the ability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources; • Potential or actual breach of contractual obligations that require us to maintain letters of credit or other credit support arrangements; • Potential or actual breach of financial covenants in credit agreements or credit arrangements; • Potential or actual cross- defaults in other credit agreements, credit arrangements or operating or financing agreements; or • Termination of cash management arrangements and / or delays in accessing or actual loss of funds subject to cash management arrangements. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and / or projected business operations and financial condition and results of operations. In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by companies with whom we do business, which in turn could have a material adverse effect on our current and / or projected business operations, results of operations and financial condition. For example, a company may fail to make payments when due, default under its agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a company could be adversely affected by any of the liquidity or other risks that are described above as factors~~ that could **negatively** ~~result in material adverse impacts on us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. The bankruptcy or insolvency of any company with whom we do business, any breach or default by a company with whom we do business or the loss of any significant supplier relationship could have a material adverse~~ impact ~~on~~ our ~~business. Changes in tax law could adversely affect our business and~~ financial condition. The rules dealing with U. S. federal, state ~~,~~ and local income taxation are constantly under review by persons involved in the legislative process and by the ~~U. S.~~ Internal Revenue Service and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or ~~holders of~~ our **stockholders** ~~common stock~~ . ~~In recent years, many such changes~~ **We will assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we** have **operations** ~~been made and changes are likely~~ to **determine** ~~continue to occur in~~ the **potential** ~~future. Future changes in tax laws could have a material adverse~~ effect on our business ~~, cash flow, financial condition~~ **and any assumptions we will make about** ~~or~~ **our** ~~results of operations~~ **future taxable income** . We ~~urge investors~~ **cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were** to ~~consult with~~ **be enacted. For example, the United States recently enacted the IRA, which implements, among** ~~their~~ -- **other** ~~legal and~~ **changes, a 1 % excise** tax ~~advisers regarding the implications of changes in tax laws~~ on **certain** ~~an investment in our common~~ stock **buybacks** ~~. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock. 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. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations~~ . In addition, **beginning** ~~any testing by us conducted~~ in **2022,** ~~connection with Section 404 of~~ the ~~Sarbanes- Oxley~~ **Tax Cuts and Jobs** Act ~~of 2002, as amended, or~~ **eliminates the currently available option to deduct research and development expenditures and requires taxpayers to amortize** ~~the~~ **them generally** ~~Sarbanes- Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls~~ over ~~financial reporting~~ **five years. The U. S. Congress is considering legislation** that ~~are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Insufficient internal controls could~~ **would restore** ~~also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock. We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these~~ -- **the** ~~controls annually.~~ **current deductibility of research and**

development expenditures, ~~However~~ **however** , ~~for as long as we are an " emerging growth company " under the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 of the Sarbanes- Oxley Act. We could be an " emerging growth company " up until December 31, 2023. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management' s assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation. Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. As has been widely reported, global credit and financial markets have experienced extreme volatility and disruptions recently, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, uncertainty about economic stability and increased inflation. There~~ **there is** ~~can be~~ no assurance that **the provision** ~~further deterioration in credit and financial markets and confidence in economic conditions~~ will ~~not~~ **be repealed or otherwise modified. Such changes, among others, may adversely affect** ~~occur~~ -- **our** ~~. Our~~ **effective tax rate, results of operation and** general business ~~strategy may~~ **conditions. Our ability to utilize our net operating loss carryforwards and certain other tax attributes is expected to be limited. Our ability to utilize our net operating loss carryforwards and certain other tax attributes to offset future taxable income or tax liabilities is expected to be limited. If we earn taxable income, such limitations could result in increased future income tax liability to us, and our future cash flows could** be adversely affected ~~by any~~ **. In general, our ability to use our federal and state net operating loss and credits carryforwards to reduce future taxable liabilities is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income or tax liabilities to use all of our carryforwards. Under current law, federal net operating loss carryforwards generated in taxable periods beginning after December 31, 2017, may be carried forward indefinitely, but for taxable years beginning after December 31, 2020 the deductibility of** such **net operating loss carryforwards is limited to 80 % of taxable income** ~~economic downturn, volatile business environment or continued unpredictable and unstable market conditions~~ . ~~If the current equity and credit markets deteriorate~~ **Federal net operating losses generated prior to December 31** , ~~or do~~ **2017, however, have a 20- year carryforward period, but are** not **subject** ~~improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. We may also fail~~ to ~~secure additional financing altogether~~ **the 80 % limitation** . **Similar** ~~Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy~~ --- **state law limitations may apply** ~~, financial performance and stock price and could require us to delay or abandon clinical development plans~~ . In addition, **under Sections 382 and 383 of** ~~there~~ -- **the** ~~is a risk that~~ **Internal Revenue Code of 1986, as amended (the " Code "), federal net operating loss and credit carryforwards may become subject to an annual limitation in the event** one or more ~~of~~ **stockholders** ~~our~~ - **or groups of stockholders who** ~~current service providers, manufacturers, collaboration partners and other business partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on~~ **own** ~~schedule and on budget. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks. At December 31, 2022, we had $ 112. 0 million of cash, cash equivalents and marketable securities. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or marketable securities since December 31, 2022, no assurance can be given that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Our financial condition and results of operations may also be impacted by other factors we may not be able to control, such as global supply chain disruptions, global trade disputes or political instability. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn. Securities class action and derivative lawsuits and other legal proceedings are often brought against companies such as ours that could result in substantial costs and divert management' s attention, and our insurance policies may be inadequate and potentially expose us to unrecoverable risks. Securities class action and derivative lawsuits and other legal proceedings are often brought against companies following a decline in the market price of their securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. As a result, we may be more susceptible to these types of lawsuits and legal proceedings than other companies with more stable security prices. In connection with any litigation or other legal proceedings, we could incur substantial costs, and such costs and any related settlements or judgments may not be covered by insurance. Litigation and other disputes may divert management' s attention and resources away from running our business and could otherwise negatively affect our reputation. Any of the foregoing items could have a material adverse effect on our business. We have limited director and officer insurance and commercial insurance policies. Any significant insurance claims would have a material adverse effect on our business, financial condition and results of operations. Insurance availability, coverage terms and pricing continue to vary with market conditions, and insurance coverage is increasingly expensive. We have observed rapidly changing conditions in the insurance markets relating to nearly all areas of traditional corporate insurance and such conditions have resulted in higher premium costs, higher policy deductibles and lower coverage limits. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify, however, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. If we are unable to obtain insurance~~ at **least 5 %** ~~an acceptable cost or otherwise protect against litigation often brought against companies following a decline in the market price~~ of ~~their securities, we will be exposed to significant liabilities that may materially and adversely affect our business and financial position. Actions of activist stockholders could cause us to incur substantial costs, divert management' s attention and resources, and have an adverse effect on our business. Stockholder activism, which could take many forms or arise in a variety of situations, has been increasing recently. From time to time, we may be subject to proxy~~

solicitations or proposals by activist stockholders urging us to take certain corporate actions, or otherwise effect changes or assert influence on our board of directors and management. For example, volatility in the price of our common stock or other reasons may in the future cause us to become the target of stockholder activism. If activist stockholder activities ensue, our business could be adversely affected because responding to proxy contests and reacting to other actions by activist stockholders can be costly and time- consuming, disrupt our operations and divert the attention of management and our employees. For example, we may be required to retain the services of various professionals to advise us on activist stockholder matters, including legal, financial and communications advisors, the costs of which may negatively impact our future financial results. In addition, perceived uncertainties as to our future direction, strategy or leadership created as a consequence of activist stockholder initiatives may result in the loss of potential business opportunities, harm our ability to enter into strategic transactions, harm our ability to attract new investors, customers, employees and joint venture partners and cause our stock price to experience periods of volatility or stagnation. Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations, and those of our CDMOs, our CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man- made disasters or business interruptions for which we are predominantly self- insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man- made or natural disaster or other business interruption. Our internal computer systems, or those used by our CDMOs, CROs or other contractors or consultants, may fail or suffer security breaches. Despite the implementation of security measures, our internal computer systems and those of our future CDMOs, future CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. If such a system failure or security breach were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we may rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, including potential lawsuits from patients, collaborators, employees and / or stockholders, and the further development and commercialization of our product candidates could be delayed. Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and / or negligent conduct that fails to: comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the U. S. and similar foreign fraudulent misconduct laws, report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the U. S., our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. Our relationships with healthcare providers and physicians and third- party payors will be subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. Healthcare providers, physicians and third- party payors in the U. S. and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third- party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti- Kickback Statute, the False Claims Act, laws and regulations related to the reporting of payments to physicians and teaching hospitals, and HIPAA, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission (s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record- keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. For additional information, see " Item 1. Business — Governmental Regulation — Other Regulatory Matters. " The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies often scrutinize interactions between healthcare companies and healthcare providers, and this scrutiny has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as

~~responding to possible investigations by government authorities, can be time- and resource- consuming and can divert~~ a company' s ~~attention from~~ **stock increase** ~~the~~ **their** ~~business. The failure to comply~~ **ownership by more than 50 percentage points over their lowest ownership percentage** ~~with~~ **within** ~~any of~~ **a rolling** ~~these~~ **three - year period (referred** ~~laws or regulatory requirements subjects entities~~ to **as** ~~possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can~~ **an " ownership change "). Similar** ~~result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and~~ state ~~funded healthcare programs, contractual damages and~~ **law limitations may apply. There may also be periods during which** the **use** ~~curtailment or restricting~~ of ~~our~~ **net** ~~operations~~ **operating loss carryforwards** ~~, as well as additional reporting obligations~~ and ~~oversight if we become subject to a corporate integrity agreement or~~ other **tax attributes** ~~agreement to resolve allegations of non- compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management' s attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way. In connection with our IPO, we adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations, guidance or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions~~ are **suspended** ~~instituted against us, and we are not successful in defending ourselves or asserting our~~ **or** ~~rights~~ **otherwise limited** ~~, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of~~ which could **accelerate** ~~adversely affect our~~ **or permanently increase taxes owed** ~~ability to operate our business and our results of operations~~ . **Following** ~~In addition,~~ the **Reverse Merger,** ~~approval and commercialization of any of~~ our **tax carryforwards** ~~product candidates outside the U. S.~~ will **be attributable to both the historic pre- Reverse Merger net operating losses of Former Dianthus and the historic pre- Reverse Merger net operating losses and credits of Dianthus. As of December 31, 2023, we had federal net operating loss carryforwards of $ 320. 7 million, all of which can be carried forward indefinitely. As of December 31, 2023, Dianthus had state net operating loss carryforwards of $ 299. 1 million, which begin to expire in 2035. As of December 31, 2023, Dianthus** also **had available research** ~~likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices. As a public company, and particularly after we are no longer an~~ **and orphan drug tax credit carryforwards** ~~" emerging growth company, " we will incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also anticipate that we will incur costs associated with relatively recently adopted corporate governance requirements, including requirements of the SEC and the Nasdaq Global Market. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time- consuming and costly. We also expect that these rules and regulations may make it more difficult and more expensive~~ for **federal** ~~us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers. We are currently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Pursuant to Section 404 of the Sarbanes- Oxley Act, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. While we remain an~~ **and state income tax purposes of $ 14. 8 million** ~~emerging growth company, however, we will not be required to include an~~ **and $ 3** ~~attestation report on internal control over financial reporting issued by our independent registered public accounting firm~~ . **5 million, respectively** ~~We conduct a process each year to document and evaluate our internal control over financial reporting~~ , which **begin** ~~is both costly and challenging. In this regard, we dedicate internal resources, engage outside consultants and adopt a detailed work plan~~ to **expire** ~~assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result~~ in **2035** ~~an~~ **and 2030, respectively** ~~adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements~~ . We have ~~broad discretion over the use of our cash and investments and may~~ not ~~use them effectively. Our management~~ **conducted a formal study to assess whether an ownership change** has **occurred** ~~broad discretion to use our~~ - **or** ~~cash~~ **whether there have been multiple ownership changes since inception; however, the Reverse Merger is expected to result in** ~~and~~ - **an ownership change. For** ~~investments to fund our operations and could spend~~ these **reasons, we** ~~funds in~~

~~ways that~~ do not ~~improve our results~~ **expect to be able to utilize a material portion** of **the net** ~~operations~~ **operating** ~~or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial~~ losses ~~that could have a material adverse effect on our business, cause the price of our common stock to decline~~ and ~~delay the development of our product candidates. Pending the use of our cash and investments to fund our operations, we may invest these resources in a manner that does not produce income or that loses value. If securities or industry analysts do not publish~~ research ~~or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline. The trading market for our common stock may be influenced, in part, by the research and reports that industry or securities analysts publish about us or our business. If no or few securities or industry analysts cover our business, or one or more of the analysts who cover us issues an~~ **and orphan drug tax credit carryforwards** ~~adverse opinion about our company, our stock price may decline~~ . **64** ~~If one or more of these analysts ceases research coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Additionally, if analyst estimates for the commercial value of our product candidates differ materially from the ultimate commercial value of such candidates, the price of our common stock may decline and our ability to raise capital may be impaired. 85~~