Risk Factors Comparison 2025-03-11 to 2024-03-21 Form: 10-K

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SUMMARY OF RISK FACTORS • 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 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; • 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 **current or** 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 **Tenacia** ~~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 **may** ~~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 **continue to** 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~~ **has** incurred significant operating losses ~~and has~~ **. We have** utilized substantially all of our resources ~~to conduct~~ **conducting** research and development activities (including with respect to our DNTH103 program) ~~and~~ **, ~~undertake~~ undertaking** preclinical studies of product candidates, conducting ~~a~~ clinical ~~trial~~ **trials** of ~~our most advanced product candidate~~ and ~~the~~ manufacturing **DNTH103** ~~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~~ **future** clinical trials will begin or be completed on time, if at all. In addition, while we initiated ~~a~~ **two** Phase 2 clinical **trials and one Phase 3 clinical** trial ~~of~~ **with** DNTH103 in patients with gMG ~~in the first quarter of 2024~~ **, MMN and CIDP, respectively**, 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 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 **net proceeds from our ATM offering, and** have incurred significant recurring losses, including net losses of $ **85. 0 million and $** 43. 6 ~~million and $ 28. 5~~ million for the years ended December 31, **2024 and** 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 **and a Phase 3 clinical trial**, 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~~ **future** 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 **continue to** incur additional costs associated with operating as a public company that **we** ~~Former Dianthus~~ did not incur as a private company. Accordingly, we will require substantial additional funding to continue our operations. Based on our 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 currently expect. Our future capital requirements will depend on many factors, including: • the timing and progress of preclinical and clinical development activities; • the number and scope of preclinical and clinical programs we pursue; • our ability to establish an acceptable safety profile with IND- enabling toxicology studies to enable clinical trials; • successful patient enrollment in, and the initiation and completion of, larger and later- stage clinical trials; • per subject trial costs; • the number ~~and ,~~ extent **and scope** of trials required for regulatory approval; • the countries in which the trials are conducted; • the length of time required to enroll eligible subjects in clinical trials; • the number 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 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 third parties, if any, and the performance of any such third party; • hiring and retaining research and development personnel; • our arrangements with our contract development and manufacturing organizations (“ CDMOs ”), and contract research organizations (“ CROs ”); • development and timely delivery of commercial- grade drug formulations that can be used in our planned clinical trials and for commercial launch; • the impact of any business interruptions to our operations or to those of the third parties with whom we work; and • 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~~ **common** ~~Stock~~ **stock** and the 2024 Pre- Funded Warrants to purchase up to 4, 666, 332 shares of ~~Common~~ **common** ~~Stock~~ **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 have 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, **including resulting from public health crises, the conflict between Russia and Ukraine or the conflicts in the Middle East,** over which we may have no or 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 our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more 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. Investment in biotechnology product development is a highly speculative undertaking and entails substantial upfront expenditures and significant risks that any program will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale, 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. We do not expect to generate product revenue unless or until we successfully complete clinical development and obtains regulatory approval of, and then successfully commercialize, at least one product candidate. We may never succeed in these activities and, even if we do, may never generate product revenue or revenues that are significant or large enough to achieve profitability. If we are unable to generate sufficient revenue through the sale of any approved products, we may be unable to continue operations without additional funding. We have incurred significant net losses in each period since inception. Our net losses were $ **85. 0 million and $** 43. 6 ~~million and $ 28. 5~~ million for the years ended December 31, **2024 and** 2023 ~~and 2022~~, 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 and year to year. We anticipate that our expenses will increase substantially if and as we: • advance our existing and future programs through preclinical and clinical development, 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 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~~ **develop and manufacture our clinical supplies and access** commercial- scale cGMP **capacity and** capabilities through third- parties or our own manufacturing facility **; and • continue to operate as a public company** . In addition, our expenses will increase if, among other things, we 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 completing our clinical trials or the development 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 marketing approval for, and are successful in commercializing, one 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 **our** 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 **, medical** 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 **our** other product candidates. Our competitors have developed, are developing or may develop programs and processes competitive with DNTH103 or **our** 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. **In addition, because of the competitive landscape for autoimmune and inflammatory indications, we may also face competition for clinical trial enrollment. Patient**

enrollment will depend on many factors, including if potential clinical trial patients choose to undergo treatment with approved products or enroll in competitors' ongoing clinical trials for programs that are under development for the same indications as our programs. An increase in the number of approved products for the indications we are targeting with our product candidates may further exacerbate this competition. Our inability to enroll a sufficient number of patients could, among other things, delay our development timeline, which may further harm our competitive position. 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 a~~ 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 product candidates. We have limited experience as a company in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA or comparable foreign regulatory authorities. We have also not yet demonstrated our ability to obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Before obtaining regulatory approval for the commercial distribution of product candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of such product candidates. We or our collaborators may experience delays in initiating or completing clinical trials. We or our collaborators also may experience numerous unforeseen events during, or as a result of, any current or future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize DNTH103 or any other product candidates, including: • IRBs, the FDA or other regulators, 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 trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • clinical trial sites deviating from trial protocol or dropping out of a trial; • clinical trials of any product candidates may fail to show safety or efficacy, produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs; • the number of subjects required for clinical trials of any of our product candidates may be larger than we anticipate, especially if regulatory bodies require completion of non- inferiority or superiority trials, enrollment in these clinical trials may be slower than we anticipate or subjects may drop out of these clinical trials or fail to return for post- 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 clinical trials of any of our product candidates may be greater than we anticipate; • the quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be inadequate to initiate or complete a given clinical trial; • our inability to manufacture sufficient quantities of our product candidates for use in clinical trials, or delays in manufacturing or distribution; • reports from clinical testing of other therapies may raise safety or efficacy concerns about our product candidates; • our failure to 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 development of, or to modify existing or enter into new collaborations for, a product candidate if we experience any issues that delay 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 our ability 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 the research and development of this candidate. We initiated ~~a~~ global Phase 2 clinical **trials of DNTH103 in gMG and MMN and a global Phase 3 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 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 prefilled device) to products currently approved or in development for the indications we ~~plan to~~ **are pursuing or may in the future** pursue. DNTH103 will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales, if any. We are not permitted to market or promote this product candidate, or any other 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 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 for therapeutic effectiveness. We currently have only preclinical **data** 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 and pharmacological properties in patients than they do in laboratory studies. This technology and DNTH103 or any product candidates 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 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 and our existing or future collaborators may never receive approval to market and commercialize DNTH103 or any other product candidates. Even if we or an existing or future collaborator obtains regulatory approval, the approval may be for 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 other product candidates prove to be ineffective, unsafe or commercially unviable, our product candidates and pipeline may have little, if any, value, which may have a material and adverse effect on our business, financial condition, results of operations, cash flows, and prospects. 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. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical 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 preclinical study or 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 **or submitting a marketing application**. **During the past several years,** ~~There~~ **there was** ~~is currently~~ a global shortage of NHPs available for drug development. ~~This could cause~~ **If similar shortages occur in the future,** the cost of obtaining NHPs for our future preclinical studies ~~to~~ **may** increase significantly and ~~, if~~ the **availability of NHPs may decrease. A** shortage ~~continues,~~ could ~~also~~ result in delays to our development timelines. Furthermore, a failure of one or more clinical trials can 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. 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 product candidates. In addition, we expect to rely on patients to provide feedback on measures, which are subjective and 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 cannot be sure that the FDA or comparable foreign regulatory authorities will agree with our clinical development plan. ~~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. We cannot be sure that submission of an IND, a **Clinical Trial Application (“** 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, even if these trials begin, issues may 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; 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; delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; delays in identifying, recruiting and training suitable clinical investigators; delays in obtaining required IRB approval at each clinical trial site; difficulties in patient enrollment in our clinical trials for a variety of reasons; delays in manufacturing, testing, releasing, validating or importing / exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing; failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA’ s or any 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- scale facilities operated by third- party CDMOs and delays or failure by our 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. We could also encounter delays if a 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 safety monitoring board or equivalent body for such trial, or on account of changes to federal, state, or local laws. If we are required to conduct additional clinical trials or other testing of DNTH103 or any other product candidates beyond those that we contemplate, if we unable to successfully complete clinical trials of DNTH103 or any other product candidates, if the results of these trials are not positive or are only moderately positive 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 may initially show promise in identifying potential product candidates yet fail to yield product candidates for clinical development for a number of reasons. For example, we 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 **additional product candidates** ~~suitable active selective complement targets~~ for preclinical and clinical development, we may not be able to successfully implement our business strategy, and may have to delay, reduce the scope of, suspend or eliminate one or more of our product candidates, clinical trials or future commercialization efforts, which would negatively impact our financial condition. If we encounter difficulties enrolling patients in our **current and** future clinical trials, our clinical development activities could be delayed or otherwise adversely affected. We may experience difficulties in patient enrollment in our future clinical trials for a variety of reasons. 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 **current or** future trials for DNTH103 or any other product candidates will depend on many factors, including if patients choose to enroll in clinical trials, rather than using approved products, or if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients instead enroll in such clinical trials. Additionally, the number of patients required for clinical trials 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 trials. Even if we are able to enroll a sufficient number of patients for our ~~future~~ clinical trials, we may have difficulty maintaining patients in our clinical trials. Our inability to 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 costs or may require us to abandon one or more clinical trials altogether. Preliminary, “ topline ” or interim data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures. We have publicly disclosed and may in the future publicly disclose preliminary or topline data 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 the data. We also make assumptions, estimations, calculations and conclusions as part of our analyses of these data without the

opportunity to fully and carefully evaluate complete data. As a result, the 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 may in the future disclose interim data from our preclinical studies and clinical trials. Interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular 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 clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the preliminary, topline or interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, DNTH103 or any other product candidate may be harmed, which could harm our business, financial condition, results of operations, cash flows, and prospects. Our current or future clinical trials or those of our **current or** 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 **of our** 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, any clinical trials may not be sufficient to determine the effect and safety consequences of using our 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 our 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 could exacerbate side effects, each of which may adversely affect our ability to gain market acceptance. Market acceptance of DNTH103 or 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 sales force, marketing or distribution capabilities. To achieve commercial success for a 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 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 or 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 our development efforts and will need to successfully complete later- stage and pivotal clinical trials in order to obtain FDA, EMA, or comparable foreign regulatory approval to market 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 **or after approval** of an IND or CTA for a ~~Phase 2~~ clinical trial of DNTH103, the FDA ~~or~~ **,** EMA **or comparable foreign regulatory authorities** may recommend **or require** changes to our ~~proposed~~ **protocol or** study designs ~~, including the number~~ **that could adversely affect our study timelines** and **/ or ability** ~~size of registrational clinical trials required~~ to **enroll patients** ~~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 **and Phase 3** 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 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 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 approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and materially and adversely affect our ability 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 to be manufactured on a commercial scale and may not be able to do so for any of our product candidates, 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 the~~ ongoing military conflicts between Russian and 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 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. 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 our sole manufacturing source for DNTH103, we anticipate that 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 we are able to identify an alternative source, could negatively affect our ability to supply product candidates, including DNTH103, in a timely manner or within budget. If any CDMO on which we will rely fails to manufacture quantities of a product 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, our business, financial condition, cash flows, and prospects 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 anticipated timelines, potential future revenue and financial condition and increase our costs and expenses. Each of these risks could delay or prevent the completion of our preclinical studies and clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our products. In addition, we currently rely on foreign CROs and CDMOs, including WuXi Biologics, 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 **act** proposed **in 2024 known as the** BIOSECURE Act, sanctions, trade restrictions and other foreign regulatory requirements, which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. For example, the biopharmaceutical industry in China is strictly regulated by the Chinese government. Changes to Chinese regulations or government policies affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our collaborators in China which could have an adverse effect on our business, 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 **. It is unknown whether and to what extent new tariffs, export controls, trade restrictions, or other new laws or regulations imposed by either the new U. S. administration or by China will be adopted, or the effect that any such actions would have on us or our industry. Sustained uncertainty about, or the further escalation of, trade and political tensions between the United States and China could result in a disadvantageous research and manufacturing environment in China, particularly for U. S.- based companies, including retaliatory restrictions that hinder or potentially inhibit our ability to rely on our CDMO and other service providers that operate in China. For example, the BIOSECURE Act could prohibit, among other things, the use of U. S. government executive agency contract, grant, or loan funding to provide or to enter into, extend or renew contracts involving the use of certain equipment or services produced or provided by certain Chinese companies, which could cause us to reevaluate our relationship with our current CDMO, WuXi Biologics, which is located in China. While we have not started commercialization of drug candidates, any unfavorable government policies on international trade, such as export controls, capital controls, tariffs or other trade restrictions, may affect the demand for our drug products, the competitive position of our product candidates, and import or export of raw materials and finished product candidate used in our preclinical studies and clinical trials, particularly with respect to our manufactured product candidates that we import from China, including**

pursuant to our manufacturing arrangements and license agreement with WuXi Biologics. If any new tariffs, export controls, legislation and / or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if the U. S. government takes retaliatory trade actions due to the recent U. S.- China trade tension, such changes could have an adverse effect on our business, financial condition and results of operations . 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, raw and intermediate materials supply shortages, including those resulting from the COVID- 19 pandemic, which could 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 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 adversely 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 third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their 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 medical institutions, CROs, contract testing labs and strategic partners, to conduct and support our preclinical studies and clinical trials under agreements with us. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and 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. Nevertheless, we are responsible for ensuring that 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 of our regulatory responsibilities. We and our third- party contractors and CROs are required to comply with GCP regulations, 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 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 our 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 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 these third parties 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, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize DNTH103 or other product candidates. We have collaborations with third parties, including our existing license and development collaboration with **Tenacia** ~~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 various collaboration and license arrangements, including with **Tenacia** ~~Zenas BioPharma~~ for 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, we may in the future form or seek strategic alliances, create joint ventures or collaborations, 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, manufacture, market or sell the products covered by such agreements or may face other penalties under our 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 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 their 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 candidates or bring them to market. Risks Related to Our Business and Operations In order to successfully implement our plans and strategies, we will need to increase the size of our organization and we may experience difficulties in managing this growth. We **have experienced and** expect **to continue** 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 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, **executive** ~~Chief Medical Officer~~ **officers** ~~, 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 any of our executives or other employees. The loss of the services of our executive officers or other key employees could impede the achievement of 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 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 from the applicable foreign regulatory authority, and we may never receive such regulatory approval for any product candidates. To obtain separate regulatory approval 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 commercial sales, pricing and distribution of DNTH103 or other product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets or to receive applicable marketing approvals, our target market will be reduced and our ability to realize 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. **Cybersecurity incidents, including phishing attacks and attempts to misappropriate or compromise confidential or proprietary information or sabotage enterprise IT systems are becoming increasingly frequent and more sophisticated. Cybersecurity incidents increasingly involve the use of artificial intelligence and machine learning to launch more automated, targeted and coordinated attacks on targets. The information and data processed and stored in our technology systems, and those of our strategic partners, contract research organizations, contract manufacturers, suppliers, distributors or other third parties for which we depend to operate our business, may be vulnerable to loss, damage, denial- of- service, unauthorized access or misappropriation.** 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~~ **The security measures** we have implemented **may** ~~security measures designed to protect against security incidents, there can be no~~ **not** ~~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, **we** ~~Former Dianthus~~ could not access ~~its~~ assets held in ~~its~~ **our** account with Silicon Valley Bank for a period in March 2023, which required **us** ~~Former Dianthus~~ to obtain a short- term loan to fund ~~its~~ **our** 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~~ **previously** identified material weaknesses in our internal control over financial reporting **,** which **have been remediated** , ~~if not corrected~~ **and may identify material weaknesses in the future or otherwise fail to maintain an effective system of internal controls** , **which** could affect the reliability of our financial statements **, our investors' confidence** and have other adverse consequences **. Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a- 15 (f) under the Exchange Act. In addition, Section 404 of the Sarbanes- Oxley Act of 2002 (Section 404) and related SEC rules require management to furnish a report on the effectiveness of our internal control over financial reporting. Effective internal controls are necessary for us to provide reliable financial reports and help us to prevent fraud. The process of implementing our internal controls and complying with Section 404 is expensive and time consuming and requires significant continuous attention of management. We cannot be certain that these measures will ensure that we maintain adequate controls over our financial processes and reporting in the future** . 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~~ **previously** identified material weaknesses in our internal control over financial reporting ~~that we are currently working to remediate,~~ which ~~relate~~ **related** to: (a) general segregation of duties, including the review and approval of journal entries as well as system access that ~~has~~ **had** not been designed to allow for effective segregation of duties; and (b) our accounting software system ~~has~~ **had** certain system limitations that ~~do~~ **did** not allow for an effective control environment. Our management has concluded that ~~these~~ -- **the** ~~material weaknesses in~~ **design and operation of** our internal control over financial reporting **is effective and therefore** ~~are due to the fact~~ that ~~we have limited resources and do not have the~~ **these previously identified** ~~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~~ **have been fully** remediated ~~when our management designs and implements effective controls that operate for a sufficient period of time and management has~~ **as** ~~concluded~~ **of December 31** , ~~through testing, that~~ **2024. While we believe** ~~these~~ **the** ~~controls are effective. Our management will monitor the effectiveness of our~~ remediation **efforts both addressed** ~~plans and will make changes management determines to be appropriate. If not remediated, these~~ **the identified** material weaknesses **and also enhanced** ~~could result in material misstatements to our annual or~~ **our** ~~interim~~ **overall** financial **control environment** ~~statements that might not be prevented or detected on a timely basis~~ , **if** ~~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 **U. S.** patent applications, **which includes two provisional applications** and ~~we~~ **four non- provisional applications, one issued U. S. patent, four pending PCT (Patent Cooperation Treaty) applications, and seven pending foreign applications in China, Europe, Hong Kong, Japan and Taiwan. We additionally** 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 **only** own ~~or~~ **one issued patent, which is expected to expire** in ~~license~~ **2043, without taking** any ~~issued~~ **potential** ~~patents~~ **patent term extension into account** . 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 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 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~~ **common** ~~Stock~~ **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 demonstrate through lengthy, 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 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 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 **, or layoffs of federal workers by the federal government** . 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 an 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 if the devices do not gain and / or maintain their own regulatory approvals or clearances. Where approval of the 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 **are** ~~may in the future choose to conduct more of our clinical trials outside the United States. We~~ currently ~~intend to conduct~~ **conducting** our Phase 2 clinical trials **and our Phase 3 clinical trial** for DNTH103 in the United States and **outside the United States, and we may in the future choose to conduct more of our clinical trials** outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and 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 on its determination that the trials also complied with all applicable U. S. laws and regulations. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time- consuming and would delay or permanently halt our development of the applicable product candidates. Even if the FDA accepted such data, it could require us to modify our planned clinical trials to receive clearance to initiate such trials in the United States or to continue such trials once initiated. Other risks inherent in conducting international clinical trials include: foreign regulatory 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 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 relevant to foreign countries. Our 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 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 reference products in a way that is similar to traditional generic substitution for non- biological products is not 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 significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates. Any regulatory approvals that we may receive for DNTH103 or other product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of such product candidates, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post- approval 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, promotion, sale, distribution, import and export will be subject to comprehensive regulation 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 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, including costly new manufacturing requirements. The occurrence of any event or penalty described above may inhibit our ability to commercialize DNTH103 or other product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. We may face difficulties from healthcare legislative reform measures. Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of DNTH103 or other product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. See the section titled " Business — Government Regulation — Healthcare Reform " located elsewhere in this Annual Report on Form 10- K for a more detailed description of healthcare reforms measures that may prevent us from being able to generate revenue, attain profitability, or commercialize product candidates. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third- party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third- party payors, patient organizations and customers may expose us to broadly- applicable fraud and abuse and other 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, if approved. See the section titled " Business — Government Regulation — Other Healthcare Laws and Compliance Requirements " 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. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. 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, exclusion from government- funded healthcare programs, integrity oversight and 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. Further, defending against any such actions can be costly and time- consuming and may require significant personnel

resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Even if we are able to commercialize DNTH103 or other product candidates, 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 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 such product candidates, we will be subject to rules and regulations in those jurisdictions. Our ability to successfully commercialize any product candidates that we may develop will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. 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 " 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 affect our ability to commercialize our product candidates. We are subject to U. S. and certain foreign export and import controls, sanctions, embargoes, anti- corruption laws, and anti- money laundering laws and regulations. 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 approvals. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any. In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a therapeutic. In addition, there can be considerable pressure by governments and 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, 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 other available therapies in order to obtain or maintain reimbursement or pricing approval. 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, our business, financial condition, results of operations, cash flows, or 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 or 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 the FDA, it may not lead to a faster development or regulatory review or approval process. We may seek Fast Track Designation or Orphan Drug Designation for one or more product candidates. If a drug is intended for the treatment of a serious or life- threatening condition and 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 we believe a particular product candidate is eligible for such designations, we cannot guarantee that the 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 the designation is no longer supported by data from a clinical development program. See the section titled " Business — Government Regulation — Expedited Development and Review Programs " located elsewhere in this Annual Report on Form 10- K for a more detailed description of the process for seeking Fast Track Designation or Orphan Drug Designation. General Risk Factors Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the 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 subject to many factors, including our success in implementing our business strategy, which is subject to many risks and 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 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 use of a product candidate in clinical trials, 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 the market for our products or any prospects for commercialization of our products. Although we believe we currently maintain adequate product liability insurance for DNTH103 and other product candidates, it is possible that our liabilities could exceed our insurance coverage or that in the future we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy 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 outcome of litigation could have a 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 licensors and intellectual property rights. Litigation to defend ourselves against claims by third parties, or to enforce any rights that we may have against third parties, could result in substantial costs and diversion of our resources, causing a material adverse effect on our business, 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 the COVID- 19 pandemic~~ , political crises, geopolitical events, such as the conflict between Russia and Ukraine, or other macroeconomic conditions, which could have a material and adverse effect on our results of operations, cash flows, and financial condition. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, 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 **, although** it ~~may~~ **recently lowered interest rates, there is no guarantee that it will continue to lower rates or that it will not** 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 **and in the Middle East** 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 make 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 **may** ~~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 **that we may provide** to the **public** ~~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 **, and the markets for biotechnology and biopharmaceutical companies in particular,** 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 securities, 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 our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our Board of Directors could have an adverse effect on our operating results, financial condition and cash flows. We will **continue to** incur significant legal, accounting and other expenses as a public company that **we** ~~Former Dianthus~~ did not incur as a private company, including costs associated with public company reporting obligations under the Securities and Exchange Act of 1934, as amended (the " Exchange Act "). **Some** ~~Our management team consists~~ of ~~the~~ **our** executive officers ~~of Former Dianthus, some of whom~~ have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we 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 other disclosure and corporate governance requirements. However, we **currently** ~~expect to~~ qualify as a " smaller reporting company, " as such term is defined in Rule 12b- 2 under the Exchange Act, in at least the near term, which ~~will allow~~ **allows** us to take advantage of 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 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Once we are no longer a smaller reporting company or otherwise no longer qualify for these exemptions, we will be required to comply with additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our 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 produce accurate financial statements on a timely basis could be impaired. We are subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act and the rules and regulations of Nasdaq. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow our management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10- K filing for that year, as required by Section 404 of the Sarbanes- Oxley Act. As a private company, **we were** ~~Former Dianthus has~~ never ~~been~~ required to test ~~its~~ **our** internal controls within a specified period. This will require that we incur substantial professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner. For additional information related to the risks and uncertainties of our compliance with the Sarbanes- Oxley Act, see the section above titled " Risks Related to Our Business and Operations — We ~~have~~ **previously** identified material weaknesses in our internal control over financial reporting **,** which **have been remediated** , ~~if not corrected~~ **and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls** , **which** could affect the reliability of our financial statements **, our investors' confidence** and have other adverse consequences. " **We** ~~In addition to the material weaknesses described above, we~~ may discover ~~additional~~ weaknesses in our 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, 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 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** could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Our certificate of incorporation and bylaws and provisions under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management. Provisions of our

certificate of incorporation and 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 of Directors 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 of 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 of Directors; • limit the manner in which stockholders can remove directors from the Board of Directors; • establish advance notice requirements for nominations for election to the Board of 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 of 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 of 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 bylaws. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15 % of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our Board of Directors, they 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 then current management by making it more difficult for stockholders to replace members of the Board of Directors, which is responsible for appointing the members of management. Our 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 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, our charter or our 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 for purposes of this risk factor 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 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 for purposes of this risk factor refers to herein as the " Federal Forum Provision. " In addition, our 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 its compliance with the U. S. federal securities laws and the rules and regulations thereunder. 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 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. 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~~ **common** ~~Stock~~ **stock** will be your sole source of gain, if any, for the foreseeable future. An active trading market for our ~~Common~~ **common** ~~Stock~~ **stock** may not be sustained and our stockholders may not be able to sell their shares of ~~Common~~ **common** ~~Stock~~ **stock** for a profit, if at all. An active trading market for our shares of ~~Common~~ **common** ~~Stock~~ **stock** may not be sustained. If an active market for our ~~Common~~ **common** ~~Stock~~ **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~~ **common** ~~Stock~~ **stock** in the public market, the trading price of our ~~Common~~ **common** ~~Stock~~ **stock** could decline. In addition, shares of ~~Common~~ **common** ~~Stock~~ **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~~ **common** ~~Stock~~ **stock** are sold, the trading price of our ~~Common~~ **common** ~~Stock~~ **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~~ **58** % of our outstanding shares of ~~Common~~ **common** ~~Stock~~ **stock** as of March ~~14~~ **7**, ~~2024~~ **2025**. As a result, if these stockholders were to choose to act together, they 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~~ **common** ~~Stock~~ **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~~ **common** ~~Stock~~ **stock**, and such lack of research coverage may adversely affect the market price of our ~~Common~~ **common** ~~Stock~~ **stock**. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our ~~Common~~ **common** ~~Stock~~ **stock** could decline if one or more equity research analysts downgrade our stock or issue other 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~~ **common** ~~Stock~~ **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 may not increase the value of your investment. We have broad discretion over the use of our cash and cash equivalents ~~and the proceeds from the 2024 Private Placement~~. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Our failure to apply these resources effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our cash resources. We may be subject to adverse legislative or regulatory tax changes that could negatively impact our 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 Internal Revenue Service and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or our stockholders. We will assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations to determine the potential effect on our business and any assumptions we will make about our future taxable income. We 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 be enacted. For example, the United States ~~recently~~ enacted the IRA, which implements, among other changes, a 1 % excise tax on certain stock buybacks. In addition, beginning in 2022, the Tax Cuts and Jobs Act ~~eliminates~~ **eliminated** the ~~currently available~~ option to deduct research and development expenditures and requires taxpayers to amortize them generally over five years. The U. S. Congress is considering legislation that would restore the current deductibility of research and development expenditures, however, there is no assurance that the provision will be repealed or otherwise modified. Such changes, among others, may adversely affect our effective tax rate, results of operation and general business 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. 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. Federal net operating losses generated prior to December 31, 2017, however, have a 20- year carryforward period, but are not subject to the 80 % limitation. Similar state law limitations may apply. In addition, under Sections 382 and 383 of the 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 stockholders or groups of stockholders who own at least 5 % of a company' s stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three- year period (referred to as an " ownership change "). Similar state law limitations may apply. There may also be periods during which the use of net operating loss carryforwards and other tax attributes are suspended or otherwise limited, which could accelerate or permanently increase taxes owed. ~~Following the Reverse Merger, our tax carryforwards 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~~ **2024**, we had federal net operating loss carryforwards of $ ~~320~~ **388**. ~~7~~ **4** million, ~~all~~ of which **$ 17. 5 million will begin to expire in 2035 and the remaining** can be carried forward indefinitely. As of December 31, ~~2023~~ **2024**, ~~Dianthus~~ **we** had state net operating loss carryforwards of $ ~~299~~ **352**. ~~1~~ **3** million, which **will** begin to expire in 2035. As of December 31, ~~2023~~ **2024**, ~~Dianthus~~ **we** also had available research and orphan drug tax credit carryforwards for federal and state income tax purposes of $ ~~14~~ **19**. ~~8~~ **1** million and $ 3. ~~5~~ **7** million, respectively, which **will** begin to expire in 2035 and 2030, respectively. We have not conducted a formal study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since inception; however, the Reverse Merger is expected to result in an ownership change. For these reasons, we do not expect to be able to utilize a material portion of the net operating losses and research and orphan drug tax credit carryforwards. ~~64~~ **72**