

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20459**

**AMENDMENT No. 2
TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

Dianthus Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

81-00724163
(I.R.S. Employer
Identification No.)

7 Times Square,
43rd Floor,
New York, NY 10036
(929) 999-4055

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Ryan Savitz
Chief Financial Officer
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(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

This Amendment No. 2 to this registration statement on Form S-1 (Registration No. 333-274863) (the “Registration Statement”) is being filed to, among other things, include our financial statements and certain other information contained in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the U.S. Securities and Exchange Commission (the “SEC”) on March 21, 2024.

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The information in this prospectus is not complete and may be changed. The selling stockholders named in this prospectus may not sell these securities until the registration statement filed with the Securities and Exchange Commission (the "SEC") is effective. This prospectus is not an offer to sell these securities, and it is not soliciting an offer to buy these securities, in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MARCH 21, 2024

PRELIMINARY PROSPECTUS



Dianthus Therapeutics, Inc.

21,326,988 Shares

Common Stock

Offered by the Selling Stockholders

Pursuant to this prospectus, the selling stockholders identified herein (the "Selling Stockholders") are offering (the "Offering") on a resale basis an aggregate of up to 21,326,988 shares of common stock, par value \$0.001 per share (the "Common Stock" and, such shares of Common Stock that are being registered by this prospectus and offered on a resale basis, the "Resale Shares"), of Dianthus Therapeutics, Inc. (formerly Magenta Therapeutics, Inc.), a Delaware corporation ("Dianthus," "we," "us," "our" or the "Company"). The Resale Shares consist of:

- (i) up to 1,949,836 shares of Common Stock issued to certain former stockholders of Dianthus Therapeutics OpCo, Inc. (formerly Dianthus Therapeutics, Inc.), a Delaware corporation ("OpCo" or "Former Dianthus"), in exchange for such stockholders' OpCo common stock purchased in the OpCo pre-closing financing (as defined below) pursuant to the Subscription Agreement (as defined below) in connection with the consummation of the merger of Dio Merger Sub, Inc., a Delaware corporation ("Merger Sub"), with and into OpCo, with OpCo surviving as a wholly owned subsidiary of ours, which closed on September 11, 2023 (the "Merger"), pursuant to that certain Agreement and Plan of Merger, dated as of May 2, 2023 (the "Merger Agreement"), by and among us, OpCo and Merger Sub;
- (ii) up to 210,320 shares of Common Stock issuable upon the exercise of pre-funded warrants (the "2023 Pre-Funded Warrants") that were converted from OpCo pre-funded warrants purchased by certain former stockholders of OpCo in the OpCo pre-closing financing pursuant to the Subscription Agreement in connection with the consummation of the Merger pursuant to the Merger Agreement;
- (iii) up to 14,500,500 shares of Common Stock issued to certain institutional and accredited investors in the 2024 Private Placement (as defined below) pursuant to the Securities Purchase Agreement (as defined below); and
- (iv) up to 4,666,332 shares of Common Stock issuable upon the exercise of pre-funded warrants (the "2024 Pre-Funded Warrants" and, (as defined below) together with the 2023 Pre-Funded Warrants, the "Pre-Funded Warrants") issued to certain institutional and accredited investors in the 2024 Private Placement pursuant to the Securities Purchase Agreement.

We are not offering or selling any Resale Shares under this prospectus, and we will not receive any of the proceeds from the sale of the Resale Shares by the Selling Stockholders pursuant to this prospectus. Upon any exercise of the Pre-Funded Warrants by payment of cash, however, we will receive the nominal cash exercise price paid by the holders of the Pre-Funded Warrants. We intend to use those proceeds, if any, for general corporate purposes.

Our registration of the securities covered by this prospectus does not mean that the Selling Stockholders will offer or sell any of the Resale Shares. The Selling Stockholders may sell the Resale Shares covered by this prospectus in a number of different ways and at varying prices. We provide more information about how the Selling Stockholders may sell the Resale Shares in the section entitled "*Plan of Distribution*." Discounts, concessions, commissions and similar selling expenses attributable to the sale of the Resale Shares will be borne by the Selling Stockholder. We will pay certain fees and expenses (other than discounts, concessions, commissions and similar selling expenses) incident to the registration of the Resale Shares with the SEC.

You should carefully read this prospectus and any applicable prospectus supplement before you invest in any of the securities being offered.

Our Common Stock is traded on The Nasdaq Capital Market under the symbol "DNTH." On March 20, 2024, the last reported sales price for our Common Stock was \$27.10 per share.

An investment in our securities involves a high degree of risk. You should carefully consider the information under the heading "[Risk Factors](#)" beginning on page 9 of this prospectus and any applicable prospectus supplement.

We are a "smaller reporting company" as defined by Rule 12b-2 of the Exchange Act and are subject to reduced public company reporting requirements.

Neither the SEC nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense. The securities are not being offered in any jurisdiction where the offer is not permitted.

The date of this prospectus is _____, 2024

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 that we filed with the SEC using a “shelf” registration process. Under this shelf registration process, the Selling Stockholders may, from time to time, offer and sell the securities described in this prospectus in one or more offerings. Information about the Selling Stockholders may change over time.

This prospectus provides you with a general description of the shares the Selling Stockholders may offer. Each time the Selling Stockholders sell our shares of Common Stock using this prospectus, to the extent necessary and required by law, we will provide a prospectus supplement that will contain specific information about the terms of that offering, including the number of shares of Common Stock being offered, the manner of distribution, the identity of any underwriters or other counterparties and other specific terms related to the offering. The prospectus supplement may also add, update or change information contained in this prospectus. To the extent that any statement made in a prospectus supplement is inconsistent with statements made in this prospectus, the statements made in this prospectus will be deemed modified or superseded by those made in the prospectus supplement. You should read this prospectus and any applicable prospectus supplement before making an investment in shares of our Common Stock. See “*Where You Can Find More Information*” for more information.

Neither we nor the Selling Stockholders have authorized anyone to give any information or to make any representation other than those contained in this prospectus. The Selling Stockholders are offering to sell, and seeking offers to buy, our securities only in jurisdictions where it is lawful to do so. We have not authorized anyone to provide you with different information. This prospectus and any accompanying prospectus supplement do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the securities described in any accompanying prospectus supplement or an offer to sell or the solicitation of an offer to buy such securities in any circumstances in which such offer or solicitation is unlawful. You should assume that the information appearing in this prospectus, any prospectus supplement and any related free writing prospectus is accurate only as of their respective dates. Our business, financial condition, results of operations and prospects may have changed materially since those dates.

For investors outside of the United States, neither we nor the Selling Stockholders have done anything that would permit the offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to the offering and the distribution of this prospectus outside of the United States.

This prospectus contains estimates and other information concerning our industry, business and the potential markets for our product candidate, including data regarding the estimated size of such markets and the incidence of certain medical conditions. We obtained industry, market and competition data contained in this prospectus from academic and industry publications, research, surveys and studies conducted by third parties. We believe that the third-party data contained in this prospectus is reliable and based on reasonable assumptions. This information, to the extent it contains estimates, involves a number of assumptions and limitations, and you should not place undue reliance on such estimates. The industry in which we operate is subject to risks and uncertainties and are subject to change based on various factors, including those set forth under the section titled “*Risk Factors*.” These and other factors could cause results to differ materially from those expressed in the estimates contained in this prospectus. See also “*Cautionary Statement Concerning Forward-Looking Statements*.”

This prospectus may contain references to trademarks, trade names or service marks belonging to other entities. Solely for convenience, trademarks, trade names and service marks referred to in this prospectus may appear without the ®, SM or TM symbols, but such references are not intended to indicate, in any way, that the applicable licensor will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names. We do not intend our use or display of other companies’ trademarks, trade names or service marks in this prospectus to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This prospectus contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical fact, included in this prospectus are forward-looking statements, including, without limitation, statements concerning our plans, objectives, goals, expectations, hopes, beliefs, intentions, assumptions, projections, estimates or strategies and any underlying assumptions regarding the future, our future results of operations and financial position, including the sufficiency of our existing cash resources to fund our operations for as long as anticipated, our liquidity, capital resources, costs and expenses, capital requirements, commitments and contingencies, the development or commercial potential of DNTH103 or any other product candidate, our anticipated preclinical and clinical drug development activities, in particular with respect to DNTH103, and any timelines, developments or results in connection therewith, the efficacy, safety profile, dosing amount or frequency, method of delivery or other potential therapeutic benefits of DNTH103, the receipt or timing of potential regulatory designations, approvals and commercialization of any product candidates, market size or addressable patient population and other statements, including those included under the sections titled “*Risk Factors*,” “*Business*,” “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*” and elsewhere in this prospectus. In some cases, you can identify forward-looking statements by terms such as “aim,” “may,” “might,” “will,” “would,” “shall,” “objective,” “intend,” “target,” “should,” “could,” “can,” “expect,” “anticipate,” “believe,” “design,” “estimate,” “forecast,” “predict,” “project,” “potential,” “possible,” “plan,” “seek,” “contemplate,” “goal,” “likely” or “continue” or the negative of these terms and similar expressions intended to identify forward-looking statements, but the absence of these terms does not mean that a statement is not forward-looking. Forward-looking statements are not historical facts and are based on our current expectations and beliefs with respect to future events and their potential effects and impacts. There can be no assurance that future events affecting us will be those that have been anticipated. Given the significant risks and uncertainties, you should not place undue reliance on these forward-looking statements.

There are a number of risks, uncertainties and other factors that could cause our actual results or outcomes, or the timing of our results or outcomes, to differ materially from the forward-looking statements expressed or implied in this prospectus. Such risks, uncertainties and other factors include, among others, the following risks, uncertainties and factors:

- risks associated with the possible failure to realize certain anticipated benefits of the Merger, including with respect to future financial and operating results;
- the effect of the completion of the Merger on our business relationships, operating results and business generally;
- expectations regarding the strategies, prospects, plans, expectations and objectives of our management for future operations of the Company following the closing of the Merger;
- risks associated with our ability to manage expenses and unanticipated spending and costs that could reduce our cash resources;
- risks related to our ability to correctly estimate our operating expenses and other events;
- changes in capital resource requirements;
- our ability to obtain, maintain and protect our intellectual property rights, in particular those related to our product candidates;
- our ability to advance the development of our product candidates or preclinical activities under the timelines we anticipate in planned and future clinical trials;
- our ability to replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of our product candidates;

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- our ability to realize the anticipated benefits of our research and development programs, strategic partnerships, licensing programs or other collaborations;
- regulatory requirements or developments, and our ability to obtain necessary approvals from the U.S. Food and Drug Administration (the “FDA”) or other regulatory authorities;
- our ability to manufacture product candidates in conformity with the FDA requirements and to scale up manufacturing of our product candidates to commercial scale, if approved;
- changes to clinical trial designs and regulatory pathways;
- developments and projections relating to our expected or existing competitors or industry;
- unexpected costs, charges or expenses resulting from the Merger;
- potential adverse reactions or changes to business relationships resulting from the completion of the Merger;
- legislative, regulatory, political, geopolitical and macroeconomic developments beyond our control, including inflationary pressures, general economic slowdown or a recession, high interest rates, changes in monetary policy, instability in financial institutions, the prospect of a shutdown of the U.S. federal government, the ongoing conflict in Ukraine, conflict in the Middle East and rising tensions between China and Taiwan;
- success in retaining, recruiting or changes in, our officers, key employees or directors;
- the liquidity and trading of our securities;
- regulatory actions with respect to our product candidates or our competitors’ products and product candidates;
- our ability to successfully develop and commercialize any technology that we may in-license or products we may acquire;
- our ability to successfully operate in non-U.S. jurisdictions in which we may choose to do business, including compliance with applicable regulatory requirements and laws;
- our reliance on third-party contract development and manufacturer organizations to manufacture and supply product candidates;
- our ability to establish satisfactory pricing and obtain adequate reimbursement from government and third-party payors of products and product candidates that receive regulatory approvals, if any;
- our ability to successfully commercialize product candidates, if approved, and the rate and degree of market acceptance of such product candidates;
- risks related to our ability to obtain additional financing and raise capital as necessary to fund operations or pursue business opportunities;
- the direct and indirect effects of widespread health emergencies on our workforce, operations, financial results and cash flows;
- severe weather and seasonal factors;
- our inability to continue to grow and manage our growth effectively;
- our inability to comply with, and the effect on our business of, evolving legal standards and regulations, including those concerning data protection, consumer privacy and sustainability and evolving labor standards; and
- our ability to remediate material weaknesses or other deficiencies in our internal control over financial reporting or to maintain effective disclosure controls and procedures and internal control over financial reporting.

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There may be other factors that may cause our actual results or outcomes, or the timing of those results or outcomes, to differ materially from the forward-looking statements expressed or implied in this prospectus, including factors disclosed in the sections titled “*Risk Factors*,” “*Business*,” “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*” and elsewhere in this prospectus. You should evaluate all forward-looking statements made in this prospectus and any prospectus supplement in the context of these risks and uncertainties.

We caution you that the risks, uncertainties and other factors referred to above and elsewhere in this prospectus may not contain all of the risks, uncertainties and other factors that may affect our future results, operations and outcomes. Moreover, new risks emerge from time to time. It is not possible for us to predict all risks. In addition, we cannot assure you that we will realize the results, benefits or developments that we expect or anticipate or, even if substantially realized, that they will result in the consequences or affect us or our business in the way expected. Past performance is not indicative of future performance.

Any forward-looking statements contained in this prospectus apply only as of the date made and are expressly qualified in their entirety by the cautionary statements included in this prospectus. Except as required by law, we disclaim any intent to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changes in assumptions or otherwise.

PROSPECTUS SUMMARY

The following summary highlights certain information contained elsewhere in this prospectus. This summary provides an overview of selected information and does not contain all of the information you should consider in making your investment decision. Therefore, you should read the entire prospectus carefully before investing in our securities. You should carefully consider the information set forth under the sections titled “Risk Factors,” “Cautionary Statement Concerning Forward-Looking Statements,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the financial statements and the related notes included elsewhere in this prospectus. Unless context otherwise requires, references herein to “we,” “us,” “our,” “Dianthus” or the “Company” refer to Dianthus Therapeutics, Inc. (formerly Magenta Therapeutics, Inc.) after completion of the Merger, references to “OpCo” or “Former Dianthus” refer to Dianthus Therapeutics OpCo, Inc. (formerly Dianthus Therapeutics, Inc.), and the term “Magenta” refers to the Company prior to completion of the Merger.

ABOUT THE COMPANY

We are a clinical-stage biotechnology company focused on developing next-generation complement therapeutics for patients living with severe autoimmune and inflammatory diseases. We believe our lead novel and proprietary monoclonal antibody product candidate, DNTH103, has the potential to address a broad array of complement-dependent diseases as currently available therapies and those in development leave room for improvements in efficacy, safety, and/or dosing convenience. We have purposefully engineered DNTH103 to selectively bind to only the active form of the C1s complement protein (“C1s”) and to exhibit improved potency and an extended half-life. By selectively targeting only the active form of C1s, which drives disease pathology and constitutes only a small fraction of the total protein present in circulation, we aim to reduce the amount of drug required for a therapeutic effect. We intend to deliver our product candidate through a lower dose, less frequent, self-administered, convenient subcutaneous (“S.C.”) injection suitable for a pre-filled pen.

Our executive offices are located at 7 Times Square, 43rd Floor, New York, New York 10036, and our telephone number is (929) 999-4055. Our website address is www.dianthustx.com. Information contained on, or accessible through, our website is not incorporated by reference in this prospectus. We make our periodic and current reports available on our website, free of charge, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. No portion of our website is incorporated by reference into this prospectus. We file our annual, quarterly and special reports, proxy statements and other information with the SEC. Our filings with the SEC are also available to the public on the SEC’s website at <http://www.sec.gov>. Our Common Stock is traded on The Nasdaq Capital Market under the symbol “DNTH.”

THE OFFERING

Shares of Common Stock to be offered by the Selling Stockholders:	Up to 16,450,336 shares of Common Stock and 4,876,652 shares of Common Stock issuable upon the exercise of Pre-Funded Warrants.
Terms of the Offering:	The Selling Stockholders will determine when and how they will dispose of the shares of Common Stock registered under this prospectus for resale.
Shares of Common Stock outstanding:	As of March 14, 2024, there were 29,346,760 shares of Common Stock outstanding.
Use of Proceeds	We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale by the Selling Stockholders of the Common Stock. Upon any exercise of the Pre-Funded Warrants by payment of cash, however, we will receive the nominal cash exercise price paid by the holders of the Pre-Funded Warrants. See the section titled “Use of Proceeds” located elsewhere in this prospectus.
Risk Factors	You should read the section titled “ <i>Risk Factors</i> ” located elsewhere in this prospectus for a discussion of the risks, uncertainties and other factors to consider carefully before deciding to invest in shares of our Common Stock.
Nasdaq Capital Market symbol:	Our Common Stock is listed on The Nasdaq Capital Market under the symbol “DNTH.” We do not intend to apply for listing of the Pre-Funded Warrants on any securities exchange or nationally recognized trading system.

Except as indicated otherwise, all share numbers related to our Common Stock disclosed in this prospectus have been adjusted on a post-reverse split basis.

For additional information concerning the offering, see the section titled “*Plan of Distribution*.”

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 future clinical trials, our clinical development activities could be delayed or otherwise adversely affected;
- We have collaborations with third parties, including our existing license and development collaboration with Zenas BioPharma, Inc. (formerly Zenas BioPharma Limited) (“Zenas BioPharma”). If we are unable to maintain these collaborations, or if these collaborations are not successful, our business could be adversely affected;
- We have identified material weaknesses in our internal control over financial reporting which, if not corrected, could affect the reliability of our financial statements and have other adverse consequences;
- In order to successfully implement our plans and strategies, we will need to grow the size of our organization and we may experience difficulties in managing this growth;
- Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage;
- The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, such product candidates, and our ability to generate revenue will be materially impaired;
- We may not be able to meet requirements for the chemistry, manufacturing and control of our product candidates;
- Our product candidates for which we intend to seek approval as biologics may face competition sooner than anticipated;
- The market price of our Common Stock is expected to be volatile, the market price of our Common Stock may drop, and an active trading market for our Common Stock may not be sustained and our stockholders may not be able to sell their shares of Common Stock for a profit, if at all;

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- Provisions in our certificate of incorporation and bylaws and under Delaware law could make an acquisition of us more difficult and may discourage any takeover attempts which stockholders may consider favorable, and may lead to entrenchment of management; and
- We will incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risk factors set forth below, together with all of the other information included in this prospectus, before deciding whether to purchase our securities. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities, and the occurrence of any of these risks might cause you to lose all or part of your investment.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We have a limited operating history, have not completed any late-stage clinical trials and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.

We are a clinical-stage biotechnology company with limited operating history that have incurred significant operating losses and has utilized substantially all of our resources to conduct research and development activities (including with respect to our DNTH103 program) and undertake preclinical studies of product candidates, conducting a clinical trial of our most advanced product candidate and the manufacturing of the product candidates, business planning, developing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these activities. We have limited experience as a company in initiating, conducting or completing clinical trials. In part because of this lack of experience, we cannot be certain that our current and planned clinical trials will begin or be completed on time, if at all. In addition, while we initiated a Phase 2 clinical trial of DNTH103 in patients with generalized Myasthenia Gravis (“gMG”) in the first quarter of 2024, we have not completed a late-stage clinical trial for any product candidate, have no products approved for commercial sale and have not yet demonstrated our ability to successfully complete late-stage clinical trials (including Phase 3 or other pivotal clinical trials), obtain regulatory or marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as our business grows, we may encounter unforeseen expenses, restrictions, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with an early research and development focus to a company capable of supporting larger scale clinical trials and eventually commercial activities. We may not be successful in such a transition.

We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate clinical trials, product development programs or future commercialization efforts.

Developing biotechnology products is a very long, time-consuming, expensive and uncertain process that takes years to complete. Since our inception in 2019, we have funded our operations primarily through private financings and have incurred significant recurring losses, including net losses of \$43.6 million and \$28.5 million for the years ended December 31, 2023 and 2022, respectively. We expect our expenses to increase in connection with our ongoing activities, particularly as we prepare to conduct multiple Phase 2 clinical trials, prepare for additional investigational new drug application (“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

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manufacturing, marketing, sales and distribution activities to launch any such product. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to perform preclinical studies or clinical trials in addition to those that we currently anticipate. Because the design and outcome of our current, planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. Our future capital requirements depend on many factors, including factors that are not within our control.

We will also incur additional costs associated with operating as a public company that 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 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.

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We do not have any committed external sources of funds and adequate additional financing may not be available to us on acceptable terms, or at all. We may be required to seek additional funds sooner than planned through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Such financing may dilute our stockholders or the failure to obtain such financing may restrict our operating activities. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our business. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences and anti-dilution protections that adversely affect your rights as a stockholder. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. For example, on January 24, 2024, we completed the 2024 Private Placement in which we issued 14,500,500 shares of Common Stock and the 2024 Pre-Funded Warrants to purchase up to 4,666,332 shares of Common Stock to certain institutional and accredited investors, which resulted in dilution to our stockholders that did not participate in the 2024 Private Placement, and, to the extent that the 2024 Pre-Funded Warrants are exercised, our stockholders' ownership interests will be further diluted. If we raise additional funds through upfront payments or milestone payments pursuant to future collaborations with third parties, we may 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, 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 \$43.6 million and \$28.5 million for the years ended December 31, 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;

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- 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 commercial-scale current good manufacturing practices (“cGMP”), capabilities through third-parties or our own manufacturing facility.

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 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.

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These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, DNTH103 or other product candidates.

Our competitors have developed, are developing or may develop programs and processes competitive with DNTH103 or other product candidates and processes. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments. Our success will depend partially on our ability to develop and commercialize products that have a competitive safety, efficacy, dosing and/or presentation profile. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective, have a more attractive dosing profile or presentation or are less expensive than any products we may develop, if any, or if competitors develop competing products or if biosimilars enter the market more quickly than we are able to, if at all, and are able to gain market acceptance. See the section titled “*Business—Competition*” for a more detailed description of our competitors and the factors that may affect the success of the products that we develop.

DNTH103 and our other programs are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we or our current or future collaborators are unable to complete development of, or commercialize, our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We have no products on the market and DNTH103 and our other programs are in the early stages of development. As a result, we expect it will be many years before we commercialize any product candidate, if any. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for, and successfully commercializing, DNTH103 or other product candidates either alone or with third parties, and we cannot guarantee that we will ever obtain regulatory approval for any 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:

- regulators or institutional review boards (“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;

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- 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, a biologics license application (“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 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 clinical trial application (“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 of DNTH103 in patients with multifocal motor neuropathy (“MMN”) in the

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second quarter of 2024 and chronic inflammatory demyelinating polyneuropathy (“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 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 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.

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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. There is currently a global shortage of NHPs available for drug development. This could cause the cost of obtaining NHPs for our future preclinical studies to increase significantly and, if the shortage continues, could also result in delays to our development timelines. Furthermore, a failure of one or more clinical trials can 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 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 Good Clinical Practices "(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 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 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 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 future collaborators may reveal significant adverse events or undesirable side effects not seen in our preclinical studies and may result in a safety profile that could halt clinical development, inhibit regulatory approval or limit commercial potential or market acceptance of DNTH103 or any other product candidates or result in potential product liability claims.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects, adverse events or unexpected characteristics. While our completed preclinical studies in NHPs and our Phase 1 clinical trial in humans have not shown any such characteristics, we cannot assure you that such characteristics will not be observed in our future clinical trials. If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to such trials, patients may drop out of our trials, patients may be harmed, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether, including DNTH103. We, the FDA, EU member states, or other applicable regulatory authorities, or an IRB or ethics committee, may suspend any clinical trials of DNTH103 or any other product candidates at any time for various reasons, including a belief that subjects or patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential products developed in the biotechnology industry that initially showed therapeutic promise in early-stage studies and trials have later been found to cause side effects that prevented their further development. Other potential products have shown side effects in preclinical studies that do not present themselves in clinical trials in humans. Even if the side effects do not preclude a product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of an approved product due to its tolerability versus other therapies. In addition, a half-life extension could prolong the duration of undesirable side effects, which could also inhibit market acceptance. Treatment-emergent adverse events could also affect patient recruitment or the ability of enrolled subjects to complete our clinical trials or could result in potential product liability claims. Potential side effects associated with DNTH103, or any other product candidates, may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from DNTH103, or any other product

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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, European Medical Agency (“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 of an IND or CTA for a Phase 2 clinical trial of DNTH103, the FDA or EMA may recommend changes to our proposed study designs, including the number and size of registrational clinical trials required to be conducted in such Phase 2 programs. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of our product candidates. Additionally, even if regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or a CTA, such regulatory authorities may change their requirements in the future. The FDA, EMA or comparable foreign regulatory authorities may require the analysis of data from trials assessing different doses of the product candidate alone or in combination with other therapies to justify the selected dose prior to the initiation of large trials in a specific indication. Any delays or failure to file INDs or CTAs, initiate clinical trials, or obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all. We are

subject to similar risks related to the review and authorization of our protocols and amendments by comparable foreign regulatory authorities.

Risks Related to Our Reliance on Third Parties

We currently rely and expect to rely in the future on the use of manufacturing suites in third-party facilities or on third parties to manufacture DNTH103 and any other product candidates, and we may rely on third parties to produce and process our products, if approved. Our business could be adversely affected if we are unable to use third-party manufacturing suites or if the third-party manufacturers encounter difficulties in production.

We do not currently lease or own any facility that may be used as our clinical-scale manufacturing and processing facility and currently rely on a CDMO, WuXi Biologics (as defined below), to manufacture our product candidate used in our Phase 1 and planned Phase 2 clinical trials. We currently have a sole source relationship with WuXi Biologics for our supply of DNTH103 (see the section titled “*Business—Collaboration, License and Services Agreements*” located elsewhere in this prospectus 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

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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 proposed 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 United Kingdom ("UK"), could also negatively impact our ability to manufacture our product candidates for our planned clinical trials or have an adverse effect on our ability to secure government funding, which could adversely affect our financial condition and cause us to delay our clinical development programs.

If our CDMO, WuXi Biologics, is unable to obtain sufficient raw and intermediate materials on a timely basis or if our CDMO experiences other supply difficulties, our business may be materially and adversely affected.

We work closely with our CDMO, WuXi Biologics, to ensure their suppliers have continuity of supply of raw and intermediate materials but cannot guarantee these efforts will always be successful. Our CDMO has experienced, and may experience in the future, 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 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 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

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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 expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of preclinical and clinical drug development, technical operations, clinical operations, regulatory affairs and, potentially, sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial personnel and systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team working together in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel.

We are highly dependent on our key personnel, and we anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our managerial, scientific and medical personnel, including our Chief Executive Officer, Chief Medical Officer, Chief Financial Officer, General Counsel, Chief Accounting Officer and other members of our leadership team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of

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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

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information technology systems and those of our third-party CROs, CDMOs, other contractors (including sites performing our clinical trials), third party service providers and supply chain companies, and consultants, as well as other partners, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by employees, contractors, consultants, business partners and/or other third parties, or from cyber-attacks by malicious third parties, which may compromise system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, data.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

To the extent that any disruption or security breach were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of DNTH103, or other product candidates could be delayed. Further, our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored.

As our employees work remotely and utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations, there are risks to our information technology systems and data. Additionally, business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

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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 prospectus 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

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promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new product candidates or products resulting from a strategic alliance or acquisition that delay or prevent us from realizing the expected benefits or enhancing our business. There is no assurance that, following any such acquisition, we will achieve the synergies expected in order to justify the transaction, which could result in a material adverse effect on our business and prospects.

We maintain our cash at financial institutions, at times in balances that exceed federally-insured limits. The failure of financial institutions could adversely affect our ability to pay our operational expenses or make other payments.

Our cash held in non-interest-bearing and interest-bearing accounts can at times exceed the Federal Deposit Insurance Corporation (“FDIC”) insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank on March 10, 2023. The Federal Reserve subsequently announced that account holders would be made whole. However, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders’ access to their accounts and assets held in their accounts may be substantially delayed. For example, Former Dianthus could not access its assets held in its account with Silicon Valley Bank for a period in March 2023, which required Former Dianthus to obtain a short-term loan to fund its operations (see “*Certain Relationships and Related Party Transactions—Dianthus and Former Dianthus Transactions—Promissory Notes*” located elsewhere in this prospectus for information on the short-term loan). Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.

We have identified material weaknesses in our internal control over financial reporting which, if not corrected, could affect the reliability of our financial statements and have other adverse consequences.

A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the financial statements would not be prevented or detected on a timely basis.

We have identified material weaknesses in our internal control over financial reporting that we are currently working to remediate, which relate to: (a) general segregation of duties, including the review and approval of journal entries as well as system access that has not been designed to allow for effective segregation of duties; and (b) our accounting software system has certain system limitations that do not allow for an effective control environment.

Our management has concluded that these material weaknesses in our internal control over financial reporting are due to the fact that we have limited resources and do not have the necessary business processes and related internal controls formally designed and implemented coupled with the appropriate resources to oversee our business processes and controls.

Our management is in the process of developing a remediation plan. The material weaknesses will be considered remediated when our management designs and implements effective controls that operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. Our management will monitor the effectiveness of our remediation plans and will make changes management determines to be appropriate.

If not remediated, these material weaknesses could result in material misstatements to our annual or interim financial statements that might not be prevented or detected on a timely basis, or in delayed filing of required

periodic reports. If we are unable to assert that our internal control over financial reporting is effective under Section 404(a) of the Sarbanes-Oxley Act, or, if we become subject to Section 404(b) of the Sarbanes-Oxley Act and our independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of the internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our Common Stock could be adversely affected and we could become subject to litigation or investigations by Nasdaq, the SEC, or other regulatory authorities, all of which could require additional financial and management resources.

Risks Related to Intellectual Property

Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage.

We rely or may rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates and technologies and to prevent third parties from competing with us. Our success depends in large part on our ability to obtain and maintain patent protection for platform technologies, product candidates and their uses, as well as the ability to operate without infringing on or violating the proprietary rights of others. We own six pending patent applications, and we expect to continue to file patent applications in the United States and abroad related to discoveries and technologies that are important to our business. However, we may not be able to protect our intellectual property rights throughout the world and the legal systems in certain countries may not favor enforcement or protection of patents, trade secrets and other intellectual property. Filing, prosecuting and defending patents on product candidates worldwide would be prohibitively expensive and our intellectual property rights in some foreign jurisdictions may be less extensive than those in the United States. As such, we do not have patents in all countries or all major markets and may not be able to obtain patents in all jurisdictions even if we apply for them. Competitors may operate in countries where we do not have patent protection and could then freely use our technologies and discoveries in such countries to the extent such technologies and discoveries are publicly known or disclosed in countries where patent protection has not been requested.

Our intellectual property portfolio is at an early stage, and we do not currently own or in-license any issued patents. Our pending and future patent applications may not result in patents being issued. Any issued patents may not afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or product candidates. Even if these patents are granted, they may be difficult to enforce. Further, any issued patents that we may license or own covering our product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the United States Patent and Trademark Office (“USPTO”). Further, if we encounter delays in any clinical trials or delays in obtaining regulatory approval, the period of time during which we could market product candidates under patent protection would be reduced. Thus, the patents that we may own or license may not afford any meaningful competitive advantage.

In addition to seeking patents for some of our technology and product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in the market. In order to 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

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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 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.

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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.

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Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in us failing to obtain regulatory approval to market DNTH103 or other product candidates, which would significantly harm our business, results of operations and prospects. If we were to obtain approval, regulatory authorities may approve any such product candidate for fewer or more limited indications than we request, including failing to approve the most commercially promising indications, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for a product candidate, we will not be able to commercialize, or will be delayed in commercializing, such product candidate and our ability to generate revenue will be materially impaired.

Disruptions at the FDA and other government agencies could negatively affect the review of our regulatory submissions, which could negatively impact our business.

The ability of the FDA to review and approve regulatory submissions can be affected by a variety of factors, including disruptions caused by government shutdowns and public health crises. Such disruptions could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We may not be able to meet requirements for the chemistry, manufacturing and control of our product candidates.

In order to receive approval of our products by the FDA and comparable foreign regulatory authorities, we must show that we and our contract manufacturing partners are able to characterize, control and manufacture our drug products safely and in accordance with regulatory requirements. This includes synthesizing the active ingredient, developing 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 chemistry, manufacturing and control (“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 may in the future choose to conduct more of our clinical trials outside the United States. We currently intend to conduct our Phase 2 clinical trials for DNTH103 in the United States and outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (“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 risk evaluation and mitigation strategy (“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 prospectus 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 prospectus 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 prospectus 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

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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 prospectus 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

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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 it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, rising tensions between China and Taiwan, the

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ongoing conflict in Israel and surrounding areas, the attacks on marine vessels traversing the Red Sea and the ongoing military conflict between Russia and Ukraine have created volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may 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 is expected to be volatile, and the market price of the 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 Merger as rapidly or to the extent anticipated by financial or industry analysts;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors;
- sales of securities by us or our securityholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations or continued development of our product candidates;
- trading volume of our Common Stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;

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- adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets;
- the introduction of technological innovations or new therapies that compete with our products and services; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our Common Stock. In addition, a recession, depression or other sustained adverse market event could materially and adversely affect our business and the value of our Common Stock. In the past, following periods of volatility in the market price of a company's 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 incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.

We will incur significant legal, accounting and other expenses as a public company that Former Dianthus did not incur as a private company, including costs associated with public company reporting obligations under the Exchange Act. Our management team consists of the executive officers of Former Dianthus, some of whom have not previously managed and operated a public company. These executive officers and other 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 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 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 this prospectus and 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, Former Dianthus has never been required to test its 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 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 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 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 Stock, thereby depressing the market price of our Common 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;

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- 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 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 Stock will be your sole source of gain, if any, for the foreseeable future.

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An active trading market for our Common Stock may not be sustained and our stockholders may not be able to sell their shares of Common Stock for a profit, if at all.

An active trading market for our shares of Common Stock may not be sustained. If an active market for our Common Stock is not sustained, it may be difficult for our stockholders to sell their shares at an attractive price or at all.

Future sales of shares by existing stockholders could cause our stock price to decline.

If securityholders sell, or indicate an intention to sell, substantial amounts of our Common Stock in the public market, the trading price of our Common Stock could decline. In addition, shares of Common Stock that are subject to outstanding options or warrants of Dianthus are eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If any of the foregoing shares of Common Stock are sold, the trading price of our Common Stock could decline.

Our executive officers, directors and principal stockholders will have the ability to control or significantly influence all matters submitted to our stockholders for approval.

Our executive officers, directors and principal stockholders, in the aggregate, beneficially own approximately 66% of our outstanding shares of Common Stock as of March 14, 2024. As a result, if these stockholders were to choose to act together, 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 Stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect to not provide research coverage of our Common Stock, and such lack of research coverage may adversely affect the market price of our Common 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 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 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 Inflation Reduction Act of 2022 (“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 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 Merger, our tax carryforwards will be attributable to both the historic pre-Merger net operating losses of Former Dianthus and the historic pre-Merger net operating losses and credits of Dianthus.

As of December 31, 2023, we had federal net operating loss carryforwards of \$320.7 million, all of which can be carried forward indefinitely. As of December 31, 2023, Dianthus had state net operating loss carryforwards of \$299.1 million, which begin to expire in 2035. As of December 31, 2023, Dianthus also had available research and orphan drug tax credit carryforwards for federal and state income tax purposes of \$14.8 million and \$3.5 million, respectively, which 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 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.

BUSINESS COMBINATION OF DIANTHUS AND OPCO

On September 11, 2023, we completed our business combination with Dianthus Therapeutics OpCo, Inc. (“OpCo”) in accordance with the terms of the Merger Agreement, pursuant to which, among other matters, Dio Merger Sub, Inc. (“Merger Sub”) merged with and into OpCo, with OpCo surviving as a wholly owned subsidiary of the Company (the “Merger”). In connection with the completion of the Merger, we changed our name from “Magenta Therapeutics, Inc.” to “Dianthus Therapeutics, Inc.” (the “Name Change”), and the business conducted by the Company became primarily the business conducted by OpCo, which is a clinical-stage biotechnology company focused on developing next-generation complement therapeutics for patients living with severe autoimmune and inflammatory diseases. The Merger was intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

Immediately prior to the effective time of the Merger, Magenta effected a 1-for-16 reverse stock split of its Common Stock (the “Reverse Stock Split”). Unless noted otherwise, all references to share and per share amounts in this prospectus reflect the Reverse Stock Split.

Pursuant to the terms of the Merger Agreement, immediately prior to the effective time of the Merger, each share of OpCo preferred stock was converted into a share of OpCo common stock. At the effective time of the Merger, the Company issued an aggregate of 11,021,248 shares of Common Stock to OpCo stockholders, based on an exchange ratio of approximately 0.2181 shares of Common Stock for each share of OpCo capital stock, including those shares of OpCo common stock issued upon the conversion of OpCo preferred stock and those shares of OpCo common stock issued in the OpCo pre-closing financing, but excluding shares to be canceled pursuant to the Merger Agreement and dissenting shares, resulting in 14,813,295 shares of Common Stock being issued and outstanding immediately following the effective time of the Merger. The exchange ratio was determined in accordance with the Merger Agreement.

Immediately following the completion of the Merger, the Company’s securityholders as of immediately prior to the Merger owned approximately 23% of the outstanding shares of Common Stock on a fully diluted basis and OpCo’s securityholders, including those securityholders who purchased shares of OpCo common stock and OpCo pre-funded warrants in the OpCo pre-closing financing, owned approximately 77% of the outstanding shares of the Company on a fully diluted basis (and assuming the exercise for Common Stock of any pre-funded warrants of the Company).

In addition, the Company assumed OpCo’s Dianthus Therapeutics, Inc. 2019 Stock Plan, each outstanding and unexercised option to purchase shares of OpCo common stock immediately prior to the effective time of the Merger was assumed by the Company and converted into an option to purchase shares of Common Stock, with necessary adjustments to the number of shares and exercise price to reflect the exchange ratio, and each outstanding and unexercised warrant to purchase shares of OpCo common stock immediately prior to the effective time of the Merger (including the OpCo pre-funded warrants sold in the OpCo pre-closing financing) was converted into a warrant to purchase shares of Common Stock, with necessary adjustments to the number of shares and exercise price to reflect the exchange ratio.

The issuance of the shares of Common Stock issued to the former stockholders of OpCo, other than shares of the Common Stock issued in exchange for shares of OpCo common stock sold in the OpCo pre-closing financing, was registered with the SEC on the Company’s registration statement on Form S-4, as amended (File No. 333-267276).

The shares of Common Stock listed on The Nasdaq Capital Market, previously trading through the close of business on Monday, September 11, 2023 under the ticker symbol “MGTA,” commenced trading on The Nasdaq Capital Market, on a post-Reverse Stock Split, post-Merger basis under the ticker symbol “DNTH” on Tuesday, September 12, 2023. The Common Stock is represented by a new CUSIP number, 252828108.

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The foregoing description of the Merger Agreement contained herein does not purport to be complete and is qualified in its entirety by reference to the Merger Agreement, a copy of which is filed as Exhibit 2.1 to the Registration Statement.

Contingent Value Rights Agreement

On September 11, 2023, the Company entered into a contingent value rights agreement (the “CVR Agreement”) with Computershare Trust Company, N.A., a federally chartered trust company (“Rights Agent”), pursuant to which the Company’s pre-Merger holders of Common Stock were entitled to receive one non-transferable contingent value right (each, a “CVR”) for each outstanding share of Common Stock held by such stockholder as of the record time. The record time for the distribution of CVRs was immediately prior to the effective time of the Merger on September 11, 2023, and the payment date for the distribution of CVRs was September 14, 2023.

Pursuant to the CVR Agreement, each CVR holder is entitled to certain rights to receive a pro rata portion of the proceeds, if any, received by the Company as a result of (i) contingent payments made to the Company, such as milestone, royalty or earnout, when received under any pre-Merger disposition agreements related to the Company’s pre-Merger assets (which includes milestone payments under the April 2023 asset purchase agreements pertaining to the Company’s MGTA-145 and MGTA-45 programs and the CD117 antibodies including the clinical antibody that was used with MGTA-117) and (ii) an asset sale of the Company after the effective date of the Merger and prior to December 31, 2023, in each case, received within a three-year period following the closing of the Merger. Such proceeds are subject to certain permitted deductions, including for applicable tax payments, certain expenses incurred by the Company or its affiliates, losses incurred or reasonably expected to be incurred by the Company or its affiliates due to a third-party proceeding in connection with a disposition and certain wind-down costs.

The contingent payments under the CVR Agreement, if they become payable, will become payable to the Rights Agent for subsequent distribution to the CVR holders. In the event that no such proceeds are received, holders of the CVRs will not receive any payment pursuant to the CVR Agreement. There can be no assurance that any CVR holders will receive payments with respect thereto.

The right to the contingent payments contemplated by the CVR Agreement is a contractual right only and is not transferable, except in the limited circumstances specified in the CVR Agreement. The CVRs are not evidenced by a certificate or any other instrument and are not registered with the SEC. The CVRs do not have any voting or dividend rights and do not represent any equity or ownership interest in the Company or any of its respective affiliates. No interest will accrue on any amounts payable in respect of the CVRs.

The foregoing description of the CVR Agreement does not purport to be complete and is qualified in its entirety by the full text of the CVR Agreement, a copy of which is filed as Exhibit 10.1 to this Registration Statement.

Indemnification Agreements

On September 11, 2023, the Company entered into indemnification agreements with each of its directors and executive officers (the “Indemnification Agreements”). The Indemnification Agreements, among other things, require the Company to indemnify these individuals for certain expenses (including attorneys’ fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in the Company’s right, on account of any services undertaken by such person on behalf of the Company or that person’s status as a member of the Company’s board of directors (the “Board of Directors”) to the maximum extent allowed under Delaware law.

The foregoing description of the Indemnification Agreements is qualified in its entirety by the full text of the forms of Indemnification Agreements, copies of which are attached hereto as Exhibit 10.4 and Exhibit 10.5 to this Registration Statement.

Reverse Stock Split Amendment

Magenta convened and adjourned its special meeting of stockholders on September 8, 2023 (the “Special Meeting”). At the Special Meeting, Magenta’s stockholders approved an amendment to the amended and restated certificate of incorporation of the Company to effect the Reverse Stock Split. Following the Special Meeting, Magenta’s board of directors approved the Reverse Stock Split of Common Stock, at a ratio of 1:16. To effect the Reverse Stock Split and the Name Change, the Company filed a Fifth Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware (the “A&R Charter”), with an effective time of 11:13 a.m. Eastern Time on September 11, 2023 (“A&R Charter Effective Time”).

As of the A&R Charter Effective Time, each 16 shares of Common Stock issued and outstanding immediately prior to the Reverse Stock Split were automatically without further action on the part of the Company or any holders of such Common Stock, reclassified, combined, converted and changed into one share of Common Stock. Immediately following the Reverse Stock Split, there were approximately 3,792,087 shares of the Common Stock issued and outstanding.

No fractional shares of Common Stock were issued as a result of the Reverse Stock Split. Instead, any stockholder who would otherwise be entitled to a fractional share of Common Stock as a result of the Reverse Stock Split (after aggregating all fractions of a share to which such stockholder would otherwise be entitled) is, in lieu thereof, entitled to receive a cash payment equal to the product of such resulting fractional interest in one share of Common Stock multiplied by the closing trading price on The Nasdaq Stock Market LLC of a share of Common Stock on September 8, 2023, the last trading day immediately prior to the date on which the effective time of the Merger occurred. The Common Stock commenced trading on a post-Reverse Stock Split, post-Merger basis on September 12, 2023, represented by a new CUSIP number (252828108). The par value per share of Common Stock remained unchanged.

The foregoing description of the A&R Charter does not purport to be complete and is subject to and qualified in its entirety by the full text of the A&R Charter, a copy of which is filed as Exhibit 3.1 to this Registration Statement.

PRIVATE PLACEMENTS OF SHARES OF COMMON STOCK AND PRE-FUNDED WARRANTS

OpCo Pre-Closing Financing

On September 11, 2023, OpCo completed a private placement of shares of OpCo common stock and OpCo pre-funded warrants pursuant to the subscription agreement, by and among the OpCo and the Selling Stockholders named therein, dated as of May 2, 2023, as amended (the “Subscription Agreement”). Pursuant to and subject to the terms and conditions of the Subscription Agreement, OpCo issued and sold, and such Selling Stockholders purchased, immediately prior to the consummation of the Merger, 2,873,988 shares of OpCo common stock and 210,320 OpCo pre-funded warrants, exercisable for 210,320 shares of OpCo common stock, at a purchase price of approximately \$23.34 per share or \$23.34 per warrant, for an aggregate purchase price of approximately \$72.0 million (the “OpCo pre-closing financing” or “pre-closing financing”).

As described above, each outstanding and unexercised OpCo pre-funded warrant to purchase shares of OpCo common stock immediately prior to the effective time of the Merger was converted into a 2023 Pre-Funded Warrant, with necessary adjustments to the number of shares and exercise price to reflect the exchange ratio. The 2023 Pre-Funded Warrants have an exercise price per share equal to \$0.001 per share, subject to proportional adjustments in the event of stock splits, stock dividends and certain fundamental transactions. The aggregate exercise price of the 2023 Pre-Funded Warrants, except for a nominal exercise price of \$0.001 per warrant per share, was pre-funded to OpCo and, consequently, no additional consideration (other than the nominal exercise price) is required to be paid by the holder of the 2023 Pre-Funded Warrants to exercise the warrants. The 2023 Pre-Funded Warrants will not expire until exercised in full.

The sale of the shares of OpCo common stock and the OpCo pre-funded warrants, and the shares of OpCo common stock issuable upon exercise of the OpCo pre-funded warrants, was not registered under the Securities Act, and the OpCo pre-closing financing was intended to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving a public offering. The Selling Stockholders named in the Subscription Agreement had the intent to acquire the shares of OpCo common stock and OpCo pre-funded warrants for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the shares of OpCo common stock and OpCo pre-funded warrants issued in the OpCo pre-closing financing.

The foregoing description of the 2023 Pre-Funded Warrants contained herein does not purport to be complete and is qualified in its entirety by the full text of the form of 2023 Pre-Funded Warrant, a copy of which is filed as Exhibit 4.1 to this Registration Statement.

On September 11, 2023, pursuant to the Subscription Agreement, the Company, OpCo and the Selling Stockholders named therein entered into a registration rights agreement (the “2023 Registration Rights Agreement”), pursuant to which, among other things, the Company agreed to provide for the registration and resale of certain shares of Common Stock that are held by such Selling Stockholders from time to time, including the shares of Common Stock issued in exchange for shares of common stock of OpCo sold in the OpCo pre-closing financing and the shares of Common Stock issuable upon exercise of the 2023 Pre-Funded Warrants assumed upon conversion of the pre-funded warrants of OpCo sold in the OpCo pre-closing financing. See the section titled “*Description of Capital Stock—Registration Rights Agreements*” located elsewhere in this prospectus for further information on the 2023 Registration Rights Agreement.

2024 Private Placement

On January 24, 2024, Dianthus completed a private placement of shares of Common Stock and the 2024 Pre-Funded Warrants pursuant to the securities purchase agreement, by and among the Dianthus and the Selling Stockholders named therein, dated as of January 22, 2024 (the “Securities Purchase Agreement”). Pursuant to

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and subject to the terms and conditions of the Securities Purchase Agreement, Dianthus issued and sold, and such Selling Stockholders purchased 14,500,500 shares of Common Stock and 4,666,332 2024 Pre-Funded Warrants, exercisable for 4,666,332 shares of Common Stock, at a purchase price of \$12.00 per share or \$11.999 per 2024 Pre-Funded Warrant, which represents the per share purchase price of the Common Stock less the \$0.001 per share exercise price for each 2024 Pre-Funded Warrant, for an aggregate purchase price of approximately \$230.0 million (the “2024 Private Placement”).

The 2024 Pre-Funded Warrants have an exercise price per share equal to \$0.001 per share. The aggregate exercise price of the 2024 Pre-Funded Warrants, except for a nominal exercise price of \$0.001 per warrant per share, was pre-funded to Dianthus and, consequently, no additional consideration (other than the nominal exercise price) is required to be paid by a holder of the 2024 Pre-Funded Warrants to exercise the warrants. The 2024 Pre-Funded Warrants are exercisable at any time after the date of issuance. A holder of 2024 Pre-Funded Warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. A holder of Pre-Funded Warrants may increase or decrease this percentage to a percentage not in excess of 19.99% by providing at least 61 days’ prior notice to Dianthus. The 2024 Pre-Funded Warrants will not expire until exercised in full.

The sale of the shares of Common Stock and the 2024 Pre-Funded Warrants, and the shares of Common Stock issuable upon exercise of the 2024 Pre-Funded Warrants, was not registered under the Securities Act in reliance on the exemption from registration pursuant to Section 4(a)(2) of the Securities Act and/or Rule 506 of Regulation D promulgated thereunder, or under any state securities laws. Dianthus relied on this exemption from registration based in part on representations made by the Selling Stockholders named in the Securities Purchase Agreement. Appropriate legends were affixed to the shares of Common Stock and the 2024 Pre-Funded Warrants issued in the 2024 Private Placement.

The foregoing description of the 2024 Pre-Funded Warrants contained herein does not purport to be complete and is qualified in its entirety by the full text of the form of 2024 Pre-Funded Warrant, a copy of which is filed as Exhibit 4.3 to this Registration Statement.

On January 22, 2024, pursuant to the Securities Purchase Agreement, Dianthus and the Selling Stockholders named therein entered into a registration rights agreement (the “2024 Registration Rights Agreement”), pursuant to which, among other things, the Company agreed to provide for the registration and resale of certain shares of Common Stock that are held by such Selling Stockholders from time to time, including the shares of Common Stock issuable upon exercise of the 2024 Pre-Funded Warrants. See the section titled “*Description of Capital Stock—Registration Rights Agreements*” located elsewhere in this prospectus for further information on the Registration Rights Agreement.

MARKET PRICE AND DIVIDEND INFORMATION

Market Information and Holders

Our Common Stock is traded on The Nasdaq Capital Market under the symbol “DNTH.”

As of March 14, 2024, there were approximately 50 stockholders of record of our Common Stock based on information provided by our transfer agent. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our Common Stock for the foreseeable future. Any future determination to pay dividends will be at the discretion of the Board of Directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions and restrictions imposed by applicable laws and other factors the Board of Directors deems relevant.

USE OF PROCEEDS

We are not selling any securities under this prospectus and will not receive any proceeds from the sale of the Resale Shares covered hereby. Some of the shares of Common Stock offered hereby are issuable upon the exercise of the Pre-Funded Warrants. Upon exercise of such Pre-Funded Warrants for cash, we will receive the nominal cash exercise price paid by the holders of the Pre-Funded Warrants. We intend to use those proceeds, if any, for general corporate purposes.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes included elsewhere in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties, including those described in the section titled "Cautionary Statement Concerning Forward-Looking Statements" included elsewhere in this prospectus. Our actual results and the timing of selected events could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth under the section titled "Risk Factors" included elsewhere in this prospectus.

Overview

We are a clinical-stage biotechnology company focused on developing next-generation complement therapeutics for patients living with severe autoimmune and inflammatory diseases. We believe our lead novel and proprietary monoclonal antibody product candidate, DNTH103, has the potential to address a broad array of complement-dependent diseases as currently available therapies or those in development leave room for improvements in efficacy, safety, and/or dosing convenience. We have purposefully engineered DNTH103 to selectively bind to only the active form of the C1s complement protein and to exhibit improved potency and an extended half-life. By selectively targeting only the active form of C1s, which drives disease pathology and constitutes only a small fraction of the total protein present in circulation, we aim to reduce the amount of drug required for a therapeutic effect. We intend to deliver our product candidate through a lower dose, less frequent, self-administered, convenient subcutaneous ("S.C.") injection suitable for a pre-filled pen.

Our most advanced product candidate, DNTH103, is a clinical-stage, highly potent, highly selective and fully human monoclonal immunoglobulin G4 with picomolar binding affinity that is designed to selectively bind only to the active form of the C1s complement protein. The active form of C1s is generated during complement activation by cleavage of the inactive proenzyme C1s. As a validated complement target in the autoimmune and inflammatory field, C1s inhibition prevents further progression of the classical pathway cascade. DNTH103 is engineered with YTE half-life extension technology, a specific three amino acid change in the Fc domain, and has a pharmacokinetic profile designed to support less frequent, lower dose, self-administration as a convenient S.C. injection. Data reported from DNTH103's Phase 1 clinical trial in 60 healthy volunteers across eight dose cohorts validates the extended half-life and potent classical pathway inhibition and supports a potentially differentiated safety profile of DNTH103. The topline data confirmed its approximately 60-day half-life and highly potent classical pathway inhibition with every two weeks S.C. dosing of 300mg/2mL surpassing the calculated IC90 of 87ug/mL, establishing DNTH103's best-in-class potential to be the first self-administered subcutaneous injection dosed as infrequently as every two weeks to treat a range of autoimmune disorders. Based on the clinical data available to date, DNTH103 was generally well tolerated with no serious adverse events or complement-related infections. DNTH103 is designed to selectively target the active form of C1s, inhibiting only the classical pathway, while leaving the lectin and alternative pathways intact. As a result, DNTH103 may have a reduced risk of infections from encapsulated bacteria when compared to C5 terminal inhibitors, thus potentially avoiding a U.S. Food and Drug Administration Boxed Warning and associated REMS. We believe that DNTH103 has the potential to yield therapeutic benefit in multiple autoimmune and inflammatory disease indications where inappropriate activation of the classical pathway cascade drives or exacerbates the disease pathology by inhibiting the ability of activated C1s to effect downstream complement activity, ameliorating complement mediated cell death and disruption of normal cellular function.

2024 Private Placement

On January 24, 2024, in order to provide us with additional capital for our development programs, we completed a private placement of shares of Common Stock and the 2024 Pre-Funded Warrants pursuant to the

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Securities Purchase Agreement. Pursuant to and subject to the terms and conditions of the Securities Purchase Agreement, we issued and sold, and Selling Stockholders named in the Securities Purchase Agreement purchased, 14,500,500 shares of Common Stock and 4,666,332 2024 Pre-Funded Warrants, exercisable for 4,666,332 shares of Common Stock, at a purchase price of \$12.00 per share or \$11.999 per 2024 Pre-Funded Warrant, which represents the per share purchase price of the shares of Common Stock less the \$0.001 per share exercise price for each 2024 Pre-Funded Warrant, for an aggregate purchase price of approximately \$230.0 million.

Completion of the Merger and Pre-Closing Financing

On September 11, 2023, we completed a business combination with Former Dianthus pursuant to which, among other matters, Former Dianthus became as a wholly owned subsidiary of ours (the “Merger”). In connection with the completion of the Merger, we changed our name from “Magenta Therapeutics, Inc.” to “Dianthus Therapeutics, Inc.,” and the business conducted by us became primarily the business conducted by Former Dianthus.

Concurrently with the execution and delivery of the Merger Agreement, and in order to provide Former Dianthus with additional capital for its development programs, Former Dianthus entered into a subscription agreement, as amended (the “Subscription Agreement”), with certain investors named therein (the “Investors”). Pursuant to and subject to the terms and conditions of the Subscription Agreement, immediately prior to the effective time of the Merger, Former Dianthus issued and sold, and the Investors purchased, 2,873,988 shares of Former Dianthus common stock and 210,320 pre-funded warrants, exercisable for 210,320 shares of Former Dianthus common stock, at a purchase price of approximately \$23.34 per share or \$23.34 per warrant, for an aggregate purchase price of approximately \$72.0 million (the “pre-closing financing”).

See Note 1 to our consolidated financial statements for the year ended December 31, 2023 and 2022 included elsewhere in this prospectus for additional information.

Background

Since our inception in 2019, we have devoted substantially all of our resources to conducting research and development activities (including with respect to the DNTH103 program) and undertaking preclinical studies, conducting a clinical trial and the manufacturing of the product used in our clinical trials and preclinical studies, business planning, developing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these activities.

We do not own or operate, and currently have no plans to establish, any significant laboratory or manufacturing facilities. We rely, and expect to continue to rely, on third parties for the testing and manufacture of our product candidates, as well as for commercial manufacturing should any of our product candidates obtain marketing approval. We believe this strategy allows us to maintain a more efficient infrastructure by eliminating the need to invest in our own significant laboratory and manufacturing facilities, equipment, and personnel while also enabling us to focus expertise and resources on the development of our product candidates.

To date, we have funded our operations primarily with proceeds from the sale of capital stock and have raised aggregate gross proceeds of \$423.5 million from private placements. As of December 31, 2023, we had cash, cash equivalents and short-term investments of \$173.7 million. Based on our current operating plan, we believe that our existing cash, cash equivalents and short-term investments, together with the proceeds from our 2024 Private Placement, should be sufficient to fund our operations into the second half of 2027. Until we achieve profitability, we plan to fund our operations and capital expenditures with cash on hand and expect to seek to raise any necessary additional capital through private or public equity or debt financings, loans or other capital sources, which could include income from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. There can be no assurance that we

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will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us. If we are unable to raise sufficient additional capital, we may be compelled to consider actions such as reducing the scope of our operations and planned capital expenditures or sell certain assets, including intellectual property assets.

We have incurred significant recurring losses. We generated net losses of \$43.6 million and \$28.5 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of \$89.4 million. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on a variety of factors, including the timing, scope and results of our research and development activities. We expect our expenses and capital requirements will increase substantially in connection with our ongoing activities, if and as we:

- advance the DNTH103 program through clinical development, including in any additional indications;
- advance discovery programs from preclinical development into and through clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish sales, marketing and distribution infrastructure to commercialize any approved product candidates;
- contract to manufacture any approved product candidates;
- expand clinical, scientific, management and administrative teams;
- maintain, expand, protect and enforce our intellectual property portfolio, including patents, trade secrets and know-how;
- acquire or in-license other product candidates or technologies;
- implement operational, financial and management systems; and
- operate as a public company.

We do not have any products approved for commercial sale and we have not generated any commercial revenue from product sales. Our ability to generate product revenue sufficient to achieve and maintain profitability will depend upon the successful development and eventual commercialization of DNTH103 or any future product candidates, which we expect, if it ever occurs, will take many years. We expect to spend a significant amount on development and marketing costs prior to such time. We will therefore require substantial additional capital to develop DNTH103 and any future product candidates and to support our continuing operations. We may never succeed in achieving regulatory and marketing approval for DNTH103 or any future product candidates. We may obtain unexpected results from our preclinical and clinical trials. We may elect to discontinue, delay, or modify preclinical and clinical trials of DNTH103 or any future product candidates. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. Accordingly, until such time that we can generate a sufficient amount of revenue from product sales or other sources, if ever, we expect to finance our operations through private or public equity or debt financings, loans or other capital sources, which could include income from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. However, we may be unable to raise additional capital from these sources on favorable terms, or at all. Our failure to obtain sufficient capital on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to delay, reduce or curtail our research, product development or future commercialization efforts. We may also be required to license rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. We cannot provide assurance that we will ever generate positive cash flow from operating activities. See the section titled “—*Liquidity and Capital Resources.*”

Global and Macroeconomic Developments

Uncertainty in the global economy presents significant risks to our business. We are subject to continuing risks and uncertainties in connection with the current macroeconomic environment, including increases in inflation, rising interest rates, general economic slowdown or a recession, changes in foreign currency exchange rates, recent bank failures, the prospect of a shutdown of the U.S. federal government, geopolitical factors, including 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 conflict between Russia and Ukraine and the responses thereto, pandemics or other public health crises, such as the COVID-19 pandemic, and supply chain disruptions. While we are closely monitoring the impact of the current macroeconomic conditions on all aspects of our business, including the impacts on participants in our clinical trials, employees, suppliers, vendors, business partners and regulators, the ultimate extent of the impact on our business remains highly uncertain and will depend on future developments and factors that continue to evolve. Most of these developments and factors are outside of our control and could exist for an extended period of time. We will continue to evaluate the nature and extent of the potential impacts to Dianthus' business, results of operations, liquidity and capital resources. For additional information, see the section titled "*Risk Factors*" found elsewhere in this prospectus.

Components of Results of Operations

Revenue

Since inception, we have not generated any revenue from product sales, and we do not expect to generate any revenue from the sales of products in the foreseeable future.

We are a party to an option agreement and license agreement with Zenas BioPharma, a related party. In September 2020, we entered into an option agreement with Zenas BioPharma ("Zenas Option"), through which we provided Zenas BioPharma an option to enter into an exclusive license agreement for the development and commercialization of products arising from our research of monoclonal antibody antagonists targeting certain specific complement proteins. In June 2022, we and Zenas BioPharma executed a license agreement ("Zenas License Agreement"). The Zenas Option and Zenas License Agreement are collectively referred to as the "Zenas Agreements." The Zenas License Agreement provides Zenas BioPharma with a license in the People's Republic of China, including Hong Kong, Macau, and Taiwan (collectively, "greater China"), for the development and commercialization of sequences and products under the first antibody sequence.

Under the Zenas Agreements, the consideration payable by Zenas Biopharma includes the following: (i) a \$1.0 million upfront payment upon execution of the Zenas License Agreement; (ii) an approximate \$1.1 million payment representing reimbursement for a portion of development costs previously incurred by us; (iii) reimbursement of a portion of costs related to CMC and expenses for the first antibody sequence through the manufacture of the first two batches of drug product; (iv) reimbursement of a portion of non-CMC-related costs and expenses for the development of the first antibody sequence through the first regulatory approval; (v) development milestones totaling up to \$11.0 million; and (vi) royalties on net sales ranging from mid-single digits to low teen percentages.

In accordance with Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* ("ASC 606"), we determined that there is one combined performance obligation that consists of the license and data transfer, the CMC and non-CMC services, and the participation in a joint steering committee, and that the combined performance obligation is satisfied over time. Therefore, we will recognize the transaction price from the license agreement over our estimated period to complete our activities. We concluded that we would utilize a cost-based input method to measure our progress toward completion of our performance obligation and to calculate the corresponding amount of revenue to recognize each period. We believe this is the best measure of progress because other measures do not reflect how we transfer our performance obligation to Zenas Biopharma. In applying the cost-based input method of revenue recognition, we use actual costs incurred relative to budgeted costs expected to be incurred for the combined performance obligation. These costs consist

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primarily of third-party contract costs. Revenue will be recognized based on the level of costs incurred relative to the total budgeted costs for the performance obligations. A cost-based input method of revenue recognition requires us to make estimates of costs to complete the performance obligation. In making such estimates, judgment is required to evaluate assumptions related to cost estimates.

There is a sales or usage-based royalty exception within ASC 606 that applies when a license of intellectual property is the predominant item to which the royalty relates. In accordance with this royalty exception, we will recognize royalty revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). As of December 31, 2023 and 2022, no royalty revenue has been recognized.

We also determined that the milestone payments of \$11.0 million are variable consideration under ASC 606, which need to be added to the transaction price when it is probable that a significant revenue reversal will not occur. Based on the nature of the milestones, such as the regulatory approvals which are generally not within our control, we will not consider achievement of this milestone to be probable until the uncertainty associated with such milestone has been resolved. When it is probable that a significant reversal of revenue will not occur, the milestone payment will be added to the transaction price for which we recognize revenue. As of December 31, 2023 and 2022, no milestones had been achieved.

For the years ended December 31, 2023 and 2022, we recognized related party license revenue totaling \$2.8 million and \$6.4 million, respectively, associated with the Zenas Agreements.

If our development efforts for DNTH103 or any future product candidates are successful and result in regulatory approval, we may generate revenue from future product sales. If we enter into license or collaboration agreements for DNTH103 or any future product candidates or intellectual property, revenue may be generated in the future from such license or collaboration agreements. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of DNTH103 or any future product candidates or from license or collaboration agreements. We may never succeed in obtaining regulatory approval for DNTH103 or any future product candidates.

Operating Expenses

Research and Development

Research and development expenses account for a significant portion of our operating expenses and consist primarily of external and internal expenses incurred in connection with the discovery and development of DNTH103 or any future product candidates.

External expenses include:

- payments to third parties in connection with research and development, including agreements with third parties such as CROs, clinical trial sites and consultants;
- the cost of manufacturing products for use in our clinical trials and preclinical studies, including payments to contract development and manufacturing organizations CDMOs and consultants; and
- payments to third parties in connection with the preclinical development of future product candidates, including for outsourced professional scientific development services, consulting research and collaborative research.

Internal expenses include:

- personnel-related costs, including salaries, bonuses, related benefits and stock-based compensation expenses for employees engaged in research and development functions; and
- facilities-related expenses, depreciation, supplies, travel expenses and other allocated expenses.

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We recognize research and development expenses in the periods in which they are incurred. Our internal resources, employees and infrastructure are not directly tied to any one research or drug discovery program and are typically deployed across multiple programs. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date. We utilize CROs for research and development activities and CDMOs for manufacturing activities and we do not have significant laboratory or manufacturing facilities. Therefore, we have no material facilities expenses attributed to research and development.

Product candidates in later stages of development generally have higher development costs than those in earlier stages. As a result, we expect that our research and development expenses will increase substantially over the next several years as we advance DNTH103 into larger and later-stage clinical trials, work to discover and develop additional product candidates, seek to expand, maintain, protect and enforce our intellectual property portfolio, and hire additional research and development personnel.

The successful development of DNTH103 or any future product candidates is highly uncertain, and we do not believe it is possible at this time to accurately project the nature, timing and estimated costs of the efforts necessary to complete the development of, and obtain regulatory approval for, DNTH103 or any future product candidates. To the extent DNTH103 or any future product candidates continue to advance into larger and later-stage clinical trials, our expenses will increase substantially and may become more variable. The duration, costs and timing of development of DNTH103 or any future product candidates are subject to numerous uncertainties and will depend on a variety of factors, including:

- the timing and progress of our preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we pursue;
- our ability to establish a favorable 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 of our clinical trials required for regulatory approval;
- the countries in which our clinical trials are conducted;
- the length of time required to enroll eligible subjects in our clinical trials;
- the number of subjects that participate in our clinical trials;
- the drop-out and discontinuation rate of subjects in our clinical trials;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in our clinical 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;

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- our arrangements with our CDMOs and 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.

Any of these factors could significantly impact the costs, timing and viability associated with the development of DNTH103 or any future product candidates.

General and Administrative Expenses

General and administrative expenses primarily consist of salaries, bonuses, related benefits, and stock-based compensation expense for personnel in executive, finance, and administrative functions; professional fees for legal, consulting, accounting, and audit services; and travel expenses, technology costs and other allocated expenses. General and administrative expenses also include corporate facility costs, including insurance, rent, utilities, depreciation, and maintenance, not otherwise included in research and development expenses. We recognize general and administrative expenses in the periods in which they are incurred.

We expect that our general and administrative expenses will increase in the future to support our continued research and development activities, pre-commercial preparation activities for the product candidates and, if any product candidate receives marketing approval, commercialization activities. In addition, we anticipate that we will incur additional expenses associated with being a public company, including expenses related to accounting, audit, legal, regulatory, public company reporting and compliance, director and officer insurance, investor and public relations, and other administrative and professional services.

Other Income, Net

Other income, net, consists primarily of interest income generated from earnings on invested cash equivalents and short-term investments.

Income Tax

Since inception, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or for our earned research tax credits due to uncertainty of realizing a benefit from those items. We maintain a full valuation allowance on our federal and state deferred tax assets as we have concluded that it is more likely than not that the deferred assets will not be utilized.

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Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following table summarizes our results of operations and other comprehensive loss for the periods indicated:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Revenues:		
License revenue - related party	\$ 2,826	\$ 6,417
Operating expenses:		
Research and development	32,841	29,379
General and administrative	18,159	6,743
Total operating expenses	51,000	36,122
Loss from operations	(48,174)	(29,705)
Other income/(expense):		
Interest income	4,764	1,145
(Loss)/gain on currency exchange, net	(85)	136
Other expense	(60)	(52)
Total other income	4,619	1,229
Net loss	<u><u>\$(43,555)</u></u>	<u><u>\$(28,476)</u></u>
Comprehensive loss:		
Net loss	\$(43,555)	\$(28,476)
Other comprehensive income/(loss):		
Change in unrealized gains/losses related to available-for-sale debt securities	208	(161)
Total other comprehensive income/(loss)	208	(161)
Total comprehensive loss	<u><u>\$(43,347)</u></u>	<u><u>\$(28,637)</u></u>

License Revenue—Related Party

Under the terms of the Zenas Agreements, we recognized related party license revenue of \$2.8 million and \$6.4 million for the years ended December 31, 2023 and 2022, respectively. The decrease was due to a decreased amount of CMC reimbursement due from Zenas Biopharma during the year ended December 31, 2023 as a result of the substantial completion of the manufacture of the first two batches of drug product for the DNTH103 program in late 2022.

Research and Development Expenses

Research and development expenses were \$32.8 million for the year ended December 31, 2023, as compared to \$29.4 million for the year ended December 31, 2022, an increase of \$3.4 million. This increase was due to a \$5.3 million increase in internal research and development costs, consisting of personnel and related costs, share-based compensation, and other costs, partially offset by a \$1.9 million decrease in external research and development costs, consisting of preclinical study costs, CMC activities, third-party consulting services, clinical operation activities, license and milestone payments and discovery activities.

The \$5.3 million increase in internal research and development costs was due to a \$4.5 million increase in personnel and related costs, a \$0.5 million increase in share-based compensation, and a \$0.3 million increase in

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other costs. The increases were primarily due to the expansion of our research and development function with additional headcount to support the Phase 1 clinical trial activities of our lead product candidate, DNTH103.

The \$1.9 million decrease in external research and development costs was due to a \$2.1 million decrease in expenses related to our lead product candidate, DNTH103, partially offset by a \$0.2 million increase in discovery activities. The \$2.1 million decrease in expenses related to DNTH103 resulted from decreases of \$3.9 million in CMC activity costs, \$1.3 million in preclinical study costs and \$1.2 million in license and milestone payments, partially offset by increases of \$4.1 in clinical operations activity costs and \$0.2 million in third-party consulting costs. The decreased amount of CMC activities resulted from the substantial completion of the manufacture of the first two batches of drug product for the DNTH103 program in late 2022. The decreased amount of preclinical study costs resulted from the completion of major toxicology studies related to DNTH103 in 2023. The decreased amount of license and milestone payments resulted from the achievement of certain milestones in 2022. The increased amount of clinical operations activity costs resulted from the commencement of the Phase 1 clinical trial in November 2022. The increased consulting costs resulted from the engagement of consultants to assist with regulatory filings and other activities related to DNTH103. The \$0.2 million increase in discovery expenses related to development activities of potential molecules beyond DNTH103 in 2023.

General and Administrative Expenses

General and administrative expenses were \$18.2 million for the year ended December 31, 2023, as compared to \$6.7 million for the year ended December 31, 2022, an increase of \$11.5 million. The increase was primarily due to increases of \$4.0 million in severance costs related to former employees of Magenta, \$2.5 million in personnel-related costs, \$1.7 million in professional services costs, \$1.6 million in insurance costs, including director and officer insurance, \$0.9 million in share-based compensation, and \$0.8 million in other general and administrative expenses.

Income Tax

The provision for income taxes consists primarily of income taxes related to federal and state jurisdictions in which we conduct business. We maintain a full valuation allowance on our federal and state deferred tax assets as we have concluded that it is more likely than not that the deferred assets will not be utilized.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from operations. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of our lead product candidate, DNTH103, or any future product candidates. We expect that our research and development and general and administrative costs will continue to increase significantly, including in connection with conducting clinical trials and manufacturing for our lead product candidate or any future product candidates to support potential future commercialization and providing general and administrative support for our operations, including the costs associated with operating as a public company. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources. See the section titled “*Risk Factors*” found elsewhere in this prospectus for additional risks associated with our substantial capital requirements.

To date, we have funded our operations primarily through private placements of capital stock for gross proceeds of \$423.5 million.

Future Capital Requirements

Since inception, we have not generated any revenue from product sales. We do not expect to generate any meaningful product revenue unless and until we obtain regulatory approval of and commercialize DNTH103 or

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any future product candidates, and we do not know when, or if, that will occur. Until we can generate significant revenue from product sales, if ever, we will continue to require substantial additional capital to develop DNTH103 or any future product candidates and fund operations for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities as described in greater detail below. We are subject to all the risks incident in the development of new biopharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may harm our business.

In order to complete the development of DNTH103 or any future product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize product candidates, if approved, we will require substantial additional capital. Accordingly, until such time that we can generate a sufficient amount of revenue from product sales or other sources, if ever, we expect to seek to raise any necessary additional capital through private or public equity or debt financings, loans or other capital sources, which could include income from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. To the extent that we raise additional capital through equity financings or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, including restricting our operations and limiting our ability to incur liens, issue additional debt, pay dividends, repurchase our Common Stock, make certain investments or engage in merger, consolidation, licensing, or asset sale transactions. If we raise capital through collaborations, partnerships, and other similar arrangements with third parties, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We may be unable to raise additional capital from these sources on favorable terms, or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from recent bank failures, other general macroeconomic conditions and otherwise. The failure to obtain sufficient capital on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to delay, reduce or curtail our research, product development or future commercialization efforts. We cannot provide assurance that we will ever generate positive cash flow from operating activities.

To date, we have funded our operations primarily with proceeds from the sale of capital stock and have raised aggregate gross proceeds of \$423.5 million. However, we have incurred significant recurring losses. We had an accumulated deficit of \$89.4 million as of December 31, 2023. As of December 31, 2023, we had cash, cash equivalents and short-term investments of \$173.7 million. Based on our current operating plan, we believe that our existing cash, cash equivalents and short-term investments, together with the proceeds from our 2024 Private Placement, should be sufficient to fund our operations into the second half of 2027. Until we achieve profitability, we plan to fund our operations and capital expenditures with cash on hand and expect to seek to raise any necessary additional capital through private or public equity or debt financings, loans or other capital sources, which could include income from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. There can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us. If we are unable to raise sufficient additional capital, we may be compelled to consider actions such as reducing the scope of our operations and planned capital expenditures or sell certain assets, including intellectual property assets.

We based projections of operating capital requirements on our current operating plan, which includes several assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than we expect.

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Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount and timing of our capital requirements. Our future funding requirements will depend on many factors, including:

- the scope, timing, progress, results, and costs of researching and developing DNTH103, and conducting larger and later-stage clinical trials;
- the scope, timing, progress, results, and costs of researching and developing other future product candidates that we may pursue;
- the costs, timing, and outcome of regulatory review of our product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing, and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade products and sufficient inventory to support commercial launch;
- the revenue, if any, received from commercial sale of our products, should any of product candidates receive marketing approval;
- the cost and timing of attracting, hiring, and retaining skilled personnel to support our operations and continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish, maintain, and derive value from collaborations, partnerships or other marketing, distribution, licensing, or other strategic arrangements with third parties on favorable terms, if at all;
- the extent to which we acquire or in-license other product candidates and technologies, if any; and
- the costs associated with operating as a public company.

A change in the outcome of any of these or other factors with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we may need additional capital to meet the capital requirements associated with such operating plans.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Net cash used in operating activities	\$ (36,861)	\$ (29,070)
Net cash provided by/(used in) investing activities	20,253	(59,819)
Net cash provided by financing activities	133,574	96,676
Increase in cash, cash equivalents and restricted cash	<u>\$ 116,966</u>	<u>\$ 7,787</u>

Cash Flows from Operating Activities

For the year ended December 31, 2023, net cash used in operating activities consisted of a net loss of \$43.6 million, partially offset by a decrease in net operating assets and liabilities of \$4.9 million and net non-cash operating expenses of \$1.8 million. The decrease in net operating assets and liabilities was primarily attributable to a decrease in receivable from Zenas BioPharma of \$4.4 million, a decrease in unbilled receivable from Zenas

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BioPharma of \$0.8 million, an increase in accounts payable, accrued expenses and lease liabilities of \$0.7 million and a decrease in prepaid expenses and other current assets of \$0.1 million, partially offset by an increase in other assets of \$1.0 million and a decrease in deferred revenue of \$0.1 million. The non-cash operating expenses consisted mainly of stock-based compensation expense of \$2.9 million and amortization of right-of-use lease assets of \$0.3 million, partially offset by accretion of discount on short-term investments of \$1.4 million.

For the year ended December 31, 2022, net cash used in operating activities consisted of a net loss of \$28.5 million and an increase in net operating assets and liabilities of \$1.7 million, partially offset by net non-cash operating expenses of \$1.1 million. The increase in net operating assets and liabilities was primary attributable to increases in receivable from related party of \$4.2 million and prepaid expenses and other current assets of \$0.7 million, partially offset by increases in accounts payable, accrued expenses and lease liabilities of \$2.3 million and deferred revenue of \$0.9 million. The non-cash operating expenses consisted mainly of stock-based compensation expense of \$1.5 million and amortization of right-of-use lease assets of \$0.1 million, partially offset by accretion on short-term investments of \$0.6 million.

Cash Flows from Investing Activities

For the year ended December 31, 2023, net cash provided by investing activities consisted of \$77.8 million of proceeds from maturities of short-term investments, partially offset by \$57.4 million of purchases of short-term investments and \$0.1 million of capital expenditures.

For the year ended December 31, 2022, net cash used in investing activities consisted of \$61.7 million of purchases of short-term investments and \$0.1 million of capital expenditures, partially offset by \$2.0 million of proceeds from maturities of short-term investments.

Cash Flows from Financing Activities

For the year ended December 31, 2023, net cash provided by financing activities primarily consisted of \$67.8 million of net proceeds from the sale of shares of Former Dianthus common stock in the pre-closing financing and net cash acquired in connection with the reverse recapitalization of \$69.7 million, partially offset by \$3.9 million of reverse recapitalization transactions costs.

For the year ended December 31, 2022, net cash provided by financing activities consisted of \$96.7 million of net proceeds from the issuance of the Dianthus Series A convertible preferred stock.

Contractual Obligations and Commitments

Lease Obligations

We lease space under operating leases agreements for administrative offices in New York, New York, and Waltham, Massachusetts and wet laboratory space in Watertown, Massachusetts, which expire in August 2025, January 2025 and August 2025, respectively.

Research and Development and Manufacturing Agreements

We enter into agreements with certain vendors for the provision of goods and services, which includes manufacturing services with CDMOs and development and clinical trial services with CROs. These agreements may include certain provisions for purchase obligations and termination obligations that could require payments for the cancellation of committed purchase obligations or for early termination of the agreements. The amount of the cancellation or termination payments vary and are based on the timing of the cancellation or termination and the specific terms of the agreement. These obligations and commitments are not presented separately.

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License and Collaboration Agreements

In August 2019, Former Dianthus entered into a license agreement with Alloy Therapeutics, LLC (“Alloy”) for (i) a worldwide, non-exclusive license to use the Alloy technology solely to generate Alloy antibodies and platform assisted antibodies for internal, non-clinical research purposes, and (ii) with respect to Alloy antibodies and platform assisted antibodies that are selected by us for inclusion into a partnered antibody program, a worldwide, assignable license to make, have made, use, offer for sale, sell, import, develop, manufacture, and commercialize products comprising partnered antibody programs selected from Alloy antibodies and platform assisted antibodies in any field of use. In addition to annual license fees, we are obligated to pay development and commercial milestone payments of up to \$12.8 million for the first partnered antibody, which has been selected for the DNTH103 program. The license agreement was amended in October 2022 to extend the agreement to a potential second partnered antibody. In addition to annual license fees, we are obligated to pay development and commercial milestone payments of up to \$18.1 million for a second partnered antibody, if and when selected.

In September 2022, Former Dianthus entered into a commercial platform license agreement and services agreement with two subsidiaries of Ligand Pharmaceuticals Incorporated (“Ligand”). In November 2022, Ligand spun-off these subsidiaries into a separate legal entity, OmniAb, Inc. (“OmniAb”), for (i) a worldwide, non-exclusive, non-sublicensable license under the OmniAb technology to use chicken animals for generation of OmniAb antibodies for research purposes and (ii) a worldwide, non-exclusive license under the OmniAb technology to use rodent animals for generation of OmniAb antibodies for research purposes. In addition to annual license fees, we are obligated to pay development milestones payments of up to \$12.2 million and to pay royalties in the low to mid-single digits.

In July 2020, Former Dianthus entered into a collaborative research agreement with IONTAS Limited (“IONTAS”) to perform certain milestone-based research and development activities under our first development program. The agreement was amended in January 2023 to extend services to additional development programs. We are obligated to pay development and commercial milestone payments of up to £5.4 million (approximately \$6.9 million based on the December 31, 2023 exchange rate) with the first development program and of up to £2.5 million (approximately \$3.2 million based on the December 31, 2023 exchange rate) with the second development program.

Critical Accounting Policies and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States of America. The preparation of the financial statements and related disclosures requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate estimates and assumptions on a periodic basis. Our actual results may differ materially from these estimates.

We believe that the following accounting policies are critical to understanding our historical and future performance, as the policies relate to the more significant areas involving management’s judgments and estimates used in the preparation of our financial statements.

Research and Development Expenses

Research and development expenses are recorded as an expense, as incurred. Research and development expenses consists of (i) costs to engage contractors who specialize in our development activities; (ii) external research and development costs incurred under arrangements with third parties, such as CROs, CDMOs and consultants; and (iii) costs associated with preclinical and clinical activities and regulatory operations.

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We enter consulting, research, and other agreements with commercial firms, researchers, and others for the provision of goods and services. Under such agreements, we may pay for services on a monthly, quarterly, project or other basis. Such arrangements are generally cancelable upon reasonable notice and payment of costs incurred. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date, whereas payments are dictated by the terms of each agreement. As such, depending on the timing of payment relative to the receipt of goods or services, we may record either prepaid expenses or accrued services. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on our behalf.

We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. There may also be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing expenses, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We account for stock-based compensation awards in accordance with ASC Topic 718, *Compensation—Stock Compensation*, (“ASC 718”). ASC 718 requires all stock-based payments, including grants of stock options and restricted stock, to be recognized in the consolidated statements of operations and comprehensive loss based on their fair values. All of our stock option awards are subject only to service-based vesting conditions. We estimate the fair value of our stock-based awards using the Black-Scholes option pricing model, which requires the input of assumptions, including (a) the fair value of the common stock, (b) the expected stock price volatility, (c) the calculation of expected term of the award, (d) the risk-free interest rate and (e) expected dividends. We estimate the fair value of the restricted stock awards using the fair value of our Common Stock. Forfeitures are recognized as they are incurred.

Prior to the Merger, management utilized valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately Held Company Equity Securities Issued as Compensation*, to estimate the fair value of Former Dianthus’ common stock. Each valuation methodology included estimates and assumptions that required our judgment. These estimates and assumptions included objective and subjective factors, including external market conditions, the prices at which Former Dianthus sold shares of convertible preferred stock, the superior rights and preferences of the convertible preferred stock senior to Former Dianthus’ common stock at the time, and a probability analysis of various liquidity events, such as a public offering or sale of Former Dianthus, under differing scenarios. Changes to the key assumptions used in the valuations could have resulted in materially different fair values of Former Dianthus’ common stock at each valuation date. Following the Merger, the fair value of our Common Stock is based on the closing stock price on the date of grant as reported on the Nasdaq Capital Market.

Due to a lack of company-specific historical and implied volatility data, we base our estimate of expected volatility on the historical volatility of a representative group of companies with similar characteristics to us, including stage of product development and life science industry focus. We believe the group selected has sufficiently similar economic and industry characteristics and includes companies that are most representative of our business.

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We use the simplified method, as prescribed by the SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term. The risk-free interest rate is based on observed interest rates appropriate for the term of the awards. The dividend yield assumption is based on history and expectation of paying no dividends.

Compensation expense related to stock-based awards is calculated on a straight-line basis by recognizing the grant date fair value, over the associated service period of the award, which is generally the vesting term.

Revenue Recognition—Zenas Agreements

We analyze the Zenas Agreements pursuant to ASC 606. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. As part of the accounting for contracts with customers, management develops assumptions that require judgment to determine whether promised goods and services represent distinct performance obligations and the standalone selling price for each performance obligation identified in the contract. This evaluation is subjective and requires us to make judgments about the promised goods and services and whether those goods and services are separable from other aspects of the contract. Further, determining the standalone selling price for performance obligations requires significant judgment, and when an observable price of a promised good or service is not readily available, we consider relevant assumptions to estimate the standalone selling price, including, as applicable, market conditions, development timelines, probabilities of technical and regulatory success and forecasted revenues.

We evaluate the performance obligations promised in the contract that are based on goods and services that will be transferred to the customer and determined whether those obligations are both (i) capable of being distinct and (ii) distinct in the context of the contract. Goods or services that meet these criteria are considered distinct performance obligations. We estimate the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration or variable consideration. At the inception of each arrangement that includes variable consideration, we evaluate the amount of potential transaction price and the likelihood that the transaction price will be received. We utilize either the most likely amount method or expected value method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration that is included in the transaction price may be constrained and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

We apply judgment in determining whether a combined performance obligation is satisfied at a point in time or over time, and, if over time, concluding upon the appropriate method of measuring progress to be applied for purposes of recognizing revenue. We evaluate the measure of progress each reporting period and, as estimates related to the measure of progress change, related revenue recognition is adjusted accordingly. Changes in the estimated measure of progress are accounted for prospectively as a change in accounting estimate.

When two or more contracts are entered into with the same customer at or near the same time, we evaluate the contracts to determine whether the contracts should be accounted for as a single arrangement. Contracts are combined and accounted for as a single arrangement if one or more of the following criteria are met: (i) the contracts are negotiated as a package with a single commercial objective; (ii) the amount of consideration to be paid in one contract depends on the price or performance of the other contract; or (iii) the goods or services promised in the contracts (or some goods or services promised in each of the contracts) are a single performance obligation.

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Because the Zenas Agreements were negotiated with a single commercial objective, they are treated as a combined contract for accounting purposes. We assessed the Zenas Agreements in accordance with ASC 606 and concluded that it represents a contract with a customer and is within the scope of ASC 606. We determined that there is one combined performance obligation that consists of the license and data transfer, the research and development services, and the participation in the joint steering committee. We determined that Zenas BioPharma's right to exercise an option with respect to a second antibody sequence does not represent a material right.

We determined that the combined performance obligation is satisfied over time; therefore, we will recognize the transaction price from the license agreement over our estimated period to complete our activities. We concluded that we would utilize a cost-based input method to measure our progress toward completion of our performance obligation and to calculate the corresponding amount of revenue to recognize each period. We believe this is the best measure of progress because other measures do not reflect how we transfer our performance obligation to Zenas Biopharma. In applying the cost-based input method of revenue recognition, we use actual costs incurred relative to budgeted costs expected to be incurred for the combined performance obligation. These costs consist primarily of third-party contract costs. Revenue will be recognized based on the level of costs incurred relative to the total budgeted costs for the performance obligations. A cost-based input method of revenue recognition requires us to make estimates of costs to complete our performance obligation. In making such estimates, judgment is required to evaluate assumptions related to cost estimates. We will re-evaluate the estimate of expected costs to satisfy the performance obligation each reporting period and will make adjustments for any significant changes.

Upfront payments and fees are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until we perform our obligations under these arrangements. Where applicable, amounts are recorded as unbilled revenue when our right to consideration is unconditional. We do not assess whether a contract with a customer has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less.

CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Dismissal of Independent Registered Public Accounting Firm

KPMG LLP (“KPMG”) served as the independent registered public accounting firm of the Company prior to the completion of the Merger. On September 11, 2023, following the completion of the Merger, KPMG was dismissed as the independent registered public accounting firm of the Company. The decision to dismiss KPMG was approved by the Audit Committee of the Board of Directors.

The reports of KPMG on the consolidated financial statements of the Company for the fiscal years ended December 31, 2022 and 2021 did not contain an adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles.

During the Company’s two most recent fiscal years and the subsequent period from January 1, 2023 to September 11, 2023, there were (i) no disagreements (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions thereto) with KPMG on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreement, if not resolved to the satisfaction of KPMG, would have caused it to make reference to the subject matter of the disagreement in connection with its report and (ii) no reportable events (as described in Item 304(a)(1)(v) of Regulation S-K).

The Company provided KPMG with a copy of the disclosures made in this section and requested KPMG to furnish the Company with a letter addressed to the SEC stating whether it agrees with the statements made by the Company and, if not, stating the respects in which it does not agree. A copy of KPMG’s letter to the SEC dated September 12, 2023 regarding these statements was filed as Exhibit 16.1 to the Company’s Current Report on Form 8-K filed on September 12, 2023.

Appointment of New Independent Registered Public Accounting Firm

Deloitte & Touche LLP (“Deloitte”) served as the independent registered public accounting firm of OpCo prior to the completion of the Merger. On September 11, 2023, following the completion of the Merger, the Audit Committee approved the appointment of Deloitte as the independent registered public accounting firm of the Company. The Company’s engagement of Deloitte was subject to completion of Deloitte’s standard client acceptance procedures and execution of an engagement letter, which was fully executed by the Company on October 19, 2023.

During the fiscal years ended December 31, 2022 and 2021 and the subsequent interim period through October 19, 2023, neither the Company, nor anyone on its behalf, consulted Deloitte regarding (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company’s consolidated financial statements, and no written report or oral advice was provided to the Company by Deloitte that Deloitte concluded was an important factor considered by the Company in reaching a decision as to any accounting, auditing or financial reporting issue or (ii) any matter that was the subject of a “disagreement” (as that term is defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) or a “reportable event” (as that term is defined in Item 304(a)(1)(v) of Regulation S-K).

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company, as defined by Rule 12b-2 under the Exchange Act, and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

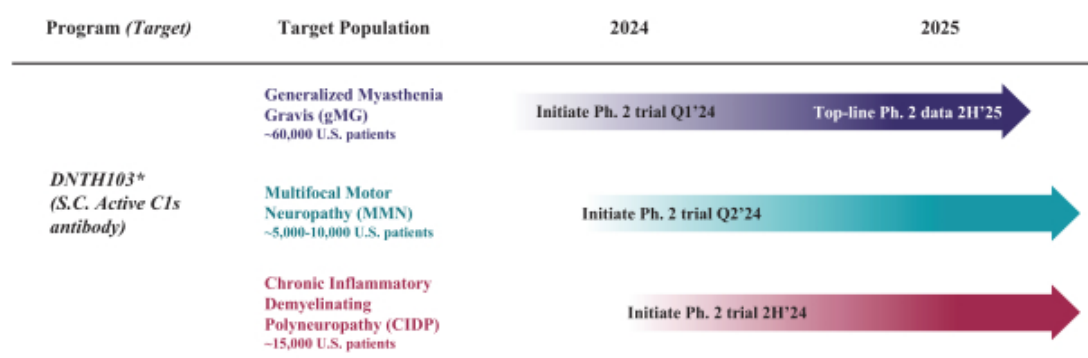
BUSINESS

Overview

We are a clinical-stage biotechnology company. On September 11, 2023, we completed a business combination with Former Dianthus pursuant to which, among other matters, Former Dianthus became as a wholly owned subsidiary of ours. In connection with the completion of the Merger, we changed our name from “Magenta Therapeutics, Inc.” to “Dianthus Therapeutics, Inc.,” and the business conducted by us became primarily the business conducted by Former Dianthus. We were incorporated as a Delaware corporation in June 2015 and Former Dianthus was incorporated as a Delaware corporation in May 2019.

We are focused on developing next-generation complement therapeutics for patients living with severe autoimmune and inflammatory diseases. We believe our lead novel and proprietary monoclonal antibody product candidate, DNTH103, has the potential to address a broad array of complement-dependent diseases as currently available therapies and those in development leave room for improvements in efficacy, safety, and/or dosing convenience. We have purposefully engineered DNTH103 to selectively bind to only the active form of the C1s complement protein and to exhibit improved potency and an extended half-life. By selectively targeting only the active form of C1s, which drives disease pathology and constitutes only a small fraction of the total protein present in circulation, we aim to reduce the amount of drug required for a therapeutic effect. We intend to deliver our product candidate through a lower dose, less frequent, self-administered, convenient subcutaneous injection suitable for a pre-filled pen.

Our Pipeline-in-a-Product Potential for DNTH103, a Next-Generation Complement Therapeutic



* We hold world-wide rights excluding rights to Greater China, which are outlicensed to Zenas BioPharma.

DNTH103

Our most advanced product candidate, DNTH103, is a clinical-stage, highly potent, highly selective and fully human monoclonal immunoglobulin G4 with picomolar binding affinity that is designed to selectively bind only to the active form of the C1s complement protein. The active form of C1s is generated during complement activation by cleavage of the inactive proC1s (as defined below). As a validated complement target in the autoimmune and inflammatory field, C1s inhibition prevents further progression of the classical pathway cascade. DNTH103 is engineered withYTE half-life extension technology, a specific three amino acid change in the Fc domain, and has a pharmacokinetic (“PK”) profile designed to support less frequent, lower dose, self-administration as a convenient S.C. injection.

Clinical Data and Development Plans

Data from DNTH103's Phase 1 clinical trial in 60 healthy volunteers across eight dose cohorts validates the extended half-life and potent classical pathway inhibition and supports a potentially differentiated safety profile of DNTH103. The topline data confirmed its approximately 60-day half-life and highly potent classical pathway inhibition with every two weeks ("Q2W") S.C. dosing of 300mg/2mL surpassing the calculated IC90 (as defined below) of 87ug/mL, establishing DNTH103's best-in-class potential to be the first self-administered subcutaneous injection dosed as infrequently as Q2W to treat a range of autoimmune disorders. Based on the clinical data available to date, DNTH103 was generally well tolerated with no serious adverse events ("SAEs") or complement-related infections. DNTH103 is designed to selectively target the active form of C1s, inhibiting only the classical pathway, while leaving the lectin and alternative pathways intact. As a result, DNTH103 may have a reduced risk of infections from encapsulated bacteria when compared to C5 terminal inhibitors, thus potentially avoiding an FDA Boxed Warning and REMS. We believe that DNTH103 has the potential to yield therapeutic benefit in multiple autoimmune and inflammatory disease indications where inappropriate activation of the classical pathway cascade drives or exacerbates the disease pathology by inhibiting the ability of activated C1s to effect downstream complement activity, ameliorating complement mediated cell death and disruption of normal cellular function.

We evaluated DNTH103 in a first-in-human Phase 1 single ascending dose ("SAD") and multiple ascending dose ("MAD") clinical trial in New Zealand to explore the safety, tolerability, PK, and pharmacodynamics ("PD") of DNTH103 in healthy volunteers. We reported data from 60 healthy volunteers that have been dosed across eight cohorts, including six SAD cohorts: 1mg/kg intravenous ("I.V."), 10mg/kg I.V., 30mg/kg I.V., 50mg/kg I.V., 300mg S.C. and 600mg S.C.; and two MAD cohorts: 300mg S.C. and 600mg S.C. Based on the clinical data available to date, DNTH103 has been generally well-tolerated, demonstrating favorable PK and PD data, supporting its target product profile. Based on data from the 60 healthy volunteers, DNTH103 has a half-life of approximately 60 days. With these data, we conducted a PK simulation that demonstrates the steady state serum concentration of DNTH103, when dosed 300mg S.C. Q2W following an initial I.V. loading dose, exceeds the serum concentration required to surpass 90% classical pathway inhibition in a hemolytic assay ("IC90") estimated to be 87ug/mL. We believe, based on published scientific literature related to other complement therapies, that the IC90 will be sufficient to achieve clinical activity in patients with gMG.

Overview of Development Plans in Target Indications

MG is a rare, chronic autoimmune disorder characterized by muscle weakness due to complement-mediated damage to the muscle endplate. MG affects the voluntary muscles of the body, especially those that control the eyes, mouth, throat, limbs and in severe cases, muscles which support breathing. Clinically, MG can be classified as either ocular or generalized. In ocular MG, impairment is limited to the eye muscles, with symptoms such as diplopia (double vision) and ptosis (drooping of the upper eyelid). Approximately 80% of ocular MG cases progress to gMG. Patients with gMG may experience impaired vision, speech, and mobility; shortness of breath; difficulty swallowing and eating; and fatigue, all of which can have a profound negative effect on activities of daily life. gMG can result in a myasthenia crisis, a life-threatening condition, with very high fatality rates if left untreated. gMG crisis causes severe weakness of the diaphragm and chest muscles that support breathing, resulting in respiratory paralysis and requiring admission to the intensive care unit and the need for ventilatory support.

MG has an estimated prevalence of approximately 70,000 individuals in the United States. However, given this disease is often underdiagnosed, estimated diagnosed prevalence of MG in the United States has been reported to be as high as approximately 90,000 individuals. The disease affects both men and women, but often presents earlier in women. Approximately 85% of MG patients demonstrate elevated serum levels of acetylcholine receptor ("AChR") antibodies, which disrupt signal transmission at the neuromuscular junction.

As gMG becomes more severe in patients, the treatment burden meaningfully increases due to the need for higher dose or more frequent intravenous infusions. In addition, approved C5 complement inhibitor therapies which have demonstrated efficacy in AChR positive gMG patients, have an FDA Boxed Warning and an associated REMS due to the risk of serious meningococcal infections. Moreover, up to approximately 80% of patients fail to achieve complete stable remission on existing therapies.

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We believe DNTH103 has the potential to meaningfully transform the standard of care in gMG as a potent, lower dose, lower frequency, self-administered S.C. injection that may not have an FDA Boxed Warning or REMS. As a more patient-friendly, predictable, convenient and a less burdensome biologic, DNTH103 has the potential to become a first-line biologic treatment option. Thus, DNTH103 could compete for early treatment of AChR positive gMG patients versus intravenous immune globulin (“IVIG”), terminal complement inhibitors and neonatal fragment crystallizable receptor (“FcRn”) inhibitors, as well as for use in patients that do not adequately respond to other biologics such as IVIG or FcRn inhibitors.

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.

We plan to progress DNTH103 into Phase 2 clinical trials in additional diseases in which the classical pathway plays a significant role in the disease pathology, such as MMN and CIDP. MMN is a pure motor neuropathy associated with asymmetric deficits with predilection for upper limb involvement and has an estimated U.S. prevalence of up to approximately 10,000 individuals. MMN is progressive and causes substantial disability and loss of function, due to involvement of upper limbs. CIDP is an autoimmune and inflammatory disorder affecting the myelin that insulates and protects peripheral nerves and has an estimated U.S. prevalence of approximately 15,000 individuals. There are currently no FDA-approved complement or FcRn inhibitors in either condition and significant unmet needs remain for more effective, safe, and/or convenient therapeutics. We plan to start Phase 2 trials in these additional indications in 2024, subject to IND clearances or other regulatory authorizations. We continue to evaluate other indications where the classical pathway plays a significant role in the disease pathology and DNTH103 could address unmet medical needs.

Our Strategy

Our goal is to continue to develop next-generation complement therapeutics for the treatment of severe autoimmune and inflammatory diseases by harnessing the power of selectivity. The key components of our strategy are as follows:

- **Rapidly advance DNTH103 into a global Phase 2 clinical trial in gMG.** 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. Data from DNTH103’s Phase 1 clinical trial in 60 healthy volunteers across eight dose cohorts supports potent inhibition of the classical pathway with 300mg/2mL S.C. dosing Q2W. Based on the clinical data available to date, DNTH103 has been generally well-tolerated, with no SAEs or complement-related infections. Additionally, data from the MG in vitro proof-of-concept experiment that demonstrated DNTH103 also reduced muscle fatigue in AChR antibody positive MG patient sera, indicating an improvement in neurotransmission and muscle contraction, provide further scientific rationale for DNTH103 in gMG. We aim to generate additional data through planned clinical trials that DNTH103 has a favorable safety profile and is a potent, next-generation monoclonal antibody that can support self-administration as a convenient, lower volume, less frequent S.C. injection in a pre-filled pen, with the potential to be highly differentiated versus current treatment options.
- **Expand DNTH103 in a broad range of diseases where the classical pathway plays a significant role in the disease pathology, starting with MMN and CIDP.** The classical pathway is activated through interaction of the C1 complex with antibody-antigen complexes. We believe that therapies specifically targeting the classical pathway and C1s, such as DNTH103, would be well-suited for the potential treatment of autoimmune or inflammatory diseases where autoantibodies are implicated and there is evidence of complement-mediated damage. Beyond gMG, we are evaluating diseases in which the classical pathway plays a significant role in the disease pathology, such as MMN and CIDP. We expect to progress DNTH103 into Phase 2 clinical trials in these additional indications in 2024, starting with MMN in the second quarter of 2024 and CIDP in the second half of 2024, subject to IND clearances or other regulatory authorizations.

- **Develop additional next-generation product candidates designed to have distinct advantages over other complement therapies.** We are focused on developing next-generation therapeutics targeting the active form of complement proteins with strong biological rationale for the treatment of autoimmune and inflammatory diseases. We have a dedicated team of scientists with extensive complement and antibody experience working to expand our pipeline of investigational complement therapeutic candidates to develop and deliver novel and highly differentiated therapies for underserved patients. We expect to nominate a new development candidate for an additional complement target in the second half of 2024.
- **Collaborate strategically to maximize the value of our product candidates.** In June 2022, we licensed development and commercialization rights to Zenas BioPharma for DNTH103 in greater China. Aside from greater China, we currently hold worldwide development and commercialization rights, including through exclusive licenses, to all of our product candidates. We intend to pursue independent development and commercialization in select indications and markets where we can maximize shareholder value with a focused commercial organization. We may opportunistically explore licensing agreements, collaborations or partnerships to enhance our development efforts, develop our product candidates in larger market indications or commercialize our products where we could create more value for patients and shareholders by utilizing the resources of larger or better positioned biopharmaceutical companies.

Overview of the Complement System

The Complement System—Three Main Pathways

The complement system plays a critical role in maintaining an active innate immune system, including as the first line of defense against microbial pathogens, elimination of apoptotic cells and tissue debris, and modulation of the adaptive B and T cell response. However, uncontrolled complement activation can also be a key contributor to the pathophysiology of numerous inflammatory and autoimmune conditions.

The complement system includes more than 30 component proteins, regulators, and receptors. The figure below illustrates the three complement activation pathways, each of which has a unique trigger for initiating a cascade of events:

- *Classical Pathway:* Activated primarily by immune complexes.
- *Lectin Pathway:* Activated by mannose binding lectin interaction with sugars on the surface of pathogens or injured cells.
- *Alternative Pathway:* Automatically activated in a conformational, non-enzymatic process that leads to amplification of the classical and lectin pathways.

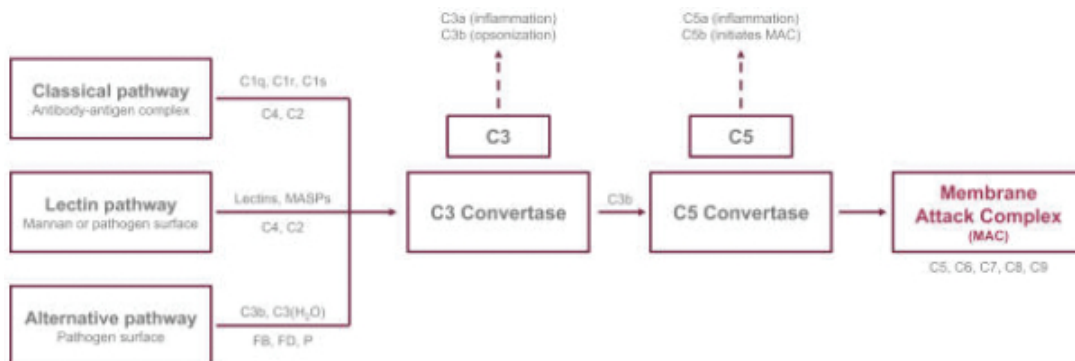
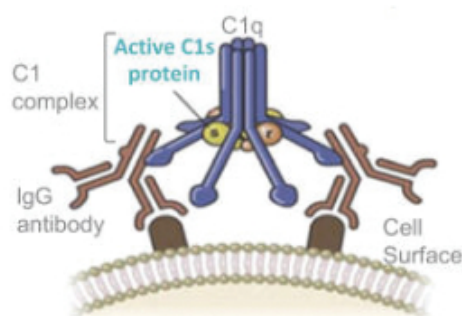


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Regardless of the activation event, all complement pathways converge at common pathway components, known as C3 and C5. When the C3 and C5 proteins are activated, they enable three principal immune responses: inflammation, opsonization and formation of the MAC, a pore forming structure that leads to the lysis of targeted cells. In a normal immune response, C3b fragments act to mark pathogens for removal from tissues or the bloodstream by phagocytes in a process known as opsonization. C3a or C5a cleaved fragments cause inflammation in the surrounding tissues, attracting phagocytes to ingest opsonized pathogens. Downstream, C5b fragments initiate the formation of the membrane attack complex (“MAC”) on pathogens, causing cell death and elimination. However, under conditions of excessive or uncontrolled activation, the complement system is believed to play a key role in the incidence and progression of several autoimmune and inflammatory diseases. Under these conditions, healthy cells may become part of a trigger for complement activation and/or become opsonized and destroyed.

Classical Pathway and the Role of C1s

The classical pathway of the complement system bridges innate and adaptive immunity. Classical pathway activation is initiated by the C1 complex. The C1 complex consists of a binding protein, C1q, and two inactive proenzymes, C1r (“proC1r”) and C1s (“proC1s”). Initiation of the classical pathway cascade occurs when C1q binds to the Fc portion of immunoglobulin G (“IgG”) or immunoglobulin M (“IgM”), as part of an immune complex as depicted in the image below. During an immune response, C1q binding to IgM or IgG antibodies that coat the surface of a cell triggers the autoactivation of proC1r, which in turn cleaves proC1s to generate the active form of C1s. In its active form, C1s is responsible for cleaving and activating C4 and C2, which leads to the downstream cascade that culminates in the terminal pathway and MAC formation.



C1s is unique to the classical pathway and thus provides a therapeutic opportunity to selectively target antibody-driven autoimmune and inflammatory disorders mediated by the classical pathway while leaving the lectin and alternative pathways intact. This may result in distinct safety advantages over current FDA-approved downstream complement inhibitors, such as those approved for the treatment of gMG, which inhibit MAC formation from all three complement pathways and currently have an FDA Boxed Warning for serious meningococcal infections and an associated REMS program.

DNTH103 for the Treatment of Generalized Myasthenia Gravis

Overview of Myasthenia Gravis

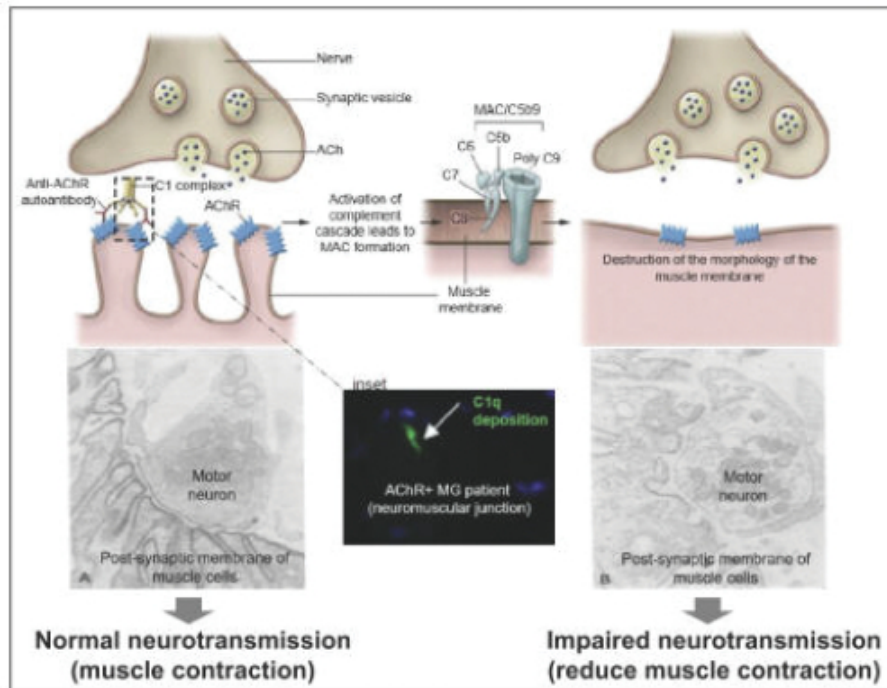
MG is a rare, chronic autoimmune disease characterized by muscle weakness due to inhibition of acetylcholine mediated muscle contraction. In MG, patients have autoantibodies directed against specific proteins of the neuromuscular endplate. MG is most commonly diagnosed in women between 20 and 39 years of age, and in men between 50 and 70 years of age. Clinically, MG can be classified as either ocular or generalized (gMG). In ocular MG, impairment is limited to the eye muscles, with symptoms such as diplopia and ptosis. Approximately 80% of ocular MG cases progress to gMG. MG has an estimated prevalence of approximately 70,000 individuals in the United States. However, given this disease is often underdiagnosed, estimated diagnosed prevalence of MG in the United States has been reported to be as high as approximately 90,000

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individuals. Common symptoms of gMG include weakness of limb muscles and dysphagia (difficulty swallowing) or slurred speech resulting from weakness of oropharyngeal muscles (those involved in jaw and throat movement). Weakness of respiratory muscles is of particular concern, as it may lead to myasthenic crisis, a life-threatening condition requiring ventilatory support that occurs in approximately 15-20% of gMG patients. Patients with gMG may experience impaired vision, speech, and mobility; shortness of breath; difficulty swallowing and eating; and fatigue, all of which can have a profound negative effect on activities of daily life. Measures of both mental and physical health indicate a substantially lower quality of life for patients with gMG compared with the general population. Quality of life can be further negatively impacted in patients with refractory MG in terms of disease exacerbations, emergency department visits, and hospitalizations.

Role of Classical Pathway and C1s in the Pathogenesis of Myasthenia Gravis

In approximately 85% of gMG cases antibodies to the acetylcholine receptors are identified (AChR+ gMG patients). These autoantibodies bind to the acetylcholine receptor and activate C1q which activates C1r. C1r in turn activates C1s which undergoes a conformational change allowing it to cleave C4 and initiating the classical complement pathway. Classical pathway activation ultimately results in MAC associated destruction at the motor end plate. As illustrated in the figure below, antibody-mediated classical complement activation leads to significant damage at the neuromuscular junction in patients with gMG, with the loss of characteristic anatomical folds.



Current gMG Treatments and their Limitations

The acetylcholinesterase inhibitor pyridostigmine has been used to treat neuromuscular symptoms of gMG since the 1950s. However, most patients require additional immunosuppressants such as steroids, azathioprine, mycophenolate, cyclosporine A, or rituximab. Although these therapies have shown some success, many patients continue to have unmet need and experience undesirable side effects, and none of these therapies have been approved for gMG. The treatment landscape for MG has continued to evolve. Plasmapheresis (“PLEX”) and IVIG therapy are therapeutic options, although these are more invasive treatments often reserved for MG crisis.

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FcRn targeted therapy is another treatment for gMG. FcRn promotes activity of pathogenic autoantibodies by protecting IgG from degradation. Efgartigimod, marketed as Vyvgart, is a humanized anti-FcRn-IgG1 Fc fragment that is designed to reduce the level of all serum IgG and AChR antibodies and was approved by the FDA for the treatment of gMG in adult patients who are AChR antibody positive in 2021. Vyvgart's current dosing paradigm is 10 mg/kg administered as an I.V. infusion over one hour once weekly for four weeks. In patients weighing 120 kg or more, the recommended dose is 1200 mg per infusion. An S.C. formulation of Vyvgart, Vyvgart Hytrulo, was approved by the FDA in 2023. The S.C. formulation dosing paradigm is 1008 mg per injection over approximately thirty to ninety seconds once weekly for four weeks and administration must be by a healthcare professional. For both formulations, patients are then required to go off treatment allowing IgG level to return towards baseline prior to re-dosing, with a recommended waiting period of at least 50 days from the start of the previous treatment cycle.

Complement inhibitors for the treatment of AChR antibody-positive gMG emerged in 2017 with eculizumab, marketed as Soliris, a recombinant humanized monoclonal antibody against complement protein C5. More recently, another C5 inhibitor, ravulizumab, marketed as Ultomiris, was approved by the FDA for the treatment of adult patients with gMG who are AChR antibody positive in 2022. These treatments require higher dose I.V. infusions and carry the risk of life-threatening infections such as meningococcal infections due to being terminal complement inhibitors, and, as a result, have an FDA Boxed Warning and an associated REMS program.

As such, we believe DNTH103 has the potential to meaningfully transform the standard of care in gMG as a potent, lower dose, lower frequency, self-administered S.C. injection with no FDA Boxed Warning or REMS or requirement for cycling of treatment such as with FcRn inhibitors. As it is designed to be a more patient-friendly, predictable, convenient and a less burdensome biologic, DNTH103 has the potential to become a first-line biologic treatment option. Thus, DNTH103 could compete for early treatment of AChR positive gMG patients versus IVIG, terminal complement inhibitors and FcRn inhibitors, as well as for use in patients that do not adequately respond to other biologics such as IVIG or FcRn inhibitors.

DNTH103 for the Treatment of Other Autoimmune and Inflammatory Diseases

The classical pathway is activated through interaction of the C1 complex with antibody-antigen complexes. We believe it is therefore rational to propose that compounds specifically targeting the classical pathway and specifically C1s, such as DNTH103, would be well-suited for the potential treatment of autoimmune or inflammatory disease conditions where autoantibodies are implicated, such as MMN and CIDP.

Overview of Multifocal Motor Neuropathy

Multifocal motor neuropathy is a pure motor neuropathy associated with asymmetric deficits with predilection for upper limb involvement. It is an underrecognized disease with U.S. prevalence estimates of up to 10,000 individuals. MMN predominantly affects males as compared to females (3:1). Clinical symptoms consist of progressive or stepwise muscle weakness in the distribution of affected peripheral nerves, without loss of sensory modalities. The muscle weakness is asymmetric and causes predominantly upper limb weakness, such as weakness in hand grip, finger movements or wrist drop. The disease is progressive and can cause substantial disability and loss of function, due to involvement of upper limbs.

Role of Classical Pathway and C1s in the Pathogenesis of MMN

Approximately 50% of patients have an IgM autoantibody against GM1, a genetic disorder that progressively destroys nerve cells in the brain and spinal cord, that is found at nodes of Ranvier mainly in peripheral motor nerves, causing immune mediated motor neuropathy with variable conduction block. There is evidence to support the role of complement in the pathophysiology of MMN. Sera from MMN patients has been shown to activate complement in vitro. There is complement deposition in the affected nerves, and the degree of

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complement deposition correlates with the response to immunoglobulin therapy. As described below, inhibition of C1s reverses the pathological effects in a recently developed MMN model.

Current MMN Treatments and their Limitations

Intravenous and subcutaneous immunoglobulin therapy is approved by the FDA for treatment of adult patients with MMN. Most patients require chronic long-term therapy with immunoglobulins with variable response in up to 80% of patients. Steroids and PLEX are generally ineffective and can worsen clinical symptoms. Other immunosuppressants, such as rituximab, have been used with variable efficacy. Treatment options are limited and there remains a significant unmet clinical need for this disease, such as a selective C1s inhibitor in patients with MMN.

Overview of Chronic Inflammatory Demyelinating Polyneuropathy

Chronic inflammatory demyelinating polyneuropathy is an autoimmune and inflammatory disorder affecting the myelin that insulates and protects peripheral nerves. CIDP is estimated to affect approximately 15,000 in the United States. Common symptoms of the disease include weakness, loss of balance, and sensation changes in the arms or legs. In the classic or typical CIDP, there is symmetric involvement of both upper and lower limbs, characterized by weakness in the proximal (for example, shoulder region or hip region) as well as distal (for example, wrist or ankle) muscle groups. In addition, there is sensory involvement. There are several atypical forms of CIDP, characterized by varying levels of motor and sensory involvement with overlap. CIDP follows a relapsing-remitting or a progressive clinical course, which can result in substantial disability, loss of motor and sensory function, and negative impact on quality of life.

Role of Classical Pathway and C1s in the Pathogenesis of CIDP

The pathogenesis of CIDP involves a complex interplay of multiple aberrant immune responses, inflicting damage on the myelin sheath. The complement system appears to play a role in promoting macrophage-mediated demyelination. Complement deposition in sural nerve biopsies, as well as signs of increased complement activation in serum and cerebrospinal fluid of patients with CIDP, suggest complement involvement in CIDP. A recently developed human-on-a-chip conduction model (with CIDP and MMN phenotype) suggests that complement activation by CIDP and MMN patient serum is sufficient to mimic neurophysiological features of each disease and that C1s inhibition is sufficient to rescue these pathological effects.

Current CIDP Treatments and their Limitations

Over 70% of CIDP patients require ongoing treatment with immunosuppressants such as IVIG, subcutaneous immune globulin, PLEX or steroids. Despite treatment, a significant number of patients do not achieve clinical remission and there remains a significant unmet clinical need for this disease. Given the role of complement system in the disease pathology, patients may benefit from a selective C1s inhibitor.

Intellectual Property

We wholly own the patent portfolio covering our C1s selective antibodies, including three pending U.S. provisional applications, two pending PCT applications, two pending non-provisional applications in the United States and pending foreign patent applications in China, Europe, Japan and Taiwan. The applications are directed to, among other things, antibodies that selectively bind to active C1s and methods of using these antibodies, including methods of treating C1s mediated disorders, and pharmaceutical formulations comprising these antibodies. Patents issuing from these applications covering DNTH103 would be expected to expire no earlier than 2043, subject to any disclaimers or extensions. We continue to develop additional pharmaceutical formulations for DNTH103 and will file patent applications to protect the same as appropriate.

Commercial

Should any of our product candidates be approved for commercialization, we intend to develop a plan to commercialize them in the United States and other key markets, through internal infrastructure and/or external partnerships in a manner that will enable us to realize the full commercial value of our programs. Given the company's stage of development, we have not yet established a commercial organization or distribution capabilities. In June 2022, we entered into a license agreement with Zenas BioPharma for DNTH103, in which Zenas Biopharma has development and commercialization rights in the greater area of China. Aside from this area, we currently hold worldwide development and commercialization rights, including through exclusive licenses, to all of our product candidates.

Manufacturing

We do not currently own or operate facilities for product manufacturing, testing, storage, and distribution. We contract with third parties for the manufacture and distribution of our product candidates. Because we rely on contract manufacturers, we employ personnel with extensive technical, manufacturing, analytical and quality experience. Our staff has strong knowledge and understanding of the extensive regulations that govern manufacturing, documentation, quality assurance, and quality control of drug supply that are required to support our regulatory filings.

In light of the recently introduced BIOSECURE Act, which would prohibit federal agencies from entering into procurement contracts with an entity that uses biotechnology equipment or services from a biotechnology company of concern, we are considering measures to strengthen our supply chain in the event that WuXi Biologics or one of our other manufacturers is impacted. We will closely monitor the implications of the proposed legislation and how it may impact our future manufacturing strategy, and will implement mitigations and supply chain redundancies, as needed. See the risk factor entitled *"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."*

Competition

We expect to face intense competition from other biopharmaceutical companies that are developing agents for the treatment of autoimmune and inflammatory diseases.

Generalized Myasthenia Gravis.

There is significant competition in gMG. AstraZeneca's Soliris[®] and Ultomiris[®], both I.V. as well as on-body S.C. device, C5 inhibitors, Argenx's Vyvgart[®] (efgartigimod) and Vyvgart[®] Hytrulo, an I.V. and S.C. FcRn inhibitor, respectively, and UCB S.A. Rystiggo[®] (rozanolixizumab), a weekly S.C. infusion FcRn inhibitor and Zilbrysq[®] (zilucoplan), a daily S.C. injection C5 inhibitor, are approved by the FDA for the treatment of gMG in patients who are AChR positive. There are several other companies developing compounds in mid-to late-stage clinical development for the treatment of gMG using various approaches and modalities.

Multifocal Motor Neuropathy.

Currently, Takeda's Gammagard Liquid, a 10% Immune Globulin Infusion (Human), is the only therapy approved by the FDA for MMN. There are few agents in development for MMN. Argenx's empasiprubart (ARGX-117), an I.V. C2 inhibitor that blocks both the classical and lectin pathways is in a Phase 2 clinical trial. Takeda is conducting a Japan-based Phase 3 clinical trial of TAK-771, a 10% Immune Globulin and Recombinant Human Hyaluronidase (rHuPH20) delivered as an S.C. infusion.

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Chronic Inflammatory Demyelinating Polyneuropathy.

There is significant competition in CIDP, including, among others, Pfizer's PANZYGA[®], a 10% Immune Globulin Infusion (Human), CSL Behring's Hizentra[®], a 20% Immune Globulin S.C. (Human), and Grifols Therapeutics' Gamunex-C[®], a 10% Immune Globulin Injection (Human), approved by the FDA for CIDP. Argenx has submitted a Supplemental Biologic License Application to the FDA for Vyvgart[®] Hytrulo, an FcRn inhibitor. Sanofi is conducting a Phase 2 proof-of-concept clinical trial of riliprubart (SAR445088), a C1s inhibitor. Takeda is conducting a Japan-based Phase 3 clinical trial of TAK-771, a 10% Immune Globulin and Recombinant Human Hyaluronidase (rHuPH20) delivered as an S.C. injection.

Drug development is highly competitive and subject to rapid and significant technological advancements. Our ability to compete will significantly depend upon our ability to complete necessary clinical trials and regulatory approval processes, and effectively market any drug that we may successfully develop. Our current and potential future competitors include pharmaceutical and biotechnology companies, as well as academic institutions and government agencies. The primary competitive factors that will affect the commercial success of any product candidate for which we may receive marketing approval include efficacy, safety and tolerability profile, dosing convenience, price, coverage, reimbursement and public opinion. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the biopharmaceutical industry could result in even more resources being concentrated among a small number of our competitors.

Accordingly, competitors may be more successful than us in obtaining regulatory approval for therapies and in achieving widespread market acceptance of their drugs. It is also possible that the development of a cure or more effective treatment method for any of our targeted indications by a competitor could render our product candidate non-competitive or obsolete, or reduce the demand for our product candidate before we can recover our development and commercialization expenses.

Collaboration, License and Services Agreements

Zenas BioPharma

In September 2020, we entered into an option agreement with Zenas BioPharma, under which we agreed to grant Zenas BioPharma an exclusive option for an exclusive license under certain patents and know-how with respect to antibody sequences generated in a research program directed towards the research of monoclonal antibody antagonists targeting the human Complement C1s and C2 proteins, or another human protein (each, a "Research Program"). In consideration for the option grant, we were issued Zenas BioPharma common stock equivalent to one percent of its shares outstanding prior to their Series A financing. On a Research Program-by-Research Program basis, Zenas BioPharma also agreed to pay us a one-time payment of \$1 million upon exercising the option to enter into a license agreement with respect to such Research Program. The option may only be exercised for up to two Research Programs.

On June 10, 2022, in connection with Zenas BioPharma's exercise of the option, we entered into a license agreement with Zenas BioPharma (the "Zenas License Agreement"), under which we granted Zenas BioPharma an exclusive, sublicensable license under certain patents and know-how to research, develop, manufacture, and commercialize monoclonal antibody antagonists targeting the human Complement C1s protein (including the antibody sequence of DNTH103) and, if and when the option is exercised, the human Complement C2 protein, in greater China (the "Territory"). As consideration for the license, we are eligible to receive (i) development milestone payments of up to \$11 million, (ii) an approximate \$1.1 million payment for reimbursement of a portion of development costs we previously incurred; (iii) reimbursement of a portion of certain CMC-related costs and expenses for the first antibody sequence through the manufacture of the first two batches of drug

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product; and (iv) reimbursement of a portion of certain non-CMC-related costs and expenses. Additionally, we are eligible to receive royalty payments based on a percentage of the annual net sales of the Products sold on a region-by-region basis in the Territory. The royalty rate may vary from the mid-single digits to the low double-digits based on different tiers of annual net sales of the licensed products. Zenas BioPharma is obligated to make royalty payments to us for the royalty term of the Zenas License Agreement.

Biologics Master Services Agreement — WuXi Biologics (Hong Kong) Limited

On March 22, 2021, we entered into a biologics master services agreement (the “WuXi Biologics MSA”) with WuXi Biologics (Hong Kong) Limited (“WuXi Biologics”). The WuXi Biologics MSA governs development activities and GMP manufacturing and testing for DNTH103, as well as potential future candidates, on a work order basis. Under the WuXi Biologics MSA, we are obligated to pay WuXi Biologics a service fee and all non-cancellable obligations, including potential milestone payments, in the amount specified in each work order associated with the agreement for the provision of services.

The WuXi Biologics MSA terminates on the later of (i) March 22, 2026 or (ii) the completion of services under all work orders executed by the parties prior to March 22, 2026, unless terminated earlier. The term of each work order terminates upon completion of the services under such work order, unless terminated earlier. We can terminate the WuXi Biologics MSA or any work order at any time upon 30 days’ prior written notice and immediately upon written notice if WuXi Biologics fails to obtain or maintain required material governmental licenses or approvals. Either party may terminate a work order (i) at any time upon six months’ prior notice with reasonable cause, provided however that if WuXi Biologics terminates a work order in such manner, no termination or cancellation fees shall be paid by us and (ii) immediately for cause upon (a) the other party’s material breach that remains uncured for 30 days after notice of such breach, (b) the other party’s bankruptcy or (c) a force majeure event that prevents performance for a period of at least 90 days.

Cell Line License Agreement — WuXi Biologics (Hong Kong) Limited

On March 22, 2021, we entered into a cell line license agreement (the “Cell Line License Agreement”) with WuXi Biologics. Under the Cell Line License Agreement, we received a non-exclusive, worldwide, sublicensable license to certain of WuXi Biologics’ know-how, cell line, biological materials and media and feeds to make, have made, use, sell and import certain drug products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement (the “WuXi Biologics Licensed Products”).

In consideration for the license, we agreed to pay WuXi Biologics a non-refundable license fee of \$150,000. Additionally, if we manufacture all of our commercial supplies of bulk drug product with a manufacturer other than WuXi Biologics or its affiliates, we are required to make royalty payments to WuXi Biologics in an amount equal to a fraction of a single digit percentage of global net sales of WuXi Biologics Licensed Products manufactured by a third-party manufacturer (the “Royalty”). If we manufacture part of our commercial supplies of the WuXi Biologics Licensed Products with WuXi Biologics or its affiliates, then the Royalty will be reduced accordingly on a pro rata basis.

The Cell Line License Agreement will continue indefinitely unless terminated (i) by us upon six months’ prior written notice and our payment of all undisputed amounts due to WuXi Biologics through the effective date of termination, (ii) by WuXi Biologics for a material breach by us that remains uncured for 60 days after written notice, (iii) by WuXi Biologics if we fail to make a payment and such failure continues for 30 days after receiving notice of such failure, or (iv) by either party upon the other party’s bankruptcy.

Government Regulation

The U.S. Food and Drug Administration (the “FDA”) and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development,

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testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

U.S. Biologics Regulation

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Public Health Service Act ("PHSA") and other federal, state, local, and foreign statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative action and judicial sanctions. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices regulation;
- submission to the FDA of an IND which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent IRB, or ethics committee at each clinical site before the trial is commenced;
- manufacture of the proposed biologic candidate in accordance with cGMPs;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations and current GCP requirements to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMPs, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with current GCPs; and
- FDA review and approval of a BLA to permit commercial marketing of the product for a particular indication(s) for use in the United States.

Preclinical and Clinical Development

Prior to beginning any clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product

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to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

In addition to the IND submission process, supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee (“IBC”), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment and such review may result in some delay before initiation of a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed.

Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing preclinical studies and clinical trials and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- *Phase 1.* The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- *Phase 2.* The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- *Phase 3.* The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

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In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain FDA regulatory requirements in order to use the study as support for an IND or application for marketing approval or licensure, including that the study was conducted in accordance with GCP, including review and approval by an independent ethics committee and use of proper procedures for obtaining informed consent from subjects, and the FDA is able to validate the data from the study through an onsite inspection if the FDA deems such inspection necessary. The GCP requirements encompass both ethical and data integrity standards for clinical studies.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of the product, or from a number of alternative sources, including studies initiated and sponsored by investigators. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

In addition, under the Pediatric Research Equity Act ("PREA"), a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The Food and Drug Administration Safety and Innovation Act requires that a sponsor who is planning to submit a marketing application for a biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial pediatric study plan within sixty days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within 10 months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards

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designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a REMS to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and data demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for more frequent interactions with the review team during product development and, once a BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

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A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if there is evidence it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to 10 months under standard review).

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, the FDA may require, as appropriate, that such studies be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation and priority review do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act of 1983, the FDA may grant orphan drug designation to a product candidate intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or 200,000 or more individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that product candidate. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full BLA, to market

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the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or if the holder of the orphan drug exclusivity cannot assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the product was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan drug designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;

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- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA"), includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are highly similar, or "biosimilar," to or interchangeable with an FDA-approved reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, is generally shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the product. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA. In September 2021, the FDA issued two guidance documents intended to inform prospective applicants and facilitate the development of proposed biosimilars and interchangeable biosimilars, as well as to describe the FDA's interpretation of certain statutory requirements added by the BPCIA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed 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 licensed. 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 that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitted under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In July 2018, the FDA announced an action plan to encourage the development and efficient review of biosimilars, including the establishment of a new office within the agency that will focus on therapeutic biologics and biosimilars. On December 20, 2020, Congress amended the PHSA as part of the COVID-19 relief bill to further simplify the biosimilar review process by making it optional to show that conditions of use proposed in labeling have been previously approved for the reference product, which used to be a requirement of the application. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

As discussed below, the Inflation Reduction Act of 2022 ("IRA") is a significant new law that intends to foster generic and biosimilar competition and to lower drug and biologic costs.

Other Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation: the federal Anti-Kickback Statute ("AKS"); the federal False Claims Act ("FCA"); the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and similar foreign, federal and state fraud, abuse and transparency laws.

The AKS prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program. The term remuneration has been interpreted broadly to include anything of value. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand, and prescribers and purchasers on the other. The government often takes the position that to violate the AKS, only one purpose of the remuneration need be to induce referrals, even if there are other legitimate purposes for the remuneration. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from AKS prosecution, but they are drawn narrowly and practices that involve remuneration, such as consulting agreements, that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

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Civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which can be enforced through civil whistleblower or qui tam actions, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment of federal government funds, including in federal healthcare programs, that are false or fraudulent. Pharmaceutical and other healthcare companies have been prosecuted under these laws for engaging in a variety of different types of conduct that “caused” the submission of false claims to federal healthcare programs. Under the AKS, for example, a claim resulting from a violation of the AKS is deemed to be a false or fraudulent claim for purposes of the FCA.

HIPAA created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program, including private third-party payors, and making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate the statute in order to have committed a violation.

The FDCA addresses, among other things, the design, production, labeling, promotion, manufacturing, and testing of drugs, biologics and medical devices, and prohibits such acts as the introduction into interstate commerce of adulterated or misbranded drugs or devices. The PHSA also prohibits the introduction into interstate commerce of unlicensed or mislabeled biological products.

The U.S. federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to annually report to the Centers for Medicaid & Medicare Services (“CMS”) information related to payments or other transfers of value made to various healthcare professionals including physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse-midwives, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning on January 1, 2023, California Assembly Bill 1278 requires California physicians and surgeons to notify patients of the Open Payments database established under the federal Physician Payments Sunshine Act.

We are also subject to additional similar U.S. state and foreign law equivalents of each of the above federal laws, which, in some cases, differ from each other in significant ways, and may not have the same effect, thus complicating compliance efforts. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, 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.

Data Privacy and Security

Numerous state, federal, and foreign laws govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations, govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health (“HITECH”), and their respective implementing regulations imposes data privacy, security, and breach notification obligations on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business associates and their covered subcontractors that perform certain services that involve using, disclosing, creating, receiving, maintaining, or transmitting individually identifiable protected health information (“PHI”) for or on behalf of such covered entities. These requirements imposed by HIPAA and the HITECH Act on covered entities and business associates include entering into agreements that require business associates protect PHI provided by the covered entity against

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improper use or disclosure, among other things; following certain standards for the privacy of PHI, which limit the disclosure of a patient's past, present, or future physical or mental health or condition or information about a patient's receipt of health care if the information identifies, or could reasonably be used to identify, the individual; ensuring the confidentiality, integrity, and availability of all PHI created, received, maintained, or transmitted in electronic form, to identify and protect against reasonably anticipated threats or impermissible uses or disclosures to the security and integrity of such PHI; and reporting of breaches of PHI to individuals and regulators.

Entities that are found to be in violation of HIPAA may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. A covered entity or business associate is also liable for civil money penalties for a violation that is based on an act or omission of any of its agents, which may include a downstream business associate, as determined according to the federal common law of agency. HITECH also increased the civil and criminal penalties applicable to covered entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. To the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied.

Even when HIPAA does not apply, according to the Federal Trade Commission, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

In addition, certain state laws, such as the California Consumer Privacy Act of 2018 ("CCPA"), as amended by the California Privacy Rights Act of 2020 ("CPRA"), govern the privacy and security of personal information, including health-related information, in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. The CCPA/CPRA applies to personal data of consumers, business representatives, and employees, and imposes obligations on certain businesses that do business in California, including to provide specific disclosures in privacy notices, rights to California residents in relation to their personal information. Health information falls under the CCPA/CPRA's definition of personal information where it identifies, relates to, describes, or is reasonably capable of being associated with or could reasonably be linked with a particular consumer or household — unless it is subject to HIPAA — and is included under a new category of personal information, "sensitive personal information," which is offered greater protection. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing. Additionally, our use of artificial intelligence and machine learning may be subject to laws and evolving regulations regarding the use of artificial intelligence/machine learning, controlling for data bias, and anti-discrimination.

In addition, the CPRA expands the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law. Other states, such as Virginia, Colorado, Connecticut and Utah, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While the laws in these states, like the CCPA, also exempt some data processed in the context of clinical trials, such developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product, if approved, depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement, if any, for such product by third-party payors. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Decreases in third-party reimbursement for any product or a decision by a third-party not to cover a product could reduce physician usage and patient demand for the product.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. The IRA provides CMS with significant new authorities intended to curb drug costs and to encourage market competition. For the first time, CMS will be able to directly negotiate prescription drug prices and to cap out-of-pocket costs. Each year, CMS will select and negotiate a preset number of high-spend drugs and biologics that are covered under Medicare Part B and Part D that do not have generic or biosimilar competition. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations. These price negotiations will begin in 2023, although the Medicare drug price negotiation program is currently subject to legal challenges. The IRA also provides a new “inflation rebate” covering Medicare patients that will take effect in 2023 and is intended to counter certain price increases in prescriptions drugs. The inflation rebate provision will require drug manufacturers to pay a rebate to the federal government if the price for a drug or biologic under Medicare Part B and Part D increases faster than the rate of inflation. To support biosimilar competition, beginning in October 2022, qualifying biosimilars may receive a Medicare Part B payment increase for a period of five years. Separately, if a biologic drug for which no biosimilar exists delays a biosimilar’s market entry beyond two years, CMS will be authorized to subject the biologics manufacturer to price negotiations intended to ensure fair competition. Notwithstanding these provisions, the IRA’s impact on commercialization and competition remains largely uncertain.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

The ACA, which was enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, the IRA, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program.

Other legislative changes have been proposed and adopted since the ACA was enacted, including automatic aggregate reductions of Medicare payments to providers of on average 2% per fiscal year as part of the federal budget sequestration under the Budget Control Act of 2011. These reductions went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect until 2032 unless additional action is taken by Congress.

In addition, the Bipartisan Budget Act of 2018, among other things, amended the Medicare Act (as amended by the ACA) to increase the point-of-sale discounts that manufacturers must agree to offer under the Medicare Part D coverage discount program from 50% to 70% off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs being covered under Medicare Part D.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state measures designed to, among other things, reduce the cost of prescription drugs, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, in May 2019, CMS adopted a final rule allowing Medicare Advantage Plans the option to use step therapy for Part B drugs, permitting Medicare Part D plans to apply certain utilization controls to new starts of five of the six protected class drugs, and requiring the Explanation of Benefits for Part D beneficiaries to disclose drug price increases and lower cost therapeutic alternatives, which went into effect on January 1, 2021. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

Notwithstanding the IRA, continued legislative and enforcement interest exists in the United States with respect to specialty drug pricing practices. Specifically, we expect regulators to continue pushing for transparency to drug pricing, reducing the cost of prescription drugs under Medicare, reviewing the relationship between pricing and manufacturer patient programs, and reforming government program reimbursement methodologies for drugs.

Other Government Regulation Outside of the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy, quality control, labeling, packaging, storage, record keeping, distribution, reporting, export and import, advertising, marketing and other promotional practices involving biological products as well as authorization, approval as well as post-approval monitoring and reporting of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials.

The requirements and process governing the conduct of clinical trials, including requirements to conduct additional clinical trials, product licensing, safety reporting, post-authorization requirements, marketing and promotion, interactions with healthcare professionals, pricing and reimbursement may vary widely from country to country. No action can be taken to market any product in a country until an appropriate approval application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product, which would make launch of such products commercially unfeasible in such countries.

Regulation in the European Union

European Data Laws

The collection and use of personal health data and other personal data in the EU is governed by the provisions of the European General Data Protection Regulation (EU) 2016/679 (“GDPR”), which came into force in May 2018, and related data protection laws in individual EU Member States. The GDPR imposes a number of strict obligations and restrictions on the ability to process, including collecting, analyzing and transferring, personal data of individuals, in particular with respect to health data from clinical trials and adverse event reporting. The GDPR includes requirements relating to the legal basis of the processing (such as consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the notification obligations to the national data protection authorities, and the security and confidentiality of the personal data. EU Member States may also impose additional requirements in relation to health, genetic and biometric data through their national legislation.

In addition, the GDPR imposes specific restrictions on the transfer of personal data to countries outside of the European Economic Area (“EEA”) that are not considered by the European Commission (“EC”) to provide an adequate level of data protection. Appropriate safeguards are required to enable such transfers. Among the appropriate safeguards that can be used, the data exporter may use the EC approved standard contractual clauses (“SCCs”). With regard to the transfer of data from the EEA to the United States, on July 10, 2023, the EC adopted its adequacy decision for the EU-US Data Privacy Framework. On the basis of the new adequacy decision, personal data can flow from the EEA to U.S. companies participating in the framework.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States may result in significant monetary fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater, other administrative penalties and a number of criminal offenses (punishable by uncapped fines) for organizations and, in certain cases, their directors and officers, as well as civil liability claims from individuals whose personal data was processed. Data protection authorities from the different EU Member States may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data subject in the EU data protection regimes. Guidance developed at both the EU level and at the national level in individual EU Member States concerning implementation and compliance practices are often updated or otherwise revised.

Furthermore, there is a growing trend towards the required public disclosure of clinical trial data in the EU, which adds to the complexity of obligations relating to processing health data from clinical trials. Such public disclosure obligations are provided in the new EU Clinical Trials Regulation No. 536/2014 (the “CTR”), EMA disclosure initiatives and voluntary commitments by industry. Failure to comply with these obligations could lead to government enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results. The uncertainty regarding the interplay between different regulatory frameworks, such as the CTR and the GDPR, further adds to the complexity that we face with regard to data protection regulation.

With regard to the transfer of personal data from the EEA to the UK, personal data may now freely flow from the EEA to the UK since the UK is deemed to have an adequate data protection level. However, the adequacy decisions include a ‘sunset clause’ which entails that the decisions will automatically expire four years after their entry into force. Additionally, following the UK’s withdrawal from the EU and the EEA, companies also have to comply with the UK’s data protection laws (including the UK GDPR (as defined in section 3(10) (as supplemented by section 205(4)) of the Data Protection Act 2018 (the DPA 2018)), the DPA 2018, and related data protection laws in the UK). Separate from the fines that can be imposed by the GDPR, the UK regime has the ability to fine up to the greater of £17.5 million or 4% of global turnover.

Following the UK’s withdrawal from the EU and the EEA, companies are subject to specific transfer rules under the UK regime; personal data may flow freely from the UK to the EEA, since the EEA is deemed to have an adequate data protection level for purposes of the UK regime. These UK international transfer rules broadly mirror the GDPR rules. On February 2, 2022, the UK Secretary of State laid before the UK Parliament the international data transfer agreement (“IDTA”) and the international data transfer addendum to the EC’s standard contractual clauses for international data transfers (Addendum) and a document setting out transitional provisions. The IDTA and Addendum came into force on March 21, 2022 and replaced the old SCCs for the purposes of the UK regime. However, the transitional provisions, adopted with the IDTA and the Addendum, provide that contracts concluded on or before September 21, 2022 on the basis of any old SCCs continue to provide appropriate safeguards for the purpose of the UK regime until March 21, 2024, provided that the processing operations that are the subject matter of the contract remain unchanged and reliance on those clauses ensures that the transfer of personal data is subject to appropriate safeguards.

With regard to the transfer of personal data from the UK to the United States, the UK government has adopted an adequacy decision for the United States, the UK-US Data Bridge, which came into force on October 12, 2023. The UK-US Data Bridge recognizes the United States as offering an adequate level of data protection where the transfer is to a U.S. company participating in the EU-US Data Privacy Framework and the UK Extension.

Drug and Biologic Development Process

Regardless of where they are conducted, all clinical trials included in applications for marketing authorization (“MA”) for human medicines in the EU/EEA must have been carried out in accordance with EU

regulations. This means that clinical trials conducted in the EU/EEA have to comply with EU clinical trial legislation but also that clinical trials conducted outside the EU/EEA have to comply with ethical principles equivalent to those set out in the EU/EEA, including adhering to international good clinical practice and the Declaration of Helsinki. The conduct of clinical trials in the EU is governed by the CTR, which entered into force on January 31, 2022. The CTR replaced the Clinical Trials Directive 2001/20/EC, (“Clinical Trials Directive”) and introduced a complete overhaul of the existing regulation of clinical trials for medicinal products in the EU.

Under the former regime, which will expire after a transition period of three years, respectively, as outlined below in more detail, before a clinical trial can be initiated it must be approved in each EU member state where there is a site at which the clinical trial is to be conducted. The approval must be obtained from two separate entities: the National Competent Authority (“NCA”) in the applicable EU member state(s) and one or more Ethics Committees. The NCA of the EU Member States in which the clinical trial will be conducted must authorize the conduct of the trial, and the independent ethics committee must grant a positive opinion in relation to the conduct of the clinical trial in the relevant EU member state before the commencement of the trial. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be submitted to or approved by the relevant NCA and Ethics Committees. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial must be reported to the NCA and to the Ethics Committees of the EU member state where they occur.

A more unified procedure will apply under the new CTR. A sponsor will be able to submit a single application for approval of a clinical trial through a centralized EU clinical trials portal (the “CTIS”). One national regulatory authority (the reporting EU Member State proposed by the applicant) will take the lead in validating and evaluating the application, consult and coordinate with the other concerned EU Member States. If an application is rejected, it may be amended and resubmitted through the EU clinical trials portal. If an approval is issued, the sponsor may start the clinical trial in all concerned EU Member States. However, a concerned EU Member State may in limited circumstances declare an “opt-out” from an approval and prevent the clinical trial from being conducted in such member state. The CTR also aims to streamline and simplify the rules on safety reporting, and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU Database. The CTR foresees a three-year transition period. EU Member States will work in CTIS immediately after the system has gone live. Since January 31, 2023, submission of initial clinical trial applications via CTIS is mandatory, and by January 31, 2025, all ongoing trials approved under the former Clinical Trials Directive will need to comply with the CTR and have to be transitioned to CTIS. On July 19, 2023, the EC published guidance concerning the steps to be taken in this transition. This guidance provides, among other things, that (i) documentation which was previously assessed will not be reassessed, (ii) templates that were developed and endorsed by the EU Clinical Trials Expert Group to provide compliance with the CTR do not need to be updated and (iii) there is no need to retrospectively create a site suitability form, which are only necessary for new trial sites.

Under both the former regime and the new CTR, national laws, regulations, and the applicable GCP and Good Laboratory Practice standards must also be respected during the conduct of the trials, including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use guidelines on Good Clinical Practice and the ethical principles that have their origin in the Declaration of Helsinki.

During the development of a medicinal product, the EMA and national regulators within the EU provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Committee for Medicinal Products for Human Use (“CHMP”) on the recommendation of the Scientific Advice Working Party. A fee is incurred with each scientific advice procedure but is significantly reduced for designated orphan medicines. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future Marketing Authorization Application (“MAA”) of the product concerned.

Drug Marketing Authorization

In the EEA, after completion of all required clinical testing, pharmaceutical products may only be placed on the market after obtaining a MA. To obtain an MA of a drug under European Union regulatory systems, an applicant can submit an MAA through, amongst others, a centralized or decentralized procedure. To be used or sold in the UK, a drug must have an effective MA obtained by a centralized application through EMA or a national application. National applications are governed by the Human Medicines Regulations (SI 2012/1916). Applications are made electronically through the Medicines and Healthcare products Regulatory Agency (“MHRA”) Submissions Portal. The process from application to authorizations generally takes up to 210 days, excluding time taken to provide any additional information or data required by the MHRA.

On August 30, 2023, the MHRA published detailed guidance on its recently announced new International Reliance Procedure (“IRP”) for MAAs. The IRP applies since January 1, 2024 and replaces existing EU reliance procedures to apply for authorizations from seven international regulators (e.g. Health Canada, Swiss Medic, FDA, EMA, among others). The IRP allows medicinal products approved in other jurisdictions that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update a MA in the UK or Great Britain.

Applicants can submit initial MAAs to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals.

Centralized Authorization Procedure

The centralized procedure provides for the grant of a single MA that is issued by the EC following the scientific assessment of the application by the EMA that is valid for all EU Member States as well as in the three additional EEA Member States. The centralized procedure is compulsory for specific medicinal products, including for medicines developed by means of certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (“ATMP”) and medicinal products with a new active substance indicated for the treatment of certain diseases (AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases). For medicinal products containing a new active substance not yet authorized in EEA before May 20, 2004 and indicated for the treatment of other diseases, medicinal products that constitute significant therapeutic, scientific or technical innovations or for which the grant of a MA through the centralized procedure would be in the interest of public health at EU level, an applicant may voluntarily submit an application for a MA through the centralized procedure.

Under the centralized procedure, the CHMP established at the EMA, is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA. Under the centralized procedure, the timeframe for the evaluation of an MAA by the EMA’s CHMP is, in principle, 210 days from receipt of a valid MAA. However, this timeline excludes clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP, so the overall process typically takes a year or more, unless the application is eligible for an accelerated assessment. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. Upon request, the CHMP can reduce the time frame to 150 days if the applicant provides sufficient justification for an accelerated assessment. The CHMP will provide a positive opinion regarding the application only if it meets certain quality, safety and efficacy requirements. This opinion is then transmitted to the EC, which has the ultimate authority for granting the MA within 67 days after receipt of the CHMP opinion.

Decentralized Authorization Procedure

Medicines that fall outside the mandatory scope of the centralized procedure have three routes to authorization: (i) they can be authorized under the centralized procedure if they concern a significant therapeutic,

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scientific or technical innovation, or if their authorization would be in the interest of public health; (ii) they can be authorized under a decentralized procedure where an applicant applies for simultaneous authorization in more than one EU member state; or (iii) they can be authorized in an EU member state in accordance with that state's national procedures and then be authorized in other EU countries by a procedure whereby the countries concerned agree to recognize the validity of the original, national MA (mutual recognition procedure).

The decentralized procedure permits companies to file identical MA applications for a medicinal product to the competent authorities in various EU Member States simultaneously if such medicinal product has not received marketing approval in any EU Member State before. This procedure is available for pharmaceutical products not falling within the mandatory scope of the centralized procedure. The competent authority of a single EU Member State, the reference member state, is appointed to review the application and provide an assessment report. The competent authorities of the other EU Member State, the concerned member states, are subsequently required to grant a MA for their territories on the basis of this assessment. The only exception to this is where the competent authority of an EU Member State considers that there are concerns of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the EC, whose decision is binding for all EU Member States.

Risk Management Plan

All new MAAs must include a Risk Management Plan ("RMP") describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. RMPs are continually modified and updated throughout the lifetime of the medicine as new information becomes available. An updated RMP must be submitted: (i) at the request of EMA or a national competent authority, or (ii) whenever the risk-management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit-risk profile or as a result of an important pharmacovigilance or risk-minimization milestone being reached. The regulatory authorities may also impose specific obligations as a condition of the MA. Since October 20, 2023, all RMPs for centrally authorized products are published by EMA, subject only to limited redactions.

MA Validity Period

MAAs have an initial duration of five years. After these five years, the authorization may subsequently be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the EC or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with only one additional five-year renewal. Applications for renewal must be made to the EMA at least nine months before the five-year period expires.

Additionally, the holder of a MA for an ATMP must put in place and maintain a system to ensure that each individual product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the relevant healthcare institution where the product is used. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

For the UK, the period of three years during which the drug has not been marketed in Great Britain will be restarted from the date of conversion to a Great Britain MA. Conversion refers to the procedure by which, as of January 1, 2021, MAs granted on the basis of a centralized procedure in the EU are only valid in Northern Ireland but not in Great Britain, whereas, prior EU authorizations have all been automatically converted into UK MAs effective in Great Britain only.

On the other hand, for the EU, in the case the drug has been marketed in the UK, the placing on the UK market before the end of the period starting when the UK left the EU on January 31, 2020 and ending on

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December 31, 2020 (the “Brexit Transition Period”) will be taken into account. If, after the end of the Brexit Transition Period, the drug is not placed on any other market of the remaining member states of the EU, the three-year period will start running from the last date the drug was placed on the UK market before the end of the Brexit Transition Period.

Advanced Therapy Medicinal Products

In the EU, medicinal products, including ATMPs are subject to extensive pre- and post-market regulation by regulatory authorities at both the EU and national levels. ATMPs comprise gene therapy products, somatic cell therapy products and tissue engineered products, which are genes, cells or tissues that have undergone substantial manipulation and that are administered to human beings in order to cure, diagnose or prevent diseases or regenerate, repair or replace a human tissue. Pursuant to ATMP regulation, the Committee on Advanced Therapies (“CAT”) is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CHMP and CAT are also responsible for providing guidelines on ATMPs. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs. Although such guidelines are not legally binding, compliance with them is often necessary to gain and maintain approval for product candidates.

In addition to the mandatory RMP, the holder of a MA for an ATMP must put in place and maintain a system to ensure that each individual product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the relevant healthcare institution where the product is used.

Exceptional Circumstances/Conditional Approval

Similar to accelerated approval regulations in the United States, conditional MAs can be granted in the EU in exceptional circumstances. A conditional MA can be granted for medicinal products where, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, a number of criteria are fulfilled: (i) the benefit/risk balance of the product is positive, (ii) it is likely that the applicant will be in a position to provide the comprehensive clinical data, (iii) unmet medical needs will be fulfilled by the grant of the MA and (iv) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional MA must be renewed annually.

Data and Market Exclusivity

As in the United States, it may be possible to obtain a period of market and / or data exclusivity in the EU that would have the effect of postponing the entry into the marketplace of a competitor’s generic, hybrid or biosimilar product (even if the pharmaceutical product has already received a MA) and prohibiting another applicant from relying on the MA holder’s pharmacological, toxicological and clinical data in support of another MA for the purposes of submitting an application, obtaining an MA or placing the product on the market. New Chemical Entities (“NCE”) approved in the EU qualify for eight years of data exclusivity and 10 years of marketing exclusivity.

An additional non-cumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first eight years of the 10-year marketing exclusivity period), the MA holder obtains an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies.

The data exclusivity period begins on the date of the product’s first MA in the EU. After eight years, a generic product application may be submitted and generic companies may rely on the MA holder’s data. However, a generic product cannot launch until two years later (or a total of 10 years after the first MA in the EU

of the innovator product), or three years later (or a total of 11 years after the first MA in the EU of the innovator product) if the MA holder obtains MA for a new indication with significant clinical benefit within the eight-year data exclusivity period. Additionally, another noncumulative one-year period of data exclusivity can be added to the eight years of data exclusivity where an application is made for a new indication for a well-established substance, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication. Another year of data exclusivity may be added to the eight years, where a change of classification of a pharmaceutical product has been authorized on the basis of significant pre-trial tests or clinical trials (when examining an application by another applicant for or holder of market authorization for a change of classification of the same substance the competent authority will not refer to the results of those tests or trials for one year after the initial change was authorized).

Products may not be granted data exclusivity since there is no guarantee that a product will be considered by the European Union's regulatory authorities to include a NCE. Even if a compound is considered to be a NCE and the MA applicant is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the medicinal product if such company can complete a full MAA with their own complete database of pharmaceutical tests, preclinical studies and clinical trials and obtain MA of its product.

On April 26, 2023, the EC submitted a proposal for the reform of the European pharmaceutical legislation. The current draft envisages e.g., a shortening of the periods of data exclusivity, however, there is currently neither a final version of this draft nor a date for its entry into force.

Orphan Designation and Exclusivity

The criteria for designating an orphan medicinal product in the EU are similar in principle to those in the United States. The EMA grants orphan drug designation if the medicinal product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the EU (prevalence criterion). In addition, Orphan Drug Designation can be granted if, for economic reasons, the medicinal product would be unlikely to be developed without incentives and if there is no other satisfactory method approved in the EU of diagnosing, preventing, or treating the condition, or if such a method exists, the proposed medicinal product is a significant benefit to patients affected by the condition. An application for orphan drug designation (which is not a MA, as not all orphan-designated medicines reach the authorization application stage) must be submitted first before an application for MA of the medicinal product is submitted. The applicant will receive a fee reduction for the MAA if the orphan drug designation has been granted, but not if the designation is still pending at the time the MAA is submitted, and sponsors must submit an annual report to EMA summarizing the status of development of the medicine. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Designated orphan medicines are eligible for conditional marketing authorization.

The EMA's Committee for Orphan Medicinal Products reassesses the orphan drug designation of a product in parallel with the review for a MA; for a product to benefit from market exclusivity it must maintain its orphan drug designation at the time of MA review by the EMA and approval by the EC. Additionally, any MA granted for an orphan medicinal product must only cover the therapeutic indication(s) that are covered by the orphan drug designation. Upon the grant of a MA, orphan drug designation provides up to ten years of market exclusivity in the orphan indication.

During the 10-year period of market exclusivity, with a limited number of exceptions, the regulatory authorities of the EU Member States and the EMA may not accept applications for MA, accept an application to extend an existing MA or grant MA for other similar medicinal products for the same therapeutic indication. A similar medicinal product is defined as a medicinal product containing a similar active substance or substances as contained in a currently authorized orphan medicinal product, and which is intended for the same therapeutic indication. An orphan medicinal product can also obtain an additional two years of market exclusivity for an

orphan-designated condition when the results of specific studies are reflected in the Summary of Product Characteristics (“SmPC”) addressing the pediatric population and completed in accordance with a fully compliant Pediatric Investigation Plan (“PIP”). No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, i.e. the condition prevalence or financial returns criteria under Article 3 of Regulation (EC) No. 141/2000 on orphan medicinal products. When the period of orphan market exclusivity for an indication ends, the orphan drug designation for that indication expires as well. Orphan exclusivity runs in parallel with normal rules on data exclusivity and market protection. Additionally, a MA may be granted to a “similar medicinal product” (orphan or not) for the same or overlapping indication subject to certain requirements.

Pediatric Development

In the EU, companies developing a new medicinal product are obligated to study their product in children and must therefore submit a PIP together with a request for agreement to the EMA. The EMA issues a decision on the PIP based on an opinion of the EMA’s Pediatric Committee. Companies must conduct pediatric clinical trials in accordance with the PIP approved by the EMA, unless a deferral (e.g. until enough information to demonstrate its effectiveness and safety in adults is available) or waiver (e.g. because the relevant disease or condition occurs only in adults) has been granted by the EMA. The MAA for the medicinal product must include the results of all pediatric clinical trials performed and details of all information collected in compliance with the approved PIP, unless a waiver or a deferral has been granted, in which case the pediatric clinical trials may be completed at a later date. Medicinal products that are granted a MA on the basis of the pediatric clinical trials conducted in accordance with the approved PIP are eligible for a six-month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval), or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the approved PIP are developed and submitted. An approved PIP is also required when a MA holder wants to add a new indication, medicinal form or route of administration for a medicine that is already authorized and covered by intellectual property rights.

In the UK, the MHRA has published guidance on the procedures for UK PIPs which, where possible, mirror the submission format and requirements of the EU system. EU PIPs remain applicable for Northern Ireland and EU PIPs agreed by the EMA prior to January 1, 2021 have been adopted as UK PIPs.

PRIME Designation

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The Priority Medicines (“PRIME”) scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies on the basis of compelling non-clinical data and tolerability data from initial clinical trials. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted. Importantly, once a candidate medicine has been selected for the PRIME scheme, a dedicated contact point and rapporteur from the CHMP or from CAT are appointed facilitating increased understanding of the product at EMA’s Committee level. A kick-off meeting with the CHMP/CAT rapporteur initiates these relationships and includes a team of multidisciplinary experts to provide guidance on the overall development plan and regulatory strategy. PRIME eligibility does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval.

Post-Approval Regulation

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the EC and/or the competent regulatory authorities of the EU Member States. This oversight applies both before and after grant of manufacturing licenses and MAs. It includes control of compliance with EU good manufacturing practices rules, manufacturing authorizations, pharmacovigilance rules and requirements governing advertising, promotion, sale, and distribution, recordkeeping, importing and exporting of medicinal products.

Failure by us or by any of our third-party partners, including suppliers, manufacturers and distributors to comply with EU laws and the related national laws of individual EU Member States governing the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of MA, statutory health insurance, bribery and anti-corruption or other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant an MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The holder of an MA for a medicinal product must also comply with EU pharmacovigilance legislation and its related regulations and guidelines, which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products.

These pharmacovigilance rules can impose on holders of MAs the obligation to conduct a labor intensive collection of data regarding the risks and benefits of marketed medicinal products and to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies or post-authorization safety studies to obtain further information on a medicine's safety, or to measure the effectiveness of risk- management measures, which may be time consuming and expensive and could impact our profitability. MA holders must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs") in relation to medicinal products for which they hold MAs. The EMA reviews PSURs for medicinal products authorized through the centralized procedure. If the EMA has concerns that the risk benefit profile of a product has varied, it can adopt an opinion advising that the existing MA for the product be suspended, withdrawn or varied. The agency can advise that the MA holder be obliged to conduct post-authorization Phase IV safety studies. If the EC agrees with the opinion, it can adopt a decision varying the existing MA. Failure by the MA holder to fulfill the obligations for which the EC's decision provides can undermine the ongoing validity of the MA.

More generally, non-compliance with pharmacovigilance obligations can lead to the variation, suspension or withdrawal of the MA for the product or imposition of financial penalties or other enforcement measures.

The manufacturing process for pharmaceutical products in the EU is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice ("GMP"). These requirements include compliance with EU GMP standards when manufacturing pharmaceutical products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into the European Union. Similarly, the distribution of pharmaceutical products into and within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU Member States. The

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manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with GMP, before releasing the product for commercial distribution in the EU or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

Sales and Marketing Regulations

The advertising and promotion of our products is also subject to EU laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other national legislation of individual EU Member States may apply to the advertising and promotion of medicinal products and may differ from one country to another. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's SmPC as approved by the competent regulatory authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the MA granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. All advertising and promotional activities for the product must be consistent with the approved SmPC and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription-only medicines is also prohibited in the EU. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on its promotional activities with healthcare professionals.

EU regulation with regards to dispensing, sale and purchase of medicines has generally been preserved in the UK following Brexit, through the HMRs. However, organizations wishing to sell medicines online need to register with the MHRA. Following Brexit, the requirements to display the common logo no longer apply to UK- based online sellers, except for those established in Northern Ireland.

Anti-Corruption Legislation

In the EU, interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at EU level and in the individual EU Member States. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the EU Member States. Violation of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States also must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her regulatory professional organization, and/or the competent authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the individual EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In the UK, the pharmaceutical sector is recognized as being particularly vulnerable to corrupt practices, some of which fall within the scope of the Bribery Act 2010. Due to the Bribery Act 2010's far-reaching territorial application, the potential penalized act does not have to occur in the UK to become within its scope. If the act or omission does not take place in the UK, but the person's act or omission would constitute an offense if carried out there and the person has a close connection with the UK, an offense will still have been committed. The Bribery Act 2010 is comprised of four offenses that cover (i) individuals, companies and partnerships that give, promise or offer bribes, (ii) individuals, companies and partnerships that request, agree to receive or accept bribes, (iii) individuals, companies and partnerships that bribe foreign public officials and (iv) companies and partnerships that fail to prevent persons acting on their behalf from paying bribes. The penalties imposed under the Bribery Act 2010 depend on the offence committed, harm and culpability and penalties range from unlimited fines to imprisonment for a maximum term of ten years and in some cases both.

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Regulations in the UK and Other Markets

The UK formally left the EU on January 31, 2020 and EU laws now only apply to the UK in respect of Northern Ireland as laid out in the Protocol on Ireland and Northern Ireland and as amended by the Windsor Framework sets out a long-term set of arrangements for the supply of medicines into Northern Ireland. The EU and the UK agreed on a trade and cooperation agreement (“TCA”), which includes provisions affecting the life sciences sector (including on customs and tariffs). There are some specific provisions concerning pharmaceuticals, including the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP issued documents. The TCA does not, however, contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards.

The UK government has adopted the Medicines and Medical Devices Act 2021 (the “MMDA”) to enable the UK’s regulatory frameworks to be updated following the UK’s departure from the EU. The MMDA introduces regulation-making, delegated powers covering the fields of human medicines, clinical trials of human medicines, veterinary medicines and medical devices. The MHRA has since been consulting on future regulations for medicines and medical devices in the UK.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, it may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Employees and Human Capital Resources

As of March 14, 2024, we had 53 employees, all of whom were employed full time and 37 of whom were engaged in research and development activities. 14 of our employees hold Ph.D. or M.D. degrees. None of our employees are represented by a labor union or covered under a collective bargaining agreement. We consider our relationship with our employees to be good.

Facilities

We are currently a remote-based company, and a majority of our employees work remotely. We currently lease space for administrative offices in Waltham, Massachusetts and New York, New York and wet laboratory space in Watertown, Massachusetts. Our space in Waltham is approximately 2,750 square feet under a lease that expires in January 2025, our space in New York is approximately 3,367 square feet under a lease that expires in August 2025 and our space in Watertown varies monthly based on our needs but does not exceed 1,000 square feet under a lease that expires in August 2025. Our New York office is our corporate headquarters. As the company expands, we believe suitable additional, or substitute space will be available as and when needed.

Legal Proceedings

From time to time, we may be involved in litigation and other legal proceedings arising in the ordinary course of our business. We are not currently a party to or aware of any legal proceedings that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition, results of operations or cash flows. The outcome of any claims or litigation, regardless of the merits, is inherently uncertain. Regardless of the outcome, litigation and other legal proceedings can have a material adverse impact on us, our business, financial condition, results of operations or cash flows because of defense and settlement costs, diversion of management resources, in the case of intellectual property claims, requirements to change our product candidates, change our business practices, pay monetary damages or enter into short- or long-term royalty or licensing agreements, and other factors.

MANAGEMENT

Executive Officers and Directors

Pursuant to the Merger Agreement, Magenta was entitled to designate two directors to the Board of Directors (the “Magenta Designees”) and Former Dianthus was entitled to designate six directors to the Board of Directors (the “Former Dianthus Designees”). Effective as of September 11, 2023, the following individuals continued to serve as members of the Board of Directors as the Magenta Designees: Alison F. Lawton and Anne McGeorge, and the following individuals were appointed as members of the Board of Directors as Former Dianthus Designees: Marino Garcia, Leon O. Moulder, Jr., Tomas Kiselak, Lei Meng, Paula Soteropoulos and Jonathan Violin, Ph.D.

In accordance with the terms of our Certificate of Incorporation and By-laws, our Board of Directors is divided into three classes, Class I, Class II and Class III, with members of each class serving staggered three-year terms. The members of the classes are divided as follows:

- the Class I directors are Marino Garcia and Paula Soteropoulos, and their terms will expire at the annual meeting of stockholders to be held in 2025;
- the Class II directors are Tomas Kiselak, Anne McGeorge and Jonathan Violin, Ph.D., and their terms will expire at the annual meeting of stockholders to be held in 2026; and
- the Class III directors are Alison F. Lawton, Lei Meng and Leon O. Moulder, Jr., and their terms will expire at the annual meeting of stockholders to be held in 2026.

Other than pursuant to the Merger Agreement, there were no arrangements or understandings between our newly appointed directors and any person pursuant to which they were elected. Other than as described herein, none of our newly appointed directors have a direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K. There are no family relationships among any of our directors.

On September 11, 2023, the Board of Directors appointed Marino Garcia as our President and Chief Executive Officer and principal executive officer, Ryan Savitz as our Treasurer and Chief Financial Officer and principal financial officer and Edward Carr as our Chief Accounting Officer and principal accounting officer. Each executive officer will serve at the discretion of the Board of Directors and hold office until his or her successor is duly elected and qualified or until his or her earlier resignation or removal.

There are no family relationships among any of our newly appointed principal officers. None of our newly appointed principal officers have a direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

The following table sets forth the name, age and position of each of our current directors and executive officers as of March 14, 2024:

<u>Name</u>	<u>Age</u>	<u>Position</u>
<i>Executive Officers:</i>		
Marino Garcia	57	President, Chief Executive Officer and Director
Ryan Savitz	35	Chief Financial Officer Chief Business Officer and Treasurer
Simrat Randhawa, M.D.	54	Chief Medical Officer
Adam Veness	38	Senior Vice President, General Counsel and Secretary
Edward Carr	54	Chief Accounting Officer

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<u>Name</u>	<u>Age</u>	<u>Position</u>
<i>Non-Employee Directors:</i>		
Leon O. Moulder, Jr.	66	Independent and Chairman of the Board of Directors
Tomas Kiselak	37	Independent Director
Lei Meng	51	Independent Director
Paula Soteropoulos	56	Independent Director
Jonathan Violin, Ph.D.	48	Director
Alison F. Lawton	62	Independent Director
Anne McGeorge	63	Independent Director

Executive Officers

Marino Garcia. Mr. Garcia has served as our President and Chief Executive Officer and as a member of our Board of Directors since September 2023, and as President and Chief Executive Officer and a director of Former Dianthus since November 2021. Prior to joining Former Dianthus, Mr. Garcia served as Senior Vice President, Corporate and Business Development at Zealand Pharma A/S, a biotechnology company, from October 2018 to October 2021. Mr. Garcia previously served as Executive Vice President, Chief Strategy Officer at Synergy Pharmaceuticals from March 2016 to September 2018 and was the Senior Vice President for Corporate Development for the two preceding years. Prior to Synergy, Mr. Garcia served as Vice President, US Commercial Operations and Global New Product Development at Aspreva Pharmaceuticals Corporation, a company collaborating with Roche to develop CellCept (mycophenolate mofetil) for a range of autoimmune diseases, including Lupus Nephritis, Myasthenia Gravis, and Pemphigus Vulgaris. Prior to joining Aspreva, Mr. Garcia served in various roles at large multinational biopharmaceutical companies, including Merck & Co., Pfizer Inc. and Eli Lilly and Co. Mr. Garcia received his M.B.A. from the Ivey Business School at Western University in London, Ontario and his Bachelor of Commerce from Concordia University in Montreal, Quebec. We believe that Mr. Garcia is qualified to serve on the Board of Directors because of his significant operational and senior management experience in the biopharmaceutical industry.

Ryan Savitz. Mr. Savitz has served as our Chief Financial Officer since September 2023, and was promoted to add Chief Business Officer to his title in February 2024. Mr. Savitz has served as Chief Financial Officer of Former Dianthus since June 2022. Mr. Savitz was recently promoted to Chief Financial and Business Officer on February 7, 2024. He most recently served as Managing Director in Citigroup's Healthcare Investment Banking division where he was employed from June 2010 to June 2022 and focused on advising biopharma companies on private and public capital raising, partnering, and mergers and acquisitions. Prior to becoming Managing Director, he held positions of increasing responsibility, all within the Healthcare Investment Banking division at Citigroup. Mr. Savitz received his Bachelor of Science in Finance from the Pennsylvania State University.

Simrat Randhawa, M.D. Dr. Randhawa has served as our Chief Medical Officer since September 2023 and as Chief Medical Officer of Former Dianthus since April 2022. Dr. Randhawa most recently served as Senior Vice President of Clinical and Medical Affairs at Aurinia Pharmaceuticals Inc. (Nasdaq: AUPH), an autoimmune-focused company, from February 2017 to April 2022, where he supported the clinical development of voclosporin. Dr. Randhawa has held a number of senior commercial and medical leadership roles in the autoimmune and rare disease spaces within large pharma and biotech companies such as Novartis AG and BioMarin Pharmaceutical Inc. Previously, he supported business development opportunities and integration needs in the health care sector while at McKinsey Consulting. Dr. Randhawa completed his M.D. at Drexel University and received his M.B.A. from Columbia University.

Adam Veness, Esq. Mr. Veness has served as our Senior Vice President, General Counsel and Secretary since September 2023, and Senior Vice President, General Counsel and Secretary of Former Dianthus since June 2023. Prior to joining Former Dianthus, Mr. Veness served as General Counsel and Secretary at Cyteir Therapeutics, Inc. (Nasdaq: CYT), a clinical-stage oncology company, from April 2022 until June 2023. Prior to Cyteir, Mr. Veness served as General Counsel and Secretary at Acceleron Pharma Inc., a biopharmaceutical

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company, from 2019 until Acceleron's acquisition by Merck & Co. in November 2021. Mr. Veness served in various roles at Acceleron from July 2014 until his appointment as General Counsel in 2019. During his tenure at Acceleron, Mr. Veness gained experience in roles of increasing responsibility where he served on the Executive Committee responsible for company strategy, and he led the global legal and compliance functions, including capital markets and SEC reporting obligations, corporate governance, contracts, intellectual property, employment matters, and data privacy. Prior to Acceleron, Mr. Veness was a corporate and securities attorney at the law firm, Mintz Levin, where he represented and counseled public and private companies in the biopharmaceutical, technology, and healthcare industries. Mr. Veness earned a B.A. in Political Science and Philosophy from Tulane University, and a J.D. from Boston University School of Law.

Edward Carr. Mr. Carr has served as our Chief Accounting Officer since September 2023, and as Chief Accounting Officer of Former Dianthus since April 2022. Prior to joining Former Dianthus, Mr. Carr served as Chief Financial Officer of Abeona Therapeutics (Nasdaq: ABEO), a clinical stage biotechnology company, from August 2021 to March 2022 and as Chief Accounting Officer from November 2018 to August 2021. Prior to Abeona, Mr. Carr served as Assistant Controller at Coty Inc. (NYSE: COTY), a manufacturing company, from October 2017 to November 2018 and as Chief Accounting Officer at Foster Wheeler AG (Nasdaq: FWLT), an engineering and construction company, from April 2007 to March 2017. Mr. Carr, who is a Certified Public Accountant, began his career at Ernst & Young LLP. He received his Master of Professional Accountancy and Bachelor of Business Administration from West Virginia University.

Non-Employee Directors

Leon O. Moulder, Jr. Mr. Moulder has served as Chair and a member of our Board of Directors since September 2023, and as Chair and a member of the board of directors of Former Dianthus since July 2019. Mr. Moulder is the sole Managing Member of Tellus BioVentures, a life science investment fund he founded in March 2019. Mr. Moulder also founded Zenas BioPharma, a biopharmaceutical company, in December 2019 and has served as Chairman of its board of directors since its inception and its Chief Executive Officer from its inception to April 2021 and from July 2023. From May 2010 to January 2019, Mr. Moulder was the co-founder, Chief Executive Officer and a member of the board of directors of TESARO, Inc., a formerly public biopharmaceutical company that was acquired by GlaxoSmithKline plc. From April 2009 to January 2010, Mr. Moulder served as Vice Chairman of the board of directors, President and Chief Executive Officer of Abraxis BioScience, Inc., a biotechnology company. Before that, Mr. Moulder served as Vice Chairman of Eisai Corporation of North America, a pharmaceutical company and wholly owned subsidiary of Eisai Co., Ltd., from January 2008 until January 2009, following Eisai Co., Ltd.'s acquisition of MGI PHARMA, Inc., in January 2008. Mr. Moulder served as President and Chief Executive Officer and as a member of the board of directors of MGI PHARMA, Inc. from May 2003 to January 2008. Mr. Moulder currently serves as a director for Zai Lab Ltd. (Nasdaq: ZLAB) and several privately held Tellus BioVentures portfolio companies, and he previously served on the board of Trevena, Inc. (Nasdaq: TRVN) from November 2011 until December 2023. Mr. Moulder earned a B.S. in Pharmacy from Temple University and an M.B.A. from the University of Chicago. Mr. Moulder is a Trustee of Temple University and a council member for the University of Chicago Booth School of Business. We believe that Mr. Moulder is qualified to serve on the Board of Directors because of his significant operational and senior management experience in the biopharmaceutical industry, as well as his extensive experience as a director on public and private boards in the industry.

Mr. Moulder may be deemed to have sole voting and dispositive power over the shares held by Tellus BioVentures. A summary of transactions between the Company and Tellus BioVentures is included under the section titled "*Certain Related Person Transactions—Dianthus and Former Dianthus Transactions*" located elsewhere in this prospectus, and Tellus BioVentures is also party to the Registration Rights Agreement.

Tomas Kiselak. Mr. Kiselak has served as a member of our Board of Directors since September 2023, and as a member of the board of directors of Former Dianthus since May 2021. Mr. Kiselak is a Managing Member at Fairmount Funds Management LLC, a healthcare investment firm he co-founded in April 2016. Prior to

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Fairmount, Mr. Kiselak was a managing director at RA Capital Management, LLC, a healthcare and life science investment firm. Mr. Kiselak has served as the Chairman of the board of Viridian Therapeutics, Inc. (“Viridian”) (Nasdaq: VRDN) since June 2021 and a member of the Viridian board of directors since October 2020, and as a director for Apogee Therapeutics, Inc. (Nasdaq: APGE) since June 2023, Spyre Therapeutics Inc. (Nasdaq: SYRE) since June 2023 and several private companies. He received a bachelor’s degree in Neuroscience and Economics from Amherst College. We believe that Mr. Kiselak is qualified to serve on the Board of Directors because of his experience advising biotechnology companies and as a manager of funds specializing in the area of life sciences.

Lei Meng. Ms. Meng has served as a member of our Board of Directors since September 2023, and as a member of the board of directors of Former Dianthus since April 2022 and as Senior Therapeutics Analyst on the private investment team of Avidity Partners since January 2021. Prior to Avidity, Ms. Meng was the Vice President of Marketing Analytics and Business Development and Licensing Commercial Assessments at Allergan from February 2017 to May 2020. Prior to becoming Vice President, she held positions of increasing responsibility at Allergan from March 2012 to January 2017. Prior to Allergan, Ms. Meng was a therapeutics analyst investing in public life science companies at Samlyn Capital. Prior to Samlyn, Ms. Meng had worked as a management consultant at McKinsey & Co., serving life sciences clients, and as a researcher in Medicinal Chemistry and Clinical Research at Merck & Co. Ms. Meng has been a Director of Prellis Biologics, an antibody discovery platform company, since August 2022. She received her M.B.A. from INSEAD, a Masters in Organic Chemistry from Harvard University and her Bachelors in Biochemistry from Barnard College. We believe that Ms. Meng is qualified to serve on the Board of Directors because of her extensive experience as an operator in the pharmaceutical and biotechnology industry and as an investor in life science companies.

Paula Soteropoulos. Ms. Soteropoulos has served as a member of our Board of Directors since September 2023, and as a member of the board of directors of Former Dianthus since April 2022. Ms. Soteropoulos currently serves as the Chairman of the board of Ensoma, Inc., a private venture-backed company, where she began as founding Executive Chairman in March 2020. Since January 2024, she has also served as interim CEO for Ensoma. Since November 2020, she has served on the board of directors of Rallybio Corporation (Nasdaq: RLYB). Since July 2013, she has served on the board of directors of uniQure N.V. Since January 2023, she also has served as a Venture Partner to 5AM Ventures, an investment firm. From January 2015 through September 2019, she served as President and Chief Executive Officer of Akcea Therapeutics Inc. (Nasdaq: AKCA), a biopharmaceutical company. From July 2013 to December 2014, she served as Senior Vice President and General Manager, Cardiometabolic Business and Strategic Alliances at Moderna Therapeutics Inc. Prior to this, Ms. Soteropoulos worked at Genzyme Corporation, a biotechnology company, from 1992 to 2013, most recently as Vice President and General Manager, Cardiovascular, Rare Diseases. Ms. Soteropoulos holds a Bachelor of Science degree in chemical engineering and a Master of Science degree in chemical and biochemical engineering, both from Tufts University, and holds an executive management certificate from the University of Virginia, Darden Graduate School of Business Administration. Ms. Soteropoulos serves on the Advisory Board for the Chemical and Biological Engineering Department of Tufts University. We believe that Ms. Soteropoulos is qualified to serve on the Board of Directors because of her experience advising biotechnology companies in the areas of drug development, global commercialization and manufacturing.

Jonathan Violin, Ph.D. Dr. Violin has served as a member of our Board of Directors since September 2023, and he co-founded Former Dianthus in July 2019 and has served on its board of directors since inception. Dr. Violin has served as a Venture Partner at Fairmount Funds Management LLC, a healthcare investment firm, since June 2023. Prior to joining Fairmount, Dr. Violin served as President, Chief Executive Officer and member of the Board of Viridian Therapeutics, Inc. (Nasdaq: VRDN), a biopharmaceutical company, from January 2021 to February 2023, and he previously served as President and Chief Operating Officer of Viridian from October 2020 until January 2021. He was the Co-Founder of Viridian’s predecessor and led its operations from April 2020 to its acquisition. Dr. Violin also co-founded Quellis Biosciences, Inc., a biotechnology company (acquired by Astria Therapeutics, Inc. (Nasdaq: ATXS), formerly Catabasis Pharmaceuticals, Inc.), in 2018 and, since January 2021, has served on the Astria Therapeutics board of directors. Prior to that, he co-founded and helped lead Trevena Inc. (Nasdaq: TRVN), a biotechnology company, in various roles from 2008 until November 2018,

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including most recently as Senior Vice President, Scientific Affairs and Investor Relations Officer. Dr. Violin received a Ph.D. from the Department of Pharmacology in the Biomedical Sciences Program at the University of California, San Diego, a M.B.A. with a concentration in Health Sector Management from the Fuqua School of Business at Duke University, and a B.S. in Chemical Pharmacology from Duke University. We believe that Dr. Violin is qualified to serve on the Board of Directors because of his extensive experience and innovations in the field of biotechnology and his academic expertise and accomplishments.

Alison F. Lawton. Ms. Lawton has served as a member of our Board of Directors since December 2020 and the Chair of our Board of Directors from August 2021 through the completion of the Merger. Ms. Lawton is an executive leader with more than 30 years of experience in biopharma. She served as President and Chief Executive Officer of Kaleido Biosciences, Inc., a pharmaceutical company, from August 2018 to June 2020, and served as President and Chief Operating Officer from December 2017 to August 2018. Prior to joining Kaleido, Ms. Lawton served as Chief Operating Officer at Aura Biosciences, Inc., an oncology therapeutics company, from January 2015 until December 2017, and, prior to joining Aura, served as a consultant to Aura from March 2014 to December 2014. From January 2013 to January 2014, Ms. Lawton served as Chief Operating Officer at OvaScience Inc., a life sciences company. From 2014 to 2017, Ms. Lawton also served as a biotech consultant for various companies, including as Chief Operating Officer consultant at X4 Pharmaceuticals Inc. (Nasdaq: XFOR). Prior to that, Ms. Lawton spent more than 20 years in various positions of increasing responsibility, including as Senior Vice President and General Manager of Genzyme Biosurgery, a division of Genzyme Corporation which is a global pharmaceutical company, and prior to that, Senior Vice President of Market Access at Genzyme, and subsequently at Sanofi S.A., also a global biopharmaceutical company, following the acquisition of Genzyme by Sanofi in 2011. Additionally, Ms. Lawton previously served two terms as the industry representative on the U.S. Food & Drug Administration's Cell & Gene Therapy Advisory Committee and as Chairman of the Board of the Regulatory Affairs Professional Society. Ms. Lawton has served on the board of directors of ProQR Therapeutics N.V. (Nasdaq: PRQR) since September 2014 and X4 Pharmaceuticals since October 2020 and the private companies SwanBio Therapeutics, Inc., BlueRock Therapeutics LP and AgBiome, LLC. Ms. Lawton previously served on the boards of directors of Spyre Therapeutics Inc. (Nasdaq: SYRE) (formerly known as Aeglea BioTherapeutics, Inc.) from December 2020 to January 2024, Kaleido from August 2018 to October 2020, Verastem, Inc. (Nasdaq: VSTM) from November 2012 to May 2020, CoLucid Pharmaceuticals, Inc., a formerly public biotechnology company from March 2016 until its acquisition by Eli Lilly and Company in March 2017, and Cubist Pharmaceuticals, Inc., a formerly public biopharmaceutical company, from February 2012 to December 2014 prior to its acquisition by Merck & Co. in January 2015. Ms. Lawton holds a B.Sc. in Pharmacology from Kings College, University of London. We believe that Ms. Lawton is qualified to serve on the Board of Directors based on her roles on public and private boards of directors as well as her extensive experience in the life sciences industry.

Anne McGeorge. Ms. McGeorge has been a member of our Board of Directors since June 2019. Ms. McGeorge has over 35 years of experience providing strategic guidance and operational oversight to health care organizations. Ms. McGeorge has been on the adjunct faculty at the University of North Carolina at Chapel Hill since August 2005. Ms. McGeorge currently serves on the board of directors of The Oncology Institute, Inc. (Nasdaq: TOI). She also serves on the board of directors of the private companies CitiusTech, a health care technology company, Nimbus Therapeutics, LLC, a biotech company, CLEAR Insurance, a Cayman based captive insurance company, and the National Marrow Donor Program (Be The Match), a 501(c)(3) organization, and is on the advisory board at FCA Healthcare Innovations (formerly Dioko Ventures). Additionally, Ms. McGeorge previously served on the board of directors of SOC Telemed, Inc. (Nasdaq: TLMD) from October 2020 until it was acquired by Patient Square Capital, Inc. in April 2022. Prior to her retirement in July 2017, Ms. McGeorge worked at Grant Thornton LLP where she routinely advised clients on audit and financial matters relating to the healthcare industry. During her time at Grant Thornton LLP, Ms. McGeorge was Managing Partner of Grant Thornton LLP's Health Care Industry Practice from January 2006 to July 2017 as well as Global Managing Partner for Grant Thornton International's Health Care Industry Practice from August 2015 to July 2017. Ms. McGeorge was formerly a Partner at Deloitte & Touche LLP from 2002 to 2005 and at Arthur Andersen LLP from 1997 to 2002. Ms. McGeorge received a B.B.A., Business, Accounting from the College of

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William and Mary, and an M.S., Accounting/Taxation from the University of Virginia. We believe that Ms. McGeorge is qualified to serve on the Board of Directors based on her extensive experience providing auditing and financial services for the healthcare industry.

Committees of the Board of Directors

Our Board of Directors has established an audit committee (the “Audit Committee”), a compensation committee (the “Compensation Committee”), a nominating and corporate governance committee (the “Nominating and Corporate Governance Committee”) and science and technology committee (the “Science and Technology Committee”), each of which operates pursuant to a charter adopted by the Board of Directors. We believe the functioning and composition of these committees comply with the requirements of the Sarbanes-Oxley Act of 2002, Nasdaq listing rules and SEC rules and regulations. The Board of Directors may also establish other committees from time to time to assist the Company and its Board of Directors. Each of the Audit Committee, Compensation Committee, Nominating and Corporate Governance Committee and Science and Technology Committee has the responsibilities described below.

Audit Committee

Alison F. Lawton, Anne McGeorge, and Paula Soteropoulos serve on the Audit Committee, and each qualifies as an independent director, as defined under applicable Nasdaq listing rules, meets the additional, heightened independence criteria applicable to members of the audit committee under the rules of the SEC and the applicable Nasdaq listing rules, and has sufficient knowledge in financial and auditing matters to serve on the Audit Committee. Ms. McGeorge serves as chair of the Audit Committee. Ms. McGeorge is an “audit committee financial expert” as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act.

The primary responsibilities of the Audit Committee are to oversee the Company’s accounting and financial reporting processes, including the audits of the financial statements, and the internal and external audit processes. The Audit Committee also oversees the system of internal controls established by management and our compliance with legal and regulatory requirements. The Audit Committee is also responsible for the review, consideration and approval or ratification of related party transactions as well as the oversight of the Company’s practices with respect to risk assessment and risk management. The Audit Committee oversees the independent auditors, including their independence and objectivity. The Audit Committee is empowered to retain outside legal counsel and other advisors as it deems necessary or appropriate to assist it in fulfilling its responsibilities and to approve the fees and other retention terms of the advisors.

Compensation Committee

Paula Soteropoulos, Leon O. Moulder, Jr. and Tomas Kiselak serve on the Compensation Committee, and each qualifies as an independent director, as defined under applicable Nasdaq listing rules and also meets the additional, heightened independence criteria applicable to members of the compensation committee. Ms. Soteropoulos serves as the chair of the Compensation Committee.

The primary responsibilities of the Compensation Committee are to periodically review and approve the compensation and other benefits for the Company’s senior officers and directors. This includes reviewing and approving corporate goals and objectives relevant to the compensation of the Company’s executive officers, evaluating the performance of these officers in light of the goals and objectives and setting the officers’ compensation. The Compensation Committee also administers and makes recommendations to the Board of Directors regarding equity incentive plans that are subject to the Board of Directors’ approval and approves the grant of equity awards under the plans.

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Nominating and Corporate Governance Committee

Alison F. Lawton, Lei Meng and Leon O. Moulder, Jr. serve on the Nominating and Corporate Governance Committee, and each qualifies as an independent director, as defined under applicable Nasdaq listing rules. Ms. Lawton serves as chair of the Nominating and Corporate Governance Committee.

The Nominating and Corporate Governance Committee is responsible for engaging in succession planning for the Board of Directors, developing and recommending to the Board of Directors criteria for identifying and evaluating qualified director candidates and making recommendations to the Board of Directors regarding candidates for election or reelection to the Board of Directors at each annual stockholders' meeting. In addition, the Nominating and Corporate Governance Committee is responsible for overseeing the Company's corporate governance practices and making recommendations to the Board of Directors concerning corporate governance matters. The Nominating and Corporate Governance Committee is also responsible for making recommendations to the Board of Directors concerning the structure, composition and functioning of the Board of Directors and its committees.

Science and Technology Committee

Tomas Kiselak, Lei Meng and Jonathan Violin serve on the Science and Technology Committee. Mr. Kiselak serves as chair of the Science and Technology Committee. The primary responsibilities of the Science and Technology Committee are to assist the Board of Directors in overseeing the Company's innovation, new product development and research and development activities.

Code of Conduct and Ethics

In connection with the Merger, the Board of Directors adopted a new Code of Conduct and Ethics (the "Code of Conduct"). The Code of Conduct superseded the Company's existing code of business conduct and ethics previously adopted by the Board of Directors (the "Pre-Merger Code"). The Code of Conduct applies to all directors, officers and employees of the Company.

The Code of Conduct addresses, among other matters, compliance with laws and policies, conflicts of interest, corporate opportunities, regulatory reporting, external communications, confidentiality requirements, insider trading, proper use of assets and how to report compliance concerns. The provisions of the Code of Conduct are intended to reflect current best practices and enhance the Company's personnel's understanding of the Company's standards of ethical business practices, promote awareness of ethical issues that may be encountered in carrying out an employee's or director's responsibilities and improve clarity as to how to address ethical issues that may arise.

The full text of the Code of Conduct is posted on the Company's website at www.dianthustx.com. We intend to disclose any amendments to the Code of Conduct, or any waivers of its requirements, on our website to the extent required by applicable rules. Our Audit Committee is responsible for applying and interpreting the Code of Conduct in situations where questions are presented to it. Information contained on, or that can be accessed through, the Company's website is not incorporated by reference into this prospectus and should not be considered to be a part hereof for any purpose.

The newly adopted Code of Conduct did not result in any explicit or implicit waiver of any provision of the Pre-Merger Code.

Director Independence

The Board of Directors reviews the independence of all directors in light of each director's (or any family member's, if applicable) affiliations with the Company and members of management, as well as significant holdings of our securities. The Board of Directors uses the definition of independence from Nasdaq listing rules

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to assess independence of our directors. Nasdaq listing rules have objective tests and a subjective test for determining who is an “independent director.” The subjective test states that an independent director must be a person who lacks a relationship that, in the opinion of the Board of Directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. The Board of Directors has not established categorical standards or guidelines to make these subjective determinations, but considers all relevant facts and circumstances. After considering the foregoing factors, the Board of Directors has determined each of our directors other than Marino Garcia and Jonathan Violin meets the Nasdaq independence requirements. Mr. Garcia and Dr. Violin are not considered independent due to their role as an executive officer of Dianthus and receipt of compensation for the provision of consulting services, respectively.

Former directors Drs. Bruce Booth, Thomas O. Daniel, Michael Vasconcelles, Jeffrey W. Albers and Amy Lynn Ronneberg were considered independent during the period they served on the Board. Former directors Drs. Jason Gardner and David T. Scadden were not considered independent during the period they served on the Board due to their role as an executive officer of Magenta and due to his service as chair of the Scientific Advisory Board, respectively.

EXECUTIVE COMPENSATION

This section discusses the material elements of compensation awarded to, earned by or paid to each principal executive officer of the Company during 2023, the two next most highly compensated executive officers of the Company and two additional former executive officers of the Company. The following individuals are referred to as the “Named Executive Officers” or “NEOs.”

Name	Position
Marino Garcia	Chief Executive Officer ⁽¹⁾
Ryan Savitz	Chief Financial Officer, Chief Business Officer and Treasurer ⁽²⁾
Simrat Randhawa, M.D.	Chief Medical Officer ⁽²⁾
Jason Gardner, D.Phil.	Former President and Chief Executive Officer ⁽¹⁾
Stephen Mahoney	Former President, Chief Financial and Operating Officer ⁽¹⁾
Thomas Beetham	Former Chief Legal Officer ⁽³⁾
Lisa Olson, Ph.D.	Former Chief Scientific Officer ⁽⁴⁾

- (1) Dr. Gardner served as President and Chief Executive Officer until his termination on February 7, 2023 when he was succeeded as the “principal executive officer” of the Company by Mr. Mahoney. On September 11, 2023, in connection with the Merger, Mr. Garcia was appointed President and Chief Executive Officer, and Mr. Mahoney’s employment was terminated.
- (2) Mr. Savitz and Dr. Randhawa were appointed Chief Financial Officer and Chief Medical Officer, respectively, on September 11, 2023 in connection with the Merger. Mr. Savitz was promoted to add Chief Business Officer to his title on February 7, 2024.
- (3) Mr. Beetham’s employment was terminated on September 11, 2023, in connection with the Merger.
- (4) Dr. Olson’s employment was terminated effective May 15, 2023.

2023 Summary Compensation Table

The following table presents the compensation awarded to, earned by or paid to each of the NEOs for the fiscal years ended December 31, 2023 and December 31, 2022.

Name and Principal Position	Year	Salary (\$)	Bonus (\$) ⁽¹⁾	Option Awards (\$) ⁽²⁾	Non-Equity Incentive Plan Compensation (\$) ⁽³⁾	All Other Compensation (\$) ⁽⁴⁾	Total (\$)
Marino Garcia ⁽⁵⁾ <i>President and Chief Executive Officer</i>	2023	174,863	—	—	321,159	—	496,022
Ryan Savitz ⁽⁵⁾ <i>Chief Financial Officer, Chief Business Officer and Treasurer</i>	2023	135,511	—	—	194,140	—	329,651
Simrat Randhawa, M.D. ⁽⁵⁾ <i>Chief Medical Officer</i>	2023	139,495	—	—	198,663	—	338,158
Jason Gardner, D.Phil. <i>Former President and Chief Executive Officer</i>	2023	57,861	—	—	—	609,788	667,649
	2022	565,000	—	756,413	326,288	7,147	1,654,848
Stephen Mahoney <i>Former President, Chief Financial and Operating Officer</i>	2023	309,257	539,134	118,285	—	690,000	1,656,676
	2022	448,000	—	483,680	188,160	1,047	1,120,887
Thomas Beetham <i>Former Chief Legal Officer</i>	2023	300,294	523,490	74,561	—	673,089	1,571,434
Lisa Olson, Ph.D. <i>Former Chief Scientific Officer</i>	2023	160,730	277,027	91,863	—	598,393	1,128,013
	2022	428,000	—	373,625	179,760	2,119	983,504

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- (1) Amounts in this column for 2023 represent the retention incentive bonuses paid to Messrs. Mahoney and Beetham and Dr. Olson in connection with the Merger (or, for Dr. Olson, in connection with her termination of employment), as described in further detail under “*Narrative Disclosure to Summary Compensation Table—Retention Incentive Bonuses*” below.
- (2) Amounts in this column for 2023 represent the incremental fair value of option award modifications, calculated as of the applicable modification date in accordance with the provisions of Financial Accounting Standards Board Accounting Standards Codification Topic 718, *Compensation—Stock Compensation* (“FASB ASC Topic 718”).
- (3) Amounts in this column for 2023 represent the annual cash incentive payouts earned by each NEO for performance in 2023, which are expected to be paid in February 2024. For more information regarding the 2023 annual cash incentive program, see “*Narrative Disclosure to Summary Compensation Table—2023 Annual Cash Incentives*” below.
- (4) Amounts in this column for 2023 include Company contributions to the NEOs’ accounts under the Magenta 401(k) Plan and severance payments and benefits accrued or paid during 2023, which are described in further detail under “*Additional Narrative Disclosure—Separation Agreements*” below, as set forth below:

<u>Name and Principal Position</u>	<u>Company 401(k) Contributions (\$)</u>	<u>Severance (\$)</u>	<u>Total (\$)</u>
Marino Garcia	—	—	—
Ryan Savitz	—	—	—
Simrat Randhawa	—	—	—
Jason Gardner, D.Phil.	686	609,102	609,788
Stephen Mahoney	—	690,000	690,000
Thomas Beetham	1,089	672,000	673,089
Lisa Olson	1,072	597,321	598,393

- (5) For Messrs. Garcia and Savitz and Dr. Randhawa, amounts in this column reflect compensation awarded to, earned by or paid on or after September 11, 2023 and does not reflect compensation paid by Former Dianthus prior to the Merger.

Narrative Disclosure to Summary Compensation Table

Compensation Philosophy and Process

The Company’s Board of Directors and Compensation Committee review compensation annually for all employees, including the NEOs. In setting executive base salaries and annual incentives and granting equity incentive awards, the Compensation Committee considers compensation for comparable positions in the market, the historical compensation levels of the Company’s executives, internal equity, individual performance as compared to the Company’s expectations and objectives, the Company’s desire to motivate the Company’s employees to achieve short- and long-term results that are in the best interests of the Company’s stockholders and a long-term commitment to the Company. The Company targets a general competitive position, based on independent third-party benchmark analytics to inform the mix of compensation of base salary, annual incentives or long-term incentives.

The Compensation Committee is responsible for determining the compensation of the NEOs; however, the Board of Directors, upon recommendation of the Compensation Committee, is responsible for determining the Compensation of the Chief Executive Officer. The Compensation Committee typically reviews and discusses each NEO’s proposed compensation with the Chief Executive Officer (other than his own compensation). Based on those discussions and its discretion, taking into account the factors noted above, the Compensation Committee then sets the compensation for each NEO, other than the Chief Executive Officer, and recommends the compensation for the Chief Executive Officer to the Board of Directors for approval. The Chief Executive Officer is not present for discussions regarding his own compensation.

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In 2023, the Compensation Committee retained the services of Alpine Rewards, LLC (“Alpine Rewards”) as its external independent compensation consultant. In this role, Alpine Rewards served as an advisor to the Compensation Committee on topics primarily related to the Company’s broader compensation structure, executive new hire compensation packages, executive compensation structure, peer group review, benchmarking of executive positions and equity share usage and dilution. The Board of Directors and Compensation Committee considered Alpine Rewards’ input on certain compensation matters as they deemed appropriate. The Compensation Committee requires that its compensation consultants be independent of management and performs an annual assessment of the compensation consultants’ independence to determine whether the consultants are independent. After review of the independence factors set forth by Nasdaq and the SEC, the Compensation Committee determined that the engagement of Alpine Rewards does not raise any conflict of interest.

Employment Agreements

Each of Messrs. Garcia and Savitz and Dr. Randhawa entered into an employment agreement in connection with his appointment as an executive officer of Former Dianthus, each of which was amended in connection with the Merger and his appointments as an officer of the Company. The employment agreements generally set forth the initial base salary, target annual bonus opportunity, one-time signing bonus in consideration for certain restrictive covenants (including standard confidentiality and nondisclosure, assignment of intellectual property work product and post-termination noncompetition and non-solicitation of employees, consultants and customers covenants), and eligibility for employee benefit plans. In addition, the employment agreements set forth the terms of initial stock option grants. Each employment agreement also provides for severance benefits in connection with certain terminations of employment, as described under “*Additional Narrative Disclosure—Potential Payments Upon Termination or Change in Control*” below.

Base Salary

Each NEO’s base salary is a fixed component of annual compensation for performing specific duties and functions and has been established by the Compensation Committee or Board of Directors, as applicable, taking into account each individual’s role, responsibilities, skills, and experience. Base salaries for the NEOs are reviewed annually by the Compensation Committee or Board of Directors, as applicable, typically in connection with the Company’s annual performance review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, internal equity, performance, and experience.

Base salaries are intended to provide a level of compensation sufficient to attract and retain an effective management team, when considered in combination with the other components of our executive compensation program. The relative levels of base salary are designed to reflect each NEO’s scope of responsibility and accountability. Effective with the closing of the Merger on September 11, 2023, the base salaries for Messrs. Garcia and Savitz and Dr. Randhawa were set forth below:

Name	2023 Base Salary (as of Dec. 31, 2023)
Marino Garcia	\$ 575,000
Ryan Savitz	\$ 445,600
Simrat Randhawa, M.D.	\$ 458,700

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2023 Annual Cash Incentives

The Company's cash annual incentive program is intended to reward the NEOs for meeting specified performance goals during the fiscal year. For 2023, each NEO was eligible for a target annual incentive based on a specific percentage of their earned base salaries for 2023, which are set forth below for those NEOs who were employed as of December 31, 2023 and eligible to receive a 2023 annual incentive:

<u>Name</u>	<u>2023 Target Annual Incentive (% of base salary)</u>
Marino Garcia	50%
Ryan Savitz	40%
Simrat Randhawa, M.D.	40%

The 2023 annual incentive program for Messrs. Garcia and Savitz and Dr. Randhawa was based upon achievement of corporate performance goals related to: (i) execution towards organizational readiness to initiate a phase 2 clinical trial of DNTH103 in generalized Myasthenia Gravis, (ii) strengthening the data package for DNTH103 and expanding its use in potential indications and other life cycle developments, (iii) building a pipeline of additional targets beyond DNTH103 and (iv) building an optimal high-performance organization required to achieve financial and development milestones. Following the end of 2023, the Compensation Committee recommended, and the Board of Directors approved, achievement of corporate performance and resulting annual incentive payouts at 115% of target.

Retention Incentive Bonuses

On February 23, 2023, the Compensation Committee approved retention incentive bonuses to Messrs. Mahoney and Beetham and Dr. Olson pursuant to the Company's Senior Executive Cash Incentive Bonus Plan. Each retention incentive bonus was equal to the pro-rata amount of: (i) 125% of the NEOs' 2023 base salary, plus (ii) 125% of the NEO's 2023 target bonus, in each case, subject to a maximum of 75% of such amount. The retention incentive bonuses provided for payment upon the earliest of (a) the completion of a merger or similar change of control of Company, (b) the completion of a liquidation of the Company, (c) the date of the NEO's termination by the Company not for cause (as defined in the NEO's employment agreement) or (d) any other date determined by the Compensation Committee. As a result, Dr. Olson received a retention incentive bonus of \$277,027 in connection with her termination and Messrs. Mahoney and Beetham received retention incentive bonuses of \$539,134 and \$523,490, respectively, in connection with the Merger.

Equity Awards

The Company's equity grant program is intended to align the interests of the NEOs with those of the Company's stockholders and to motivate them to make important contributions to the Company's performance. During 2023, in light of the ongoing strategic process, the Company did not make any grants of equity awards to the NEOs.

In connection with the Merger, outstanding stock options originally granted by Former Dianthus were assumed and converted into Company stock options based on the exchange ratio, subject to the same vesting terms as in effect prior to the Merger. The assumed options are described in more detail under "Outstanding Equity Awards at 2023 Fiscal Year End" below.

Modification of Stock Options

In connection with the Merger and pursuant to the terms of the Merger Agreement, all outstanding stock options held by Messrs. Mahoney and Beetham and Dr. Olson that had an exercise price that was equal to or less than \$2.00 (prior to giving effect to the 1-for-16 reverse stock split) were modified to provide that they

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will remain outstanding and exercisable until the third anniversary of the Merger (or if earlier, the original expiration date of such stock option).

Outstanding Equity Awards at 2023 Fiscal Year End

The following table presents information regarding all outstanding stock options held by each of the NEOs on December 31, 2023, after giving effect to the 1-for-16 reverse stock split. None of the NEOs held any outstanding stock awards as of December 31, 2023.

<u>Name</u>	<u>Option Awards</u>			
	<u>Number of Securities Underlying Unexercised Options (#) Exercisable</u>	<u>Number of Securities Underlying Unexercised Options (#) Unexercisable</u>	<u>Option Exercise Price (\$)</u>	<u>Option Expiration Date</u>
Marino Garcia	95,136	87,523 ⁽¹⁾	6.70	11/3/2031
	169,797	156,207 ⁽¹⁾	8.44	6/6/2032
Ryan Savitz	46,786	77,980 ⁽²⁾	8.44	6/6/2032
Simrat Randhawa	39,989	55,985 ⁽³⁾	8.44	6/6/2032
Jason Gardner, D.Phil.	—	—	—	—
Stephen Mahoney	3,906	—	18.88	9/11/2026
	8,126	—	25.12	9/11/2026
Thomas Beetham	3,125	—	18.88	9/11/2026
	4,688	—	25.12	9/11/2026
Lisa Olson	3,125	—	18.88	9/11/2026
	6,250	—	25.12	9/11/2026

- (1) These stock options vest in equal monthly installments through November 30, 2025, subject to Mr. Garcia's continued employment through each vesting date.
- (2) These stock options vest in equal monthly installments through June 30, 2026, subject to Mr. Savitz's continued employment through each vesting date.
- (3) These stock options vest in equal monthly installments through April 30, 2026, subject to Dr. Randhawa's continued employment through each vesting date.

Additional Narrative Disclosures

Retirement Benefits

We do not maintain, and no NEO is eligible to participate in, any defined benefit pension plan or nonqualified deferred compensation plan. Each NEO that remains employed as of December 31, 2023 is eligible to participate in a multiemployer tax-qualified 401(k) savings plan, which allows eligible participants to defer a portion of their compensation, within the limits prescribed by the Code and the applicable limits under the 401(k) plan, on a pre-tax or after-tax (Roth) basis. Pursuant to the terms of such 401(k) plan, we may make discretionary matching contributions; however, no such contributions have been made to date.

Prior to the Merger, each NEO other than Messrs. Garcia and Savitz and Dr. Randhawa was eligible to participate in the Company's 401(k) plan (the "Magenta 401(k) Plan"), which allowed eligible participants to defer a portion of their compensation, within the limits prescribed by the Code. The Company made matching contributions of up to 2% of eligible wages contributed by each participating employee; however, matching contributions were suspended in February 2023. The Magenta 401(k) Plan was terminated in connection with the Merger and all unvested Company matching contributions became fully vested in connection with such termination.

Potential Payments Upon Termination or Change in Control

Under their amended employment agreements, each of Messrs. Garcia and Savitz and Dr. Randhawa is eligible for severance benefits in the event of a termination by the Company without “cause” (as defined in the agreement) or resignation for “good reason” (as defined in the agreement). In the event of such termination, subject to execution and non-revocation of a release of claims, the NEO will be eligible to receive: (i) cash severance equal to nine months of base salary (or, for Mr. Garcia, 12 months) and (ii) partial reimbursement of COBRA premiums for nine months (or, for Mr. Garcia, 12 months).

Under the amendment employment agreements, in the event the NEO is terminated by the Company without cause or resigns for good reason, in each case, on or within 12 months following a sale event (as defined in the Amended and Restated Dianthus Therapeutics, Inc. Stock Option and Incentive Plan (the “Incentive Plan”)), the NEO will receive the following in lieu of the severance benefits described above, subject to execution and non-revocation of a release of claims: (i) cash severance equal to 1.0x (or, for Mr. Garcia, 1.5x), the sum of the executive’s base salary and target annual bonus; (ii) partial reimbursement of COBRA premiums for 12 months (or, for Mr. Garcia, 18 months); and (iii) full acceleration of all outstanding equity and equity-based awards. The amended employment agreements provide for a standard best after-tax provision in the event any such severance is considered a parachute payment for purposes of Section 280G of the Code.

Separation Agreements

Jason Gardner, D.Phil.

On February 7, 2023, in connection with his termination, Dr. Gardner entered into a separation letter and general release of claims with us. In consideration for the general release of claims, Dr. Gardner received the following separation payments and benefits: (i) a lump sum cash payment of \$597,352, representing 12 months of Dr. Gardner’s base salary and a pro-rated portion of his 2023 bonus target; (ii) payment for up to 12 months of group health plan continuation premiums; and (iii) up to \$1,000 in outplacement services. The separation agreement also requires Dr. Gardner’s continued compliance with his confidentiality and nondisclosure, assignment of intellectual property work product, post-termination noncompetition and non-solicitation obligations.

Stephen Mahoney

On September 11, 2023, in connection with his termination, Mr. Mahoney entered into a separation letter and general release of claims with us. In consideration for the general release of claims, Mr. Mahoney received the following separation payments and benefits: (i) a lump sum cash payment of \$627,200, representing 12 months of Mr. Mahoney’s base salary and 100% of his 2023 target incentive compensation; (ii) a lump sum cash payment of \$63,000, representing a cash payout in lieu of 12 months of group health plan continuation premiums, adjusted by 25% to offset for any tax liability associated with the payment; and (iii) outplacement services for a period of 45 days. The separation letter also requires Mr. Mahoney’s continued compliance with his confidentiality and non-disclosure, assignment of intellectual property work product and non-solicitation obligations; however, the Company waived his post-employment non-competition obligations.

Thomas Beetham

On September 11, 2023, in connection with his termination, Mr. Beetham entered into a separation letter and general release of claims with us. In consideration for the general release of claims, Mr. Beetham received the following separation payments and benefits: (i) a lump sum cash payment of \$609,000, representing 12 months of Mr. Beetham’s base salary and 100% of his 2023 target incentive compensation; (ii) a lump sum cash payment of \$63,000, representing a cash payout in lieu of 12 months of group health plan continuation premiums, adjusted by 25% to offset for any tax liability associated with the payment; and (iii) outplacement services for a period of 45 days. The separation letter also requires Mr. Beetham’s continued compliance with his

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confidentiality and non-disclosure, assignment of intellectual property work product and non-solicitation obligations; however, the Company waived his post-employment non-competition obligations.

Lisa Olson, Ph.D.

On May 12, 2023, in connection with her termination, Dr. Olson entered into a separation letter and general release of claims with us. In consideration for the general release of claims, Dr. Olson received the following separation payments and benefits: (i) a lump sum cash payment of \$384,321, representing nine months of Ms. Olson's base salary and a pro-rated portion of her 2023 target incentive compensation; (ii) payment for up to nine months of group health plan continuation premiums; and (iii) outplacement services for a period of 45 days. In addition, as a result of the Merger on September 11, 2023, which constituted a change in control occurring after August 15, 2023 and before December 31, 2023 under the separation letter, Ms. Olson also received: (A) an additional lump sum cash payment of \$171,000; and (B) up to three additional months of group health plan continuation premiums. The separation letter also requires Dr. Olson's continued compliance with her confidentiality and nondisclosure, assignment of intellectual property work product, post-termination noncompetition and non-solicitation obligations.

DIRECTOR COMPENSATION

The table below shows all compensation paid to the Company's non-employee directors during 2023. Neither Mr. Garcia nor Dr. Gardner received compensation for their service as a director and are not included in this table. The compensation received by Mr. Garcia and Dr. Gardner as employees during 2023 is presented under "Executive Compensation—2023 Summary Compensation Table" above.

<u>Name⁽¹⁾</u>	<u>Fees Earned or Paid In Cash (\$)</u>	<u>Option Awards⁽²⁾(\$)</u>	<u>Total(\$)</u>
Jeffrey W. Albers	44,597	—	44,597
Bruce Booth, D.Phil.	39,903	—	39,903
Thomas O. Daniel, M.D.	44,629	—	44,629
Tomas Kiselak ⁽³⁾	16,628	54,628	71,256
Alison F. Lawton	82,195	54,628	136,823
Anne McGeorge	68,252	54,628	122,880
Lei Meng ⁽⁴⁾	14,801	54,628	69,429
Leon O. Moulder, Jr.	25,609	54,628	80,237
Amy Lynn Ronneberg ⁽⁵⁾	40,372	—	40,372
David T. Scadden, M.D.	37,619	—	37,619
Paula Soteropoulos	38,204	54,628	92,832
Michael Vasconcelles, M.D.	38,996	—	38,996
Jonathan Violin, Ph.D.	13,592	54,628	68,220

- (1) In connection with the Merger on September 11, 2023, in accordance with the Merger Agreement, Mr. Albers, Drs. Booth, Daniel, Scadden and Vasconcelles, and Ms. Ronneberg resigned from service on the Board of Directors and Messrs. Kiselak and Moulder, Mss. Lawton, McGeorge, Meng and Soteropoulos and Dr. Violin were each appointed to the Board of Directors.
- (2) Amounts in this column reflect the grant date fair value of option awards granted under the Incentive Plan on September 11, 2023, calculated in accordance with FASB ASC Topic 718. See Note 12 to the financial statements included herein for the year ended December 31, 2023 regarding the assumptions used in determining the grant date fair value of option awards. As of December 31, 2023, each director or former director held the following outstanding stock options: Mr. Albers, 1,250; Dr. Booth, 1,250; Dr. Daniel, 1,250; Mr. Kiselak, 6,500; Ms. Lawton, 14,426; Ms. McGeorge, 12,298; Ms. Meng, 6,500; Mr. Moulder, 6,500; Ms. Ronneberg, 1,250; Dr. Scadden, 1,250; Ms. Soteropoulos, 35,292; Dr. Vasconcelles, 2,500; and Dr. Violin, 6,500.

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- (3) Mr. Kiselak is required to transfer, assign and pledge any cash consideration or similar payments that he receives as a result of his service on our Board of Directors to Fairmount Funds Management LLC. Mr. Kiselak is also required, to the extent that he elects to exercise any stock options, to transfer, assign and pledge the shares received to Fairmount Funds Management LLC.
- (4) Ms. Meng is required to transfer, assign and pledge any cash consideration or similar payments that she receives as a result of her service on our Board of Directors to Avidity Partners. Ms. Meng is also required, to the extent that she elects to exercise any stock options, to transfer, assign and pledge the shares received to Avidity Partners.
- (5) Ms. Ronneberg is required to transfer, assign and pledge any cash consideration or similar payments that she received as a result of her service on our Board of Directors to the Be The Match organization. Ms. Ronneberg is also required, to the extent that she elects to exercise any stock options, to transfer, assign and pledge the shares received to the Be The Match organization.

Under the Company's director compensation program prior to the Merger, the Company paid each non-employee director an annual cash retainer of \$35,000, with an additional annual retainer for the Chair of the Board of Directors of \$30,000. For service on the Audit Committee, directors received an additional annual cash retainer of \$7,500 (or \$15,000 for the Chair). For service on the Compensation Committee or the R&D Committee, directors received an additional annual retainer of \$5,000 (or \$10,000 for the Chair). For service on the Nominating and Corporate Governance Committee, directors received an additional annual retainer of \$4,000 (or \$8,000 for the Chair). These fees were payable in arrears in quarterly installments, pro-rated based on the number of actual days served by the director during such calendar quarter. The Company also reimbursed its non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending meetings of the Board of Directors and its committees.

Following the closing of the Merger, the Company's director compensation program was amended to provide a total compensation package that enables the Company to attract and retain qualified and experienced individuals to serve as directors and to align its directors' interests with those of its stockholders. The amended program provides for the following:

- an annual cash retainer of \$40,000 for members of the Company's Board of Directors (or \$70,000 for the chair of the Company's Board of Directors);
- an additional annual cash retainer of \$7,500 for service on the Audit Committee (or \$15,000 for service as chair of the Audit Committee);
- an additional annual cash retainer of \$5,000 for service on the Compensation Committee (or \$10,000 for service as chair of the Compensation Committee);
- an additional annual cash retainer of \$5,000 for service on the Science and Technology Committee (or \$10,000 for service as chair of the Science and Technology Committee);
- an additional annual cash retainer of \$4,000 for service on the Nominating and Corporate Governance Committee (or \$8,000 for service as chair of the Nominating and Corporate Governance Committee);
- an annual equity grant of 6,500 stock options, commencing in connection with the Merger with the next annual equity grant to occur in connection with the Company's 2024 annual shareholder meeting, in each case, subject to one-year cliff vesting on the earlier of the next annual shareholder meeting or the first anniversary of the date of grant; and
- an initial equity grant of 13,000 stock options in connection with a director's appointment to the Company's Board of Directors, subject to vesting on the third anniversary of the date of grant.

In accordance with the amended program, each member of the Board of Directors immediately following the Merger received a grant of 6,500 stock options on September 11, 2023, which vest on the earlier of the Company's 2024 annual meeting of stockholders and September 11, 2024.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information, to the extent known by us or ascertainable from public filings, with respect to the beneficial ownership of our Common Stock as of March 14, 2024 by:

- each of our directors;
- each of our named executive officers;
- all of our directors and executive officers as a group; and
- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our Common Stock.

Beneficial ownership is determined in accordance with the rules of the SEC and thus represents voting or investment power with respect to our securities. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of March 14, 2024. Shares of our Common Stock that an individual has the right to acquire within 60 days of March 14, 2024 are deemed to be outstanding and beneficially owned by the individual for the purpose of computing the percentage ownership of that individual, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. To our knowledge and subject to applicable community property rules, and except as otherwise indicated below, the persons and entities named in the table have sole voting and sole investment power with respect to all shares beneficially owned.

The percentage of beneficial ownership shown in the table below is based on a total of 29,346,760 shares of our Common Stock outstanding as of March 14, 2024.

Unless otherwise indicated, the address for each beneficial owner is c/o Dianthus Therapeutics, Inc., 7 Times Square, 43rd Floor New York, NY 10036.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Outstanding Beneficially Owned
5% Stockholders:		
Entities affiliated with 5AM Ventures ⁽¹⁾	1,682,584	5.69%
Entities affiliated with Avidity Partners ⁽²⁾	2,955,513	9.99%
FMR LLC ⁽³⁾	4,300,945	14.66%
Entities affiliated with Fairmount ⁽⁴⁾	2,950,487	9.99%
BCLS Fund III Investments, L.P. ⁽⁵⁾	2,995,191	9.99%
RA Capital Healthcare Fund, L.P. ⁽⁶⁾	2,998,194	9.99%
Entities affiliated with Venrock Healthcare Capital Partners ⁽⁷⁾	2,094,373	7.14%
Named Executive Officers and Directors:		
Marino Garcia ⁽⁸⁾	330,239	1.11%
Simrat Randhawa ⁽⁹⁾	61,987	*
Ryan Savitz ⁽¹⁰⁾	67,182	*
Leon O. Moulder, Jr. ⁽¹¹⁾	1,436,745	4.90%
Paula Soteropoulos ⁽¹²⁾	14,398	*
Tomas Kiselak ⁽⁴⁾	2,950,487	9.99%
Jonathan Violin	—	*
Lei Meng	—	*
Alison F. Lawton ⁽¹³⁾	7,926	*
Anne McGeorge ⁽¹⁴⁾	5,798	*
All executive officers and directors as a group (12 persons) ⁽¹⁵⁾	4,938,577	16.42%

* Less than 1%.

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- (1) Consists of (i) 430,776 shares of our Common Stock and 52,580 shares of our Common Stock issuable upon the exercise of 2023 Pre-Funded Warrants held by 5AM Opportunities II, L.P. (“5AM Opportunities”) and (ii) 1,041,488 shares of our Common Stock and 157,740 shares of our Common Stock issuable upon the exercise of 2023 Pre-Funded Warrants held by 5AM Ventures VII, L.P. (“5AM Ventures VII” and, together with 5AM Opportunities, the “5AM Selling Stockholders”). 5AM Partners VII, LLC (“Ventures GP”) is the sole general partner of 5AM Ventures VII and may be deemed to have sole investment and voting power over the shares held by 5AM Ventures VII. 5AM Opportunities II (GP), LLC (“Opportunities GP”) is the sole general partner of 5AM Opportunities and may be deemed to have sole investment and voting power over the shares held by 5AM Opportunities. Andrew Schwab and Kush Parmar are the managing members of each of Ventures GP and Opportunities GP and may be deemed to share voting and dispositive power over the shares held by 5AM Ventures VII and 5AM Opportunities. Each of Ventures GP, Opportunities GP, Kush Parmar and Andrew Schwab disclaims beneficial ownership of such shares, except to the extent of his respective pecuniary interest therein. Pursuant to the terms of the 2023 Pre-Funded Warrants, each of the 5AM Selling Stockholders may not exercise any portion of any 2023 Pre-Funded Warrant, which, upon giving effect to such exercise, would cause it (together with its affiliates) to own more than 9.9999% of the number of shares of our Common Stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the 2023 Pre-Funded Warrants. However, each of the 5AM Selling Stockholders may increase or decrease such percentage to any other percentage not in excess of 9.9999%, provided that (i) any increase in such percentage shall not be effective until 61 days after such notice is delivered to us and (ii) any such increase or decrease will apply only to the holder of each specific 2023 Pre-Funded Warrant and not to any other holder of 2023 Pre-Funded Warrants. The address of each of the foregoing persons is c/o 5AM Ventures, 501 2nd Street, Suite 350, San Francisco, CA 94107.
- (2) Consists of (i) 1,573,625 shares of our Common Stock and 140,014 shares of our Common Stock issuable upon the exercise of 2024 Pre-Funded Warrants held by Avidity Private Master Fund I LP (“APMF”), (ii) 1,082,525 shares of our Common Stock and 97,945 shares of our Common Stock issuable upon the exercise of 2024 Pre-Funded Warrants held by Avidity Master Fund LP (“AMF”) and (iii) 61,404 shares of our Common Stock held by Avidity Capital Fund II LP (“ACF,” and, together with APMF and AMF, the “Avidity Funds”). The general partner of each of the Avidity Funds is Avidity Capital Partners Fund (GP) LP, whose general partner is Avidity Capital Partners (GP) LLC. Avidity Partners Management LP is the investment manager of each of the Avidity Funds. Avidity Partners Management (GP) LLC is the general partner of Avidity Partners Management LP. David Witzke and Michael Gregory are the managing members of Avidity Capital Partners (GP) LLC and Avidity Partners Management (GP) LLC. Mr. Witzke and Mr. Gregory may be deemed to have shared voting and investment power over the shares held by each of the Avidity Funds. Each of Mr. Witzke and Mr. Gregory disclaim beneficial ownership of such shares, except to the extent of his respective pecuniary interest therein. Pursuant to the terms of the 2024 Pre-Funded Warrants, each of APMF and AMF may not exercise any portion of any 2024 Pre-Funded Warrant, which, upon giving effect to such exercise, would cause it (together with its affiliates) to own more than 9.99% of the number of shares of our Common Stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the 2024 Pre-Funded Warrants. However, each of APMF and AMF may increase or decrease such percentage to any other percentage not in excess of 19.99%, provided that (i) any increase in such percentage shall not be effective until 61 days after such notice is delivered to us and (ii) any such increase or decrease will apply only to the holder of each specific 2024 Pre-Funded Warrant and not to any other holder of 2024 Pre-Funded Warrants. The principal business address of each of the foregoing persons is 2828 N. Harwood Street, Suite 1220, Dallas, TX 75201.
- (3) The shares of our Common Stock listed in the table above are held by funds and accounts managed by direct or indirect subsidiaries of FMR LLC. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders’ voting agreement under which all Series B voting common

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shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. The address of FMR LLC is 245 Summer Street, Boston, MA 02210.

- (4) Consists of (i) 62,146 shares of our Common Stock held by Fairmount SPV III, LLC ("Fairmount SPV"), (ii) 58,857 shares of our Common Stock held by Fairmount Healthcare Fund L.P. ("Fairmount HF") and (iii) 2,641,834 shares of our Common Stock and 187,650 shares of our Common Stock issuable upon the exercise of 2024 Pre-Funded Warrants held by Fairmount Healthcare Fund II L.P. ("Fairmount HF II," and, together with Fairmount SPV and Fairmount HF, the "Fairmount Funds"). Fairmount Funds Management LLC ("Fairmount") is the Class A Member of Fairmount SPV. Fairmount has voting and dispositive power over the shares held by Fairmount Funds. Fairmount is the investment manager for Fairmount HF and Fairmount HF II and is the Class A Member for Fairmount SPV. The general partner of Fairmount is Fairmount Funds Management GP LLC ("Fairmount GP"), of which Peter Harwin and Tomas Kiselak are the managing members. Fairmount, Fairmount GP, Mr. Harwin, and Mr. Kiselak disclaim beneficial ownership of any of the reported securities, except to the extent of their pecuniary interest therein. Pursuant to the terms of the 2024 Pre-Funded Warrants, Fairmount HF II may not exercise any portion of any 2024 Pre-Funded Warrant, which, upon giving effect to such exercise, would cause it (together with its affiliates) to own more than 9.99% of the number of shares of our Common Stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the 2024 Pre-Funded Warrants. However, Fairmount HF II may increase or decrease such percentage to any other percentage not in excess of 19.99%, provided that (i) any increase in such percentage shall not be effective until 61 days after such notice is delivered to us and (ii) any such increase or decrease will apply only to the holder of each specific 2024 Pre-Funded Warrant and not to any other holder of 2024 Pre-Funded Warrants. The principal business address of each of the foregoing entities or persons is 200 Barr Harbor Drive, Suite 400, West Conshohocken, Pennsylvania 19428.
- (5) Consists of 2,360,059 shares of our Common Stock and 635,132 shares of our Common Stock issuable upon the exercise of 2024 Pre-Funded Warrants held by BCLS Fund III Investments, LP ("BCLS Fund III Investments"), which reflects the BCLS Beneficial Ownership Blocker (as defined below). Bain Capital Life Sciences Investors, LLC ("BCLSI") is the manager of Bain Capital Life Sciences III General Partner, LLC, which is the general partner of Bain Capital Life Sciences Fund III, L.P., which is the managing member of BCLS Fund III Investments GP, LLC, which is the general partner of BCLS Fund III Investments. As a result, BCLSI may be deemed to share voting and dispositive power with respect to the securities held by BCLS Fund III Investments. Pursuant to the terms of the 2024 Pre-Funded Warrants, BCLS Fund III Investments may not exercise any portion of any 2024 Pre-Funded Warrant, which, upon giving effect to such exercise, would cause it (together with its affiliates) to own more than 9.99% of the number of shares of our Common Stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the 2024 Pre-Funded Warrants (the "BCLS Beneficial Ownership Blocker"). However, BCLS Fund III Investments may increase or decrease such percentage to any other percentage not in excess of 19.99%, provided that (i) any increase in such percentage shall not be effective until 61 days after such notice is delivered to us and (ii) any such increase or decrease will apply only to the holder of each specific 2024 Pre-Funded Warrant and not to any other holder of 2024 Pre-Funded Warrants. The principal business address of BCLS Fund III Investments is c/o Bain Capital Life Sciences, LP, 200 Clarendon Street, Boston, MA 02116.
- (6) Consists of 2,333,000 shares of our Common Stock and 665,194 shares of our Common Stock issuable upon the exercise of 2024 Pre-Funded Warrants held by RA Capital Healthcare Fund, L.P. ("RACHF"). RA Capital Management, L.P. is the investment manager for RACHF. The general partner of RA Capital Management, L.P. is RA Capital Management GP, LLC, of which Peter Kolchinsky, Ph.D. and Rajeev Shah are the managing members. Each of RA Capital Management, L.P., RA Capital Management GP, LLC, Mr. Kolchinsky and Mr. Shah may be deemed to have voting and investment power over the securities held by RACHF. RA Capital Management, L.P., RA Capital Management GP, LLC, Mr. Kolchinsky and Mr. Shah disclaim beneficial ownership of such securities, except to the extent of any pecuniary interest

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therein. Pursuant to the terms of the 2024 Pre-Funded Warrants, RACHF may not exercise any portion of any 2024 Pre-Funded Warrant, which, upon giving effect to such exercise, would cause it (together with its affiliates) to own more than 9.99% of the number of shares of our Common Stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the 2024 Pre-Funded Warrants. However, RACHF may increase or decrease such percentage to any other percentage not in excess of 19.99%, provided that (i) any increase in such percentage shall not be effective until 61 days after such notice is delivered to us and (ii) any such increase or decrease will apply only to the holder of each specific 2024 Pre-Funded Warrant and not to any other holder of 2024 Pre-Funded Warrants. The principal business address of the persons and entities listed above is 200 Berkeley Street, 18th Floor, Boston, MA 02116.

- (7) Consists of (i) 1,919,424 shares of our Common Stock held by Venrock Healthcare Capital Partners EG, L.P. (“VHCP EG”), (ii) 159,048 shares of our Common Stock held by Venrock Healthcare Capital Partners III, L.P. (“VHCP III”) and (iii) 15,901 shares of our Common Stock held by VHCP Co-Investment Holdings III, LLC (“VCHP Co-III”) and, together with VHCP EG and VHCP III, the “Venrock Funds”). VHCP Management EG, LLC (“VHCPM EG”) is the sole general partner of VHCP EG. VHCP Management III, LLC (“VHCPM III”) is the sole general partner of VHCP III and the sole manager of VHCP Co-III. Dr. Bong Koh and Nimish Shah are the voting members of VHCPM III and VHCPM EG. The principal business address of each of the foregoing persons is 7 Bryant Park, 23rd Floor, New York, New York 10018.
- (8) Consists of options to purchase 330,239 shares of our Common Stock that are exercisable within 60 days of March 14, 2024.
- (9) Consists of (i) 4,000 shares of our Common Stock and (ii) options to purchase 57,987 shares of our Common Stock that are exercisable within 60 days of March 14, 2024.
- (10) Consists of options to purchase 67,182 shares of our Common Stock that are exercisable within 60 days of March 14, 2024.
- (11) Consists of 1,436,745 shares of our Common Stock held by Tellus BioVentures, LLC (“Tellus BioVentures”). Leon O. Moulder, Jr. may be deemed to have sole voting and dispositive power over the shares held by Tellus BioVentures. Mr. Moulder disclaims beneficial ownership of such shares, except to the extent of his pecuniary interest therein. The principal business address of Tellus BioVentures and Mr. Moulder is 10520 Trevi Isle Way, Miramar Lakes, FL 33913.
- (12) Consists of options to purchase 14,398 shares of our Common Stock that are exercisable within 60 days of March 14, 2024.
- (13) Consists of options to purchase 7,926 shares of our Common Stock that are exercisable within 60 days of March 14, 2024.
- (14) Consists of options to purchase 5,798 shares of our Common Stock that are exercisable within 60 days of March 14, 2024.
- (15) Consists of (i) 4,203,582 shares of our Common Stock, (ii) 187,650 shares of our Common Stock issuable upon the exercise of Pre-Funded Warrants and (iii) options to purchase 547,345 shares of our Common Stock that are exercisable within 60 days of March 14, 2024.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Magenta Transactions

Collaboration and Advisory Services

During the years ended December 31, 2023 and 2022, Magenta made payments for advisory and related services from Be the Match BioTherapies Collection Services, LLC (f/k/a Be the Match BioTherapies, LLC) (“BTMB”) and its affiliates, including National Marrow Donor Program (“NMDP”) in the amount of \$40,372 and \$497,858, respectively. Magenta had collaboration agreements with NMDP (as successor in interest to BTMB) which expired in December 2022. In addition, in June 2020, Magenta entered into a clinical collaboration agreement with NMDP/Be The Match to evaluate the potential utility of MGTA-145 for mobilizing and collecting hematopoietic stem cells from donors in a single day and then using them for allogeneic transplant in patients. Under the terms of this agreement, Magenta was obligated to fund up to 50% of NMDP/Be The Match clinical trial costs and provide the trial drugs to be included in research and development expense. The clinical collaboration was discontinued in the first quarter of 2023. Amy Lynn Ronneberg was formerly the president of BTMB, and she is the Chief Executive Officer of NMDP and was formerly a member of Magenta’s board of directors. These fees were paid to BTMB and its affiliates pursuant to the aforementioned agreements in amounts mutually agreed upon in advance by Magenta and BTMB. None of these fees were paid directly to Ms. Ronneberg. The fees paid to BTMB did not exceed 5% of the consolidated gross revenue of BTMB (or NMDP) during the years ended December 31, 2023 and 2022.

ImmunoGen

Dr. Michael Vasconcelles joined Magenta’s board of directors on August 15, 2022, and he joined ImmunoGen as Executive Vice President of Research, Development, and Medical Affairs on December 29, 2022. During the years ended December 31, 2023 and 2022, Magenta made payments of approximately \$140,182 and \$4.5 million, respectively, to ImmunoGen pursuant to a license agreement. None of these fees were paid directly to Dr. Vasconcelles. The fees paid to ImmunoGen did not exceed 5% of the consolidated gross revenue of ImmunoGen during the years ended December 31, 2023 and 2022.

Indemnification Agreements

Magenta previously entered into agreements to indemnify its directors and executive officers. These agreements, among other things, required Magenta to indemnify these individuals for certain expenses (including attorneys’ fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in Magenta’s right, on account of any services undertaken by such person on behalf of Magenta or that person’s status as a member of Magenta’s board of directors to the maximum extent allowed under Delaware law.

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Dianthus and Former Dianthus Transactions

Private Placements of Securities

Series A Preferred Stock Financing

In April 2022, Former Dianthus completed a preferred stock financing and issued and sold an aggregate of 23,007,017 shares of Series A Preferred Stock at a purchase price of \$4.3465 per share for aggregate gross proceeds of approximately \$100 million. The following table summarizes purchases of Former Dianthus' Series A Preferred Stock by related persons:

Participant	Shares of Series A Preferred Stock	Total Cash Purchase Price (\$)
Entities affiliated with 5AM Ventures	5,751,753	\$ 24,999,994
Entities affiliated with Avidity Partners	4,601,403	\$ 19,999,998
Entities affiliated with Fairmount	3,451,051	\$ 14,999,993
Entities affiliated with FMR LLC	5,602,210	\$ 24,350,006
Entities affiliated with Venrock Healthcare Capital Partners	1,610,490	\$ 6,999,995
Tellus BioVentures, LLC	264,583	\$ 1,150,010
Christopher J. Moulder and Meghan M. Moulder ⁽¹⁾	57,517	\$ 249,998
Lauren E. Bartlett ⁽²⁾	57,517	\$ 249,998

(1) Christopher J. Moulder and Meghan M. Moulder are immediate family members of Leon O. Moulder, Jr., director and chair of Former Dianthus.

(2) Lauren E. Bartlett is an immediate family member of Leon O. Moulder, Jr., director and chair of Former Dianthus.

Such information has not been adjusted to reflect the effects of the Reverse Stock Split.

Former Dianthus Pre-Closing Financing

On May 2, 2023, in connection with the execution of the Merger Agreement, Former Dianthus entered into the Subscription Agreement with certain investors to consummate the OpCo pre-closing financing. Pursuant to the Subscription Agreement, immediately prior to the effective time of the Merger, Former Dianthus issued and sold, and the investors purchased, (i) 2,873,988 shares of Former Dianthus common stock and (ii) 210,320 pre-funded warrants, exercisable for 210,320 shares of Former Dianthus common stock, at a purchase price of approximately \$23.34 per share or \$23.34 per warrant, for an aggregate purchase price of approximately \$72.0 million. Six of the investors or their affiliates were beneficial holders of more than 5% of Former Dianthus' capital stock, and the table below sets forth the number of shares of Former Dianthus common stock purchased by such holders at the closing of the OpCo pre-closing financing.

Participant	Shares of Dianthus Common Stock	Pre-funded Warrants of Dianthus	Total Purchase Price (\$)
5AM Ventures VII, L.P.	218,056	210,320	\$ 10,000,000
Entities affiliated with Avidity Partners	214,188	—	\$ 5,000,000
Entities affiliated with Fairmount	670,910	—	\$ 15,661,667
Entities affiliated with FMR LLC	996,616	—	\$ 23,265,000
Entities affiliated with Venrock Healthcare Capital Partners	242,532	—	\$ 5,661,667
Tellus BioVentures, LLC	39,054	—	\$ 911,673

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2024 Private Placement

On January 24, 2024, Dianthus completed the 2024 Private Placement. Pursuant to the Securities Purchase Agreement, Dianthus issued and sold, and the investors purchased, (i) 14,500,500 shares of Common Stock and (ii) 4,666,332 2024 Pre-Funded Warrants, exercisable for 4,666,332 shares of Common Stock, at a purchase price of \$12.00 per share or \$11.999 per 2024 Pre-Funded Warrant, which represents the per share purchase price of the Common Stock less the \$0.001 per share exercise price for each 2024 Pre-Funded Warrant, for an aggregate purchase price of approximately \$230.0 million. Six of the investors or their affiliates were or became upon completion of the transaction beneficial holders of more than 5% of Common Stock, and the table below sets forth the number of shares of Common Stock or 2024 Pre-Funded Warrants purchased by such holders at the closing of the 2024 Private Placement.

Participant	Shares of Common Stock	2024 Pre-Funded Warrants	Total Purchase Price (\$)
Entities affiliated with Avidity Partners	1,500,000	1,833,333	\$ 39,998,163
BCLS Fund III Investments, LP	2,333,000	1,000,333	\$ 39,998,996
Fairmount Healthcare Fund II LP	834,334	832,333	\$ 19,999,172
Entities affiliated with FMR LLC	1,958,333	—	\$ 23,499,996
RA Capital Healthcare Fund, L.P.	2,333,000	1,000,333	\$ 39,998,996
Tellus BioVentures, LLC	166,667	—	\$ 2,000,004
Entities affiliated with Venrock Healthcare Capital Partners	1,666,667	—	\$ 20,000,004

Other Agreements with Former Dianthus Stockholders

In connection with Former Dianthus' Series A Preferred Stock financing, Former Dianthus entered into amended and restated investors' rights, voting and right of first refusal and co-sale agreements containing registration rights, information rights, voting rights and rights of first refusal, among other things, with certain holders of Former Dianthus preferred stock and certain holders of Former Dianthus common stock. These stockholder agreements were terminated or no longer effective upon the closing of the Merger.

Director Compensation of Former Dianthus

Ms. Soteropoulos received compensation for service on the Former Dianthus board of directors during fiscal 2022 in the amount of \$202,396, consisting of \$22,500 in cash and \$179,896 in option awards.

License Agreements

In September 2020, we entered into an option agreement with Zenas BioPharma ("Zenas Option"), under which we agreed to grant Zenas BioPharma an exclusive option for an exclusive license under certain patents and know-how with respect to antibody sequences generated in a research program directed towards the research of monoclonal antibody antagonists targeting certain specific complement proteins. In consideration for the option grant, we were issued Zenas BioPharma common stock equivalent to one percent of its shares outstanding prior to a Series A financing. On June 10, 2022, in connection with Zenas BioPharma's exercise of the option, we entered into a license agreement with Zenas BioPharma (the "Zenas License Agreement," and together with the Zenas Option, the "Zenas Agreements"), under which we granted Zenas BioPharma an exclusive, sublicensable license under certain patents and know-how to research, develop, manufacture, and commercialize monoclonal antibody antagonists targeting certain specific complement proteins. The Zenas Agreements were negotiated with a single commercial objective and are treated as a combined contract for accounting purposes. For the years ended December 31, 2023 and 2022, the Company recognized related party license revenue totaling \$2.8 million and \$6.4 million, respectively, associated with the Zenas Agreements. As of December 31, 2023, the Company

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recorded a related party receivable of \$0.3 million, unbilled related party receivable of \$0.2 million, current deferred related party revenue of \$0.1 million and noncurrent deferred related party revenue of \$0.7 million on its consolidated balance sheet. As of December 31, 2022, the Company recorded a related party receivable of \$4.7 million, unbilled related party receivable of \$0.9 million, current deferred related party revenue of \$0.1 million and noncurrent deferred related party revenue of \$0.8 million on its consolidated balance sheet.

The Zenas Agreements may be considered related party transactions because (i) Fairmount beneficially owns more than 5% of our Common Stock, has one seat on the Board of Directors and is also a 5% or greater stockholder of Zenas BioPharma and has a seat on Zenas BioPharma's board of directors and (ii) Tellus BioVentures beneficially owns more than 5% of our Common Stock, has one seat on the Board of Directors and is also a 5% or greater stockholder of Zenas BioPharma and has a seat on Zenas BioPharma's board of directors. Mr. Moulder may be deemed to beneficially own the shares held by Tellus BioVentures. Mr. Moulder also serves as Chief Executive Officer and Chairman of the board of directors of Zenas BioPharma. The Zenas Agreements were negotiated on an arm's-length basis and are market rate transactions on terms that the Company believes are no less favorable than would have been reached with an unrelated third party.

Promissory Notes

On March 13, 2023, Fairmount Healthcare Fund LP and Fairmount Healthcare Fund II LP issued promissory notes in the aggregate principal amount of \$376,770 to Former Dianthus at an interest rate of 4.5% per annum. On March 15, 2023, Former Dianthus repaid principal and interest in the amount of \$376,862 to Fairmount Healthcare Fund LP and Fairmount Healthcare Fund II LP in satisfaction of its obligations under the promissory notes.

Registration Rights Agreements

2023 Registration Rights Agreement

On September 11, 2023, the Company entered into the 2023 Registration Rights Agreement with Former Dianthus and the Selling Stockholders named therein pursuant to which, among other things, the Company agreed to provide for the registration and resale of certain shares of Common Stock that are held by such Selling Stockholders from time to time, including the shares of Common Stock issued in exchange for shares of common stock of Former Dianthus sold in the pre-closing financing and the shares of Common Stock issuable upon exercise of the 2023 Pre-Funded Warrants assumed upon conversion of the pre-funded warrants of Former Dianthus sold in the pre-closing financing. See the section titled "*Description of Capital Stock—Registration Rights Agreements*" located elsewhere in this prospectus for further information on the 2023 Registration Rights Agreement.

2024 Registration Rights Agreement

On January 22, 2024, the Company entered into the 2024 Registration Rights Agreement with the Selling Stockholders named therein pursuant to which, among other things, the Company agreed to provide for the registration and resale of certain shares of Common Stock that are held by such Selling Stockholders from time to time, including the shares of Common Stock issuable upon exercise of the 2024 Pre-Funded Warrants. See the section titled "*Description of Capital Stock—Registration Rights Agreements*" located elsewhere in this prospectus for further information on the 2024 Registration Rights Agreement.

Dianthus Indemnification Agreements

Prior to the closing of the Merger, Former Dianthus entered into an indemnification agreement with each of its directors and purchased directors' and officers' liability insurance. The indemnification agreements required Former Dianthus to indemnify its directors to the fullest extent permitted under Delaware law.

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Immediately following the closing of the Merger, we entered into agreements, and in the future plan to enter into, agreements to indemnify our directors and executive officers. These agreements, among other things, require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of us or that person's status as a member of the Board of Directors to the maximum extent allowed under Delaware law.

Review, Approval or Ratification of Transactions with Related Parties

Immediately following the closing of the Merger, the Board of Directors adopted a written policy regarding the review and approval or ratification by our Audit Committee of related person transactions. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship or any series of similar transactions, arrangements or relationships between us or any of our subsidiaries and any related person in which the aggregate amount involved since the beginning of the Company's last completed fiscal year exceeds or is expected to exceed \$100,000 and such related person has or will have a direct or indirect interest. A related person is defined to include any executive officers, directors or director nominees or beneficial owner of more than 5% of our Common Stock and any immediate family member of any of the foregoing persons. In determining to approve or ratify any such transaction, our Audit Committee is expected to take into account, among other factors it deems appropriate, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third-party under the same or similar circumstances and the extent of the related persons interest in the transaction. Transactions involving compensation for services provided to us as an employee or director, among other limited exceptions, are deemed under the terms of the policy to have standing pre-approval by the Audit Committee but may be specifically reviewed if appropriate in light of the facts and circumstances. Any director who is a related person with respect to a transaction under review is not permitted to participate in the deliberations (other than to provide information concerning the transaction to the Audit Committee) or vote on approval of the transaction.

SELLING STOCKHOLDERS

For additional information regarding the issuances of those shares of Common Stock being registered for resale in this registration statement, see “*Business Combination of Dianthus and OpCo*” and “*Private Placements of Shares of Common Stock and Pre-Funded Warrants*” above. We are registering the shares of Common Stock in order to permit the Selling Stockholders to offer the shares for resale from time to time.

The table below lists the Selling Stockholders and other information regarding the beneficial ownership of the shares of Common Stock by each of the Selling Stockholders. The second column lists the number of shares of Common Stock beneficially owned by each Selling Stockholder, based on its ownership of the shares of Common Stock, as of March 14, 2024.

The third column lists the shares of Common Stock being offered by this prospectus by the Selling Stockholders.

The fourth column reflects the number and percentage of shares of Common Stock beneficially owned by each Selling Stockholder, assuming the sale of all of the shares offered by the Selling Stockholders pursuant to this prospectus.

The Selling Stockholders may sell all, some or none of their shares in this Offering. See “*Plan of Distribution*.”

Name of Selling Stockholders	Common Stock Beneficially Owned Before Offering	Common Stock that May Be Offered Pursuant to Prospectus	Common Stock Beneficially Owned After Offering ⁽¹⁾	
			Number	Percentage (%)
Entities affiliated with Avidity Partners ⁽²⁾	2,955,513	3,333,333 ⁽³⁾	1,217,554	4.15
Bangle & Co fbo Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund ⁽⁴⁾	500,662	302,966	197,696	*
Mag & Co fbo Fidelity Capital Trust: Fidelity Stock Selector Small Cap Fund ⁽⁴⁾	314,218	222,097	92,121	*
Mag & Co fbo Fidelity Growth Company Commingled Pool ⁽⁴⁾	1,121,042	751,744	369,298	1.26
Mag & Co fbo Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund ⁽⁴⁾	227,084	152,986	74,098	*
Mag & Co fbo Fidelity Securities Fund: Fidelity Series Small Cap Opportunities Fund ⁽⁴⁾	689,854	449,528	240,326	*
Mag & Co fbo Fidelity Select Portfolios: Biotechnology Portfolio ⁽⁴⁾	337,793	337,793	—	—
Powhatan & Co., LLC fbo Fidelity Mt. Vernon Street Trust: Fidelity Growth Company K6 Fund ⁽⁴⁾	262,231	181,889	80,342	*
Powhatan & Co., LLC fbo Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund ⁽⁴⁾	848,061	555,946	292,115	1.00
Entities affiliated with Fairmount Funds Management LLC ⁽⁵⁾	2,950,487	1,666,667 ⁽⁶⁾	1,928,503	6.57
BCLS Fund III Investments, L.P. ⁽⁷⁾	2,995,191	3,333,333	27,059	*
RA Capital Healthcare Fund, L.P. ⁽⁸⁾	2,998,194	3,333,333	—	—
Entities affiliated with 5AM Ventures ⁽⁹⁾	1,682,584	428,376	1,254,208	4.27
Tellus BioVentures, LLC ⁽¹⁰⁾	1,436,745	166,667 ⁽¹¹⁾	1,270,078	4.33
Entities affiliated with Venrock Healthcare Capital Partners ⁽¹²⁾	2,094,373	1,909,199	185,174	*
Entities affiliated with Catalio ⁽¹³⁾	883,267	761,709	121,558	*

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Name of Selling Stockholders	Common Stock Beneficially Owned Before Offering	Common Stock that May Be Offered Pursuant to Prospectus	Common Stock Beneficially Owned After Offering ⁽¹⁾	
			Number	Percentage (%)
Entities affiliated with Wedbush Securities Inc. ⁽¹⁴⁾	164,592	64,256	100,336	*
Entities affiliated with RTW Investments, LP ⁽¹⁵⁾	666,667	666,667	—	—
Entities affiliated with Great Point Partners, LLC ⁽¹⁶⁾	625,000	625,000	—	—
Entities affiliated with Octagon Capital Advisors LP ⁽¹⁷⁾	1,356,667	583,333	773,334	2.64
Janus Henderson Biotech Innovation Master Fund Limited ⁽¹⁸⁾	375,000	375,000	—	—
Entities affiliated with Vestal Point Capital, LP ⁽¹⁹⁾	468,233	333,333	134,900	*
Logos Opportunities Fund IV LP ⁽²⁰⁾	333,333	333,333	—	—
Woodline Master Fund LP ⁽²¹⁾	208,333	208,333	—	—
Ally Bridge MedAlpha Master Fund L.P. ⁽²²⁾	166,968	166,667	301	*
StemPoint Capital Master Fund LP ⁽²³⁾	83,500	83,500	—	—

* Less than 1%.

- (1) Assumes that all the shares of Common Stock of the Selling Stockholders covered by this prospectus are sold and that the Selling Stockholders do not acquire any additional shares of Common Stock before the completion of this Offering. However, as each Selling Stockholder can offer all, some or none of its Common Stock, no definitive estimate can be given as to the number of shares of Common Stock that any Selling Stockholder will ultimately offer or sell under this prospectus.
- (2) Shares listed under “Common Stock Beneficially Owned Before Offering” consist of (i) 1,573,625 shares of Common Stock and 140,014 shares of Common Stock issuable upon the exercise of 2024 Pre-Funded Warrants held by Avidity Private Master Fund I LP (“APMF”), (ii) 1,082,525 shares of Common Stock and 97,945 shares of Common Stock issuable upon the exercise of 2024 Pre-Funded Warrants held by Avidity Master Fund LP (“AMF”) and (iii) 61,404 shares of Common Stock held by Avidity Capital Fund II LP (“ACF,” and, together with APMF and AMF, the “Avidity Funds”). The general partner of each of the Avidity Funds is Avidity Capital Partners Fund (GP) LP, whose general partner is Avidity Capital Partners (GP) LLC. Avidity Partners Management LP is the investment manager of each of the Avidity Funds. Avidity Partners Management (GP) LLC is the general partner of Avidity Partners Management LP. David Witzke and Michael Gregory are the managing members of Avidity Capital Partners (GP) LLC and Avidity Partners Management (GP) LLC. Mr. Witzke and Mr. Gregory may be deemed to have shared voting and investment power over the shares held by each of the Avidity Funds. Each of Mr. Witzke and Mr. Gregory disclaim beneficial ownership of such shares, except to the extent of his respective pecuniary interest therein. Pursuant to the terms of the 2024 Pre-Funded Warrants, each of APMF and AMF may not exercise any portion of any 2024 Pre-Funded Warrant, which, upon giving effect to such exercise, would cause it (together with its affiliates) to own more than 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the 2024 Pre-Funded Warrants. However, each of APMF and AMF may increase or decrease such percentage to any other percentage not in excess of 19.99%, provided that (i) any increase in such percentage shall not be effective until 61 days after such notice is delivered to us and (ii) any such increase or decrease will apply only to the holder of each specific 2024 Pre-Funded Warrant and not to any other holder of 2024 Pre-Funded Warrants. The principal business address of each of the foregoing persons is 2828 N. Harwood Street, Suite 1220, Dallas, TX 75201.
- (3) Consists of (i) 882,592 shares of Common Stock purchased by APMF in the 2024 Private Placement and 1,078,723 shares of Common Stock issuable upon the exercise of 2024 Pre-Funded Warrants purchased by APMF in the 2024 Private Placement and (ii) 617,408 shares of Common Stock purchased by AMF in the 2024 Private Placement and 754,610 shares of Common Stock issuable upon the exercise of 2024 Pre-Funded Warrants purchased by AMF in the 2024 Private Placement.

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- (4) These funds and accounts are managed by direct or indirect subsidiaries of FMR LLC. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. The address of these funds and accounts is 245 Summer Street, Boston, MA 02210.
- (5) Shares listed under "Common Stock Beneficially Owned Before Offering" consist of (i) 62,146 shares of Common Stock held by Fairmount SPV III, LLC ("Fairmount SPV"), (ii) 58,857 shares of Common Stock held by Fairmount Healthcare Fund L.P. ("Fairmount HF") and (iii) 2,641,834 shares of Common Stock and 187,650 shares of Common Stock issuable upon the exercise of 2024 Pre-Funded Warrants held by Fairmount Healthcare Fund II L.P. ("Fairmount HF II," and, together with Fairmount SPV and Fairmount HF, the "Fairmount Funds"). Fairmount Funds Management LLC ("Fairmount") is the Class A Member of Fairmount SPV. Fairmount has voting and dispositive power over the shares held by Fairmount Funds. Fairmount is the investment manager for Fairmount HF and Fairmount HF II and is the Class A Member for Fairmount SPV. The general partner of Fairmount is Fairmount Funds Management GP LLC ("Fairmount GP"), of which Peter Harwin and Tomas Kiselak are the managing members. Fairmount, Fairmount GP, Mr. Harwin, and Mr. Kiselak disclaim beneficial ownership of any of the reported securities, except to the extent of their pecuniary interest therein. Pursuant to the terms of the 2024 Pre-Funded Warrants, Fairmount HF II may not exercise any portion of any 2024 Pre-Funded Warrant, which, upon giving effect to such exercise, would cause it (together with its affiliates) to own more than 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the 2024 Pre-Funded Warrants. However, Fairmount HF II may increase or decrease such percentage to any other percentage not in excess of 19.99%, provided that (i) any increase in such percentage shall not be effective until 61 days after such notice is delivered to us and (ii) any such increase or decrease will apply only to the holder of each specific 2024 Pre-Funded Warrant and not to any other holder of 2024 Pre-Funded Warrants. The principal business address of each of the foregoing entities or persons is 200 Barr Harbor Drive, Suite 400, West Conshohocken, Pennsylvania 19428.
- (6) Consists of 834,334 shares of Common Stock purchased by Fairmount HF II in the 2024 Private Placement and 832,333 shares of Common Stock issuable upon the exercise of 2024 Pre-Funded Warrants purchased by Fairmount HF II in the 2024 Private Placement.
- (7) Shares listed under "Common Stock Beneficially Owned Before Offering" consist of 2,360,059 shares of Common Stock and 635,132 shares of Common Stock issuable upon the exercise of 2024 Pre-Funded Warrants held by BCLS Fund III Investments, LP ("BCLS Fund III Investments"), which reflects the BCLS Beneficial Ownership Blocker (as defined below). Bain Capital Life Sciences Investors, LLC ("BCLSI") is the manager of Bain Capital Life Sciences III General Partner, LLC, which is the general partner of Bain Capital Life Sciences Fund III, L.P., which is the managing member of BCLS Fund III Investments GP, LLC, which is the general partner of BCLS Fund III Investments. As a result, BCLSI may be deemed to share voting and dispositive power with respect to the securities held by BCLS Fund III Investments. Pursuant to the terms of the 2024 Pre-Funded Warrants, BCLS Fund III Investments may not exercise any portion of any 2024 Pre-Funded Warrant, which, upon giving effect to such exercise, would cause it (together with its affiliates) to own more than 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the 2024 Pre-Funded Warrants (the "BCLS Beneficial Ownership Blocker"). However, BCLS Fund III Investments may increase or decrease such percentage to any other percentage not in excess of 19.99%, provided that (i) any increase in such percentage shall not be effective until 61 days after such notice is delivered to us and (ii) any such increase or decrease will apply only to the holder of each specific

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2024 Pre-Funded Warrant and not to any other holder of 2024 Pre-Funded Warrants. The principal business address of BCLS Fund III Investments is c/o Bain Capital Life Sciences, LP, 200 Clarendon Street, Boston, MA 02116.

- (8) Shares listed under “Common Stock Beneficially Owned Before Offering” consist of 2,333,000 shares of Common Stock and 665,194 shares of Common Stock issuable upon the exercise of 2024 Pre-Funded Warrants held by RA Capital Healthcare Fund, L.P. (“RACHF”). RA Capital Management, L.P. is the investment manager for RACHF. The general partner of RA Capital Management, L.P. is RA Capital Management GP, LLC, of which Peter Kolchinsky, Ph.D. and Rajeev Shah are the managing members. Each of RA Capital Management, L.P., RA Capital Management GP, LLC, Mr. Kolchinsky and Mr. Shah may be deemed to have voting and investment power over the securities held by RACHF. RA Capital Management, L.P., RA Capital Management GP, LLC, Mr. Kolchinsky and Mr. Shah disclaim beneficial ownership of such securities, except to the extent of any pecuniary interest therein. Pursuant to the terms of the 2024 Pre-Funded Warrants, RACHF may not exercise any portion of any 2024 Pre-Funded Warrant, which, upon giving effect to such exercise, would cause it (together with its affiliates) to own more than 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the 2024 Pre-Funded Warrants. However, RACHF may increase or decrease such percentage to any other percentage not in excess of 19.99%, provided that (i) any increase in such percentage shall not be effective until 61 days after such notice is delivered to us and (ii) any such increase or decrease will apply only to the holder of each specific 2024 Pre-Funded Warrant and not to any other holder of 2024 Pre-Funded Warrants. The principal business address of the persons and entities listed above is 200 Berkeley Street, 18th Floor, Boston, MA 02116.
- (9) Shares listed under “Common Stock Beneficially Owned Before Offering” consist of (i) 430,776 shares of Common Stock and 52,580 shares of Common Stock issuable upon the exercise of 2023 Pre-Funded Warrants held by 5AM Opportunities II, L.P. (“5AM Opportunities”) and (ii) 1,041,488 shares of Common Stock and 157,740 shares of Common Stock issuable upon the exercise of 2023 Pre-Funded Warrants held by 5AM Ventures VII, L.P. (“5AM Ventures VII” and, together with 5AM Opportunities, the “5AM Selling Stockholders”). 5AM Partners VII, LLC (“Ventures GP”) is the sole general partner of 5AM Ventures VII and may be deemed to have sole investment and voting power over the shares held by 5AM Ventures VII. 5AM Opportunities II (GP), LLC (“Opportunities GP”) is the sole general partner of 5AM Opportunities and may be deemed to have sole investment and voting power over the shares held by 5AM Opportunities. Andrew Schwab and Kush Parmar are the managing members of each of Ventures GP and Opportunities GP and may be deemed to share voting and dispositive power over the shares held by 5AM Ventures VII and 5AM Opportunities. Each of Ventures GP, Opportunities GP, Kush Parmar and Andrew Schwab disclaims beneficial ownership of such shares, except to the extent of his respective pecuniary interest therein. Pursuant to the terms of the 2023 Pre-Funded Warrants, each of the 5AM Selling Stockholders may not exercise any portion of any 2023 Pre-Funded Warrant, which, upon giving effect to such exercise, would cause it (together with its affiliates) to own more than 9.9999% of the number of shares of Common Stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the 2023 Pre-Funded Warrants. However, each of the 5AM Selling Stockholders may increase or decrease such percentage to any other percentage not in excess of 9.9999%, provided that (i) any increase in such percentage shall not be effective until 61 days after such notice is delivered to us and (ii) any such increase or decrease will apply only to the holder of each specific 2023 Pre-Funded Warrant and not to any other holder of 2023 Pre-Funded Warrants. The principal business address of each of the foregoing persons is c/o 5AM Ventures, 501 2nd Street, Suite 350, San Francisco, CA 94107.
- (10) Shares listed under “Common Stock Beneficially Owned Before Offering” consist of 1,436,745 shares of Common Stock held by Tellus BioVentures, LLC (“Tellus BioVentures”). Leon O. Moulder, Jr. may be deemed to have sole voting and dispositive power over the shares held by Tellus BioVentures. Mr. Moulder disclaims beneficial ownership of such shares, except to the extent of his pecuniary interest therein. The principal business address of Tellus BioVentures and Mr. Moulder is 10520 Trevi Isle Way, Miramar Lakes, FL 33913.
- (11) Consists of 166,667 shares of Common Stock purchased by Tellus BioVentures in the 2024 Private Placement.

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- (12) Shares listed under “Common Stock Beneficially Owned Before Offering” consist of (i) 1,919,424 shares of Common Stock held by Venrock Healthcare Capital Partners EG, L.P. (“VHCP EG”), (ii) 159,048 shares of Common Stock held by Venrock Healthcare Capital Partners III, L.P. (“VHCP III”) and (iii) 15,901 shares of Common Stock held by VHCP Co-Investment Holdings III, LLC (“VCHP Co-III” and, together with VHCP EG and VHCP III, the “Venrock Funds”). VHCP Management EG, LLC (“VHCPM EG”) is the sole general partner of VHCP EG. VHCP Management III, LLC (“VHCPM III”) is the sole general partner of VHCP III and the sole manager of VHCP Co-III. Dr. Bong Koh and Nimish Shah are the voting members of VHCPM III and VHCPM EG. The principal business address of each of the foregoing persons is 7 Bryant Park, 23rd Floor, New York, New York 10018.
- (13) Shares listed under “Common Stock Beneficially Owned Before Offering” consist of (i) 635,539 shares of Common Stock held by Catalio Nexus Fund III, LP (“Catalio Nexus Fund”), (ii) 175,453 shares of Common Stock held by Catalio Public Equities Master Fund, LP (“Catalio Master Fund”) and (iii) 72,275 shares of Common Stock held by certain managed accounts advised by Catalio Capital Management, LP (the “Managed Accounts” and, together with Catalio Nexus Fund and Catalio Master Fund, the “Catalio Funds”). Catalio Capital Management, LP is the investment advisor to each of the Catalio Funds. R. Jacob Vogelstein disclaims beneficial ownership of the securities, except to the extent of his respective pecuniary interest therein. Mr. Vogelstein holds the power to vote and dispose of the securities held by the Catalio Funds. The principal business address of this person and these entities is 512 West 22nd Street, 5th Floor, New York, NY 10011.
- (14) Shares listed under “Common Stock Beneficially Owned Before Offering” consist of (i) 64,256 shares of Common Stock held by Wedbush Healthcare Partners 2023 Fund, LLC (the “Wedbush 2023 Fund”) and (ii) 100,336 shares of Common Stock held by Wedbush Healthcare Partners 2022 Fund, LLC (the “Wedbush 2022 Fund”), which entity, while not a Selling Stockholder, is an affiliate of Wedbush 2023 Fund. The managing member of each of the funds is Wedbush Securities Inc., which may be deemed to beneficially own the shares held by Wedbush 2022 Fund and Wedbush 2023 Fund. The principal business address for these entities is Wedbush Center, 1000 Wilshire Blvd., Los Angeles, CA 90017.
- (15) Shares listed under “Common Stock Beneficially Owned Before Offering” consist of 666,667 shares of Common Stock held in the aggregate by RTW Master Fund, Ltd. and RTW Innovation Master Fund, Ltd. (collectively, the “RTW Funds”). RTW Investments, LP (“RTW”), in its capacity as the investment manager of the RTW Funds, has the power to vote and the power to direct the disposition of the shares held by the RTW Funds. Accordingly, RTW may be deemed to be the beneficial owner of such shares held by the RTW Funds. Roderick Wong, M.D., as the Managing Partner of RTW, has the power to direct the vote and disposition of the shares held by RTW. Dr. Wong disclaims beneficial ownership of the shares held by the RTW Funds, except to the extent of his pecuniary interest therein. The principal business address of RTW is 40 10th Avenue, Floor 7, New York, New York, 10014, and the address of Dr. Wong and each of the RTW Funds is c/o RTW Investments, LP, 40 10th Avenue, Floor 7, New York, NY 10014.
- (16) Shares listed under “Common Stock Beneficially Owned Before Offering” consist of (i) 345,000 shares of our Common Stock held by Biomedical Value Fund, L.P. (“BVF”), (ii) 237,500 shares of Common Stock held by Biomedical Offshore Value Fund, LTD. (“BOVF”) and (iii) 42,500 shares of Common Stock held by Cheyne Select Master Fund ICAV – Cheyne Global Equity Fund (“CGEF” and, together with BVF and BOVF, the “GPP Entities”). Great Point Partners, LLC (“GPP LLC”) is the investment manager of BVF and BOVF and the sub-advisor to CGEF, and by virtue of such status may be deemed to be the beneficial owner of the shares held by the GPP Entities. Each of Dr. Jeffrey R. Jay, M.D., as Senior Managing Member of GPP LLC, and Mr. Ortav Yehudai, as Managing Director of GPP LLC, has voting and investment power with respect to shares held by the GPP Entities, and therefore may be deemed to be the beneficial owner of the shares held by the GPP Entities. Notwithstanding the above, GPP LLC, Dr. Jay and Mr. Yehudai disclaim beneficial ownership of the shares held by the GPP Entities except to the extent of their respective pecuniary interests. The principal business address of the GPP Entities is 165 Mason Street, 3rd Floor, Greenwich, CT 06830.
- (17) Shares listed under “Common Stock Beneficially Owned Before Offering” consist of (i) 1,065,000 shares of Common Stock held by Octagon Investments Master Fund LP and (ii) 291,667 shares of Common Stock held by Octagon Private Opportunities Fund II LP. Octagon Capital Advisors LP is the Investment Manager of Octagon Investments Master Fund LP and Octagon Private Opportunities Fund II LP. Ting Jia, Ph.D. is the Founder, Managing Member and Chief Investment Officer of Octagon Capital Advisors LP. By virtue of

such relationships, Dr. Jia and Octagon Capital Advisors LP may be deemed to have voting and investment power of the shares held by Octagon Investments Master Fund LP and Octagon Private Opportunities Fund II LP. Each of Dr. Jia and Octagon Capital Advisors LP disclaims beneficial ownership of the shares held by Octagon Investments Master Fund LP and Octagon Private Opportunities Fund II LP, except to the extent of his or its pecuniary interest therein, if any. The principal business address for each of Dr. Jia, Octagon Capital Advisors LP, Octagon Investments Master Fund LP and Octagon Private Opportunities Fund II LP is 654 Madison Avenue, 21st Floor, New York, NY 10065.

- (18) Shares listed under “Common Stock Beneficially Owned Before Offering” consist of 375,000 shares of Common Stock held by Janus Henderson Biotech Innovation Master Fund Limited (the “Fund”). Such shares owned by the Fund may be deemed to be beneficially owned by Janus Henderson Investors US LLC (“Janus”), an investment adviser registered under the Investment Advisers Act of 1940, who acts as investment adviser for the Fund set forth above and has the ability to make decisions with respect to the voting and disposition of the shares subject to the oversight of the board of trustees (or similar entity) of the Fund. Under the terms of its management contract, Janus has overall responsibility for directing the investments of the Fund in accordance with the Fund’s investment objective, policies and limitations. The Fund has one or more portfolio managers appointed by and serving at the pleasure of Janus who makes decisions with respect to the disposition of the shares. The address for Janus is 151 Detroit Street, Denver, CO 80206. The portfolio managers for the Fund are Andrew Acker, Daniel S. Lyons and Agustin Mohedas.
- (19) Shares listed under “Common Stock Beneficially Owned Before Offering” consist of (i) 203,653 shares held by Vestal Point Master Fund, LP and (ii) 264,580 shares held by an account separately managed by Vestal Point Capital, LP. The sole general partner of Vestal Point Master Fund, LP is Vestal Point Partners GP, LLC. The managing member of Vestal Point Partners GP, LLC is Ryan Wilder. The sole general partner of Vestal Point Capital, LP is Vestal Point Capital, LLC. The managing member of Vestal Point Capital, LLC is Mr. Wilder. As a result, Mr. Wilder may be deemed to have voting and investment power over the securities held by Vestal Point Master Fund, LP and the account separately managed by Vestal Point Capital, LP. Mr. Wilder disclaims beneficial ownership of such securities, except to the extent of his pecuniary interest therein. The address of these entities and Mr. Wilder is c/o Vestal Point Capital, LP, 632 Broadway, Suite 602, New York, NY 10012.
- (20) Shares listed under “Common Stock Beneficially Owned Before Offering” consist of 333,333 shares of Common Stock held by Logos Opportunities Fund IV LP (“Logos Opportunities”). Logos Opportunities IV GP LLC (“Logos Opportunities GP”) is the general partner of Logos Opportunities. Arsani William and Graham Walmsley are the members of Logos Opportunities GP. Mr. William and Mr. Walmsley each disclaim beneficial ownership of these shares, except to the extent of each of their pecuniary interest in such shares, if any. The principal address of Logos Opportunities is 1 Letterman Drive, Building C, Suite C3-350, San Francisco, CA 94129.
- (21) Shares listed under “Common Stock Beneficially Owned Before Offering” consist of 208,333 shares of Common Stock held by Woodline Master Fund LP (“Woodline Fund”). Woodline Partners LP serves as the investment manager of Woodline Fund and may be deemed to be the beneficial owner of the shares. Woodline Partners LP disclaims any beneficial ownership of these shares. The principal business address of this fund and account is 4 Embarcadero Center, Suite 34590, San Francisco, CA 94111.
- (22) Shares listed under “Common Stock Beneficially Owned Before Offering” consist of 166,968 shares of Common Stock held by Ally Bridge MedAlpha Master Fund L.P. (“MedAlpha”). Mr. Fan Yu is the sole shareholder of ABG Management Ltd., which is the sole member of Ally Bridge Group (NY) LLC, which manages investments of MedAlpha. As such, each of the foregoing entities and Mr. Fan Yu may be deemed to share beneficial ownership of the shares held by MedAlpha. Each of them disclaims any such beneficial ownership. The principal business address of MedAlpha is c/o Ally Bridge Group (NY) LLC, 430 Park Avenue, 12th Floor, New York, NY 10022.
- (23) Shares listed under “Common Stock Beneficially Owned Before Offering” consist of 83,500 shares of Common Stock held by StemPoint Capital Master Fund LP (“StemPoint Fund”). StemPoint Capital LP (“StemPoint”) serves as investment advisor to StemPoint Fund. StemPoint exercises voting and investment power over the shares held by StemPoint Fund pursuant to investment management agreements. StemPoint hereby disclaims beneficial ownership of the shares held by StemPoint Fund. The principal business address of StemPoint Fund is 520 Madison Avenue, 19th Floor, New York, NY 10022.

PLAN OF DISTRIBUTION

We are registering the Resale Shares issued to the Selling Stockholders to permit the sale, transfer or other disposition of these shares by the Selling Stockholders or their donees, pledgees, transferees or other successors-in-interest from time to time after the date of this prospectus. We are not selling any Resale Shares under this prospectus and will not receive any of the proceeds from the sale by the Selling Stockholders of the Resale Shares. We will, or will procure to, bear all fees and expenses incident to our obligation to register the Resale Shares.

Each Selling Stockholder of the securities and any of their pledgees, assignees, donees, transferees or other successors-in-interest may, from time to time, sell, transfer or otherwise dispose of any or all of their securities covered hereby on the principal trading market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A Selling Stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the Selling Stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2121; and in the case of a principal transaction a markup or markdown in compliance with FINRA Rule 2121.

In connection with the sale of the securities or interests therein, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The Selling Stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities that require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). The Selling Stockholders also may transfer the securities

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in other circumstances, in which case the transferees, pledgees, donees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The Selling Stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

We are required to pay certain fees and expenses incurred by us incident to the registration of the securities. We have agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the earlier of the date that the securities (i) have been sold, pursuant to this prospectus or pursuant to Rule 144, or (ii) the date on which the securities may be resold by the Selling Stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, and without the requirement for us to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the Common Stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the Common Stock by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

DESCRIPTION OF CAPITAL STOCK

The following is a description of our capital stock and does not purport to be complete and is subject to, and qualified in its entirety by, our fifth amended and restated certificate of incorporation (“charter”) and our second amended and restated bylaws (“bylaws”). You should refer to our charter and our bylaws for the actual terms of our capital stock. Copies of our charter and bylaws may be obtained as described under the heading “Where You Can Find More Information” in this prospectus.

Authorized Capital Stock

Our authorized capital stock consists of 150,000,000 shares of Common Stock and 10,000,000 shares of undesignated preferred stock, par value \$0.001 per share (“Preferred Stock”).

Common Stock

Dividends

Holders of Common Stock are entitled to receive dividends ratably, if any, as may be declared by our board of directors out of legally available funds, subject to any preferential dividend rights of any Preferred Stock then outstanding.

Voting

Holders of Common Stock are entitled to one vote for each share of Common Stock held of record for the election of directors of Dianthus and on all matters submitted to a vote of the stockholders. The holders of Common Stock do not have any cumulative voting rights.

Distributions on Liquidation

In the event of our dissolution, liquidation or winding up, holders of Common Stock are entitled to share ratably in our net assets legally available after the payment of all our debts and other liabilities, subject to the preferential rights of any Preferred Stock then outstanding. The rights, preferences and privileges of holders of Common Stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of Preferred Stock that we may designate and issue in the future.

Other Rights

Holders of Common Stock are not entitled to preemptive, subscription, redemption or conversion rights, and no sinking fund provisions are applicable to Common Stock.

Preferred Stock

Under our charter, our board of directors is authorized, without further action by the stockholders, to designate and issue up to an aggregate of 10,000,000 shares of Preferred Stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of Common Stock. Our board of directors may authorize the issuance of Preferred Stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of Common Stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation.

The purpose of authorizing our board of directors to issue Preferred Stock in one or more series and determine the number of shares in the series and its rights, preferences, privileges and restrictions is to eliminate

delays associated with a stockholder vote on specific issuances. The issuance of Preferred Stock, while providing flexibility in connection with possible future financings and acquisitions and other corporate purposes could, under certain circumstances, have the effect of delaying, deferring or preventing a change in control of the company. As of the date of this prospectus, there are no shares of Preferred Stock outstanding, and we have no present plans to issue any shares of Preferred Stock.

Anti-Takeover Effects of Delaware Law and Provisions of Our Charter and Bylaws

Certain provisions of the General Corporation Law of Delaware (the “DGCL”) and of our charter and bylaws could have the effect of delaying, deferring or discouraging another party from acquiring control of Dianthus. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and, as a consequence, they might also inhibit temporary fluctuations in the market price of our Common Stock that often result from actual or rumored hostile takeover attempts. These provisions are also designed in part to encourage anyone seeking to acquire control of Dianthus to first negotiate with our board of directors. These provisions might also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests. However, we hold that the advantages gained by protecting our ability to negotiate with any unsolicited and potentially unfriendly acquirer outweigh the disadvantages of discouraging such proposals, including those priced above the then-current market value of our Common Stock, because, among other reasons, the negotiation of such proposals could improve their terms.

Delaware Anti-Takeover Statute

We are subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a three-year period following the date that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by the board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation or any direct or indirect majority-owned subsidiary of the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition (in one or more transactions) involving the interested stockholder of 10% or more of either the aggregate market value of all (i) the assets of the corporation or (ii) the outstanding capital stock of the corporation, involving the interested stockholder;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation or by any direct or indirect majority-owned subsidiary of the corporation of any stock of the corporation or any subsidiary to the interested stockholder;

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- subject to exceptions, any transaction involving the corporation or any direct or indirect majority-owned subsidiary of the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation or of any subsidiary beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation or any direct or indirect majority-owned subsidiary.

In general, Section 203 defines an “interested stockholder” as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person that is an affiliate or associate of the corporation and who beneficially owned 15% or more of the outstanding voting stock of the corporation at any time within the three year period immediately prior to the date of determining whether such entity or person is an interested stockholder, and any affiliate or associate of that entity or person.

Choice of Forum

Our bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware shall be 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 against us or any of our current or former directors, officers, employees or stockholders 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 we refer to herein as the “Delaware Forum Provision.” The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our bylaws further provide that, unless we consent in writing to an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, which we refer 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.

We recognize that the Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on 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 the filing of lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. Alternatively, if the Federal Forum Provision is found inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have an adverse effect on our business, financial condition or results of operations. The Court of Chancery of the State of Delaware or the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Board Composition and Filling Vacancies

In accordance with our charter, our board is divided into three classes serving staggered three-year terms, with one class being elected each year. Our charter also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an

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election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of the remaining directors then in office, even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No Written Consent of Stockholders

Our charter provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This requirement may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of Stockholders

Our charter and our bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to Our Charter and Our Bylaws

As required by the DGCL, any amendment of our charter must first be approved by a majority of our board of directors, and, if required by law or our charter, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, limitation of liability, the amendment of our bylaws and the amendment of our charter must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class.

Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws, and may also be amended by the affirmative vote of at least two-thirds of the outstanding shares entitled to vote on the amendment, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated Preferred Stock

Our charter provides for 10,000,000 authorized shares of Preferred Stock. The existence of authorized but unissued shares of Preferred Stock may enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in

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the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of Preferred Stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. The issuance of shares of Preferred Stock could decrease the amount of earnings and assets available for distribution to holders of shares of Common Stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Nasdaq Capital Market Listing

Our Common Stock is listed on The Nasdaq Capital Market under the symbol “DNTH.”

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock is Computershare Trust Company, N.A. The transfer agent and registrar’s address is 150 Royall Street, Canton, Massachusetts 02021, and its telephone number is (800) 962-4284.

Registration Rights Agreements

2023 Registration Rights Agreement

Pursuant to the Subscription Agreement, the Company, OpCo and the Selling Stockholders entered into the Registration Rights Agreement, pursuant to which, among other things, the Company agreed to provide for the registration and resale of certain shares of Common Stock that are held by the Selling Stockholders from time to time, including the shares of Common Stock issued in exchange for shares of common stock of OpCo sold in the OpCo pre-closing financing and the shares of Common Stock issuable upon exercise of the Pre-Funded Warrants assumed upon conversion of the pre-funded warrants of OpCo sold in the OpCo pre-closing financing.

Pursuant to the Registration Rights Agreement, the Company agreed to prepare and file a shelf registration statement covering the resale of the Common Stock within 45 days of the closing of the Merger pursuant to Rule 415 of the Securities Act, and to use its reasonable best efforts to keep such registration statement continuously effective under the Securities Act until the earlier of (a) the date that all registrable securities covered by such registration statement (i) have been sold, thereunder or pursuant to Rule 144, or (ii) may be sold without volume or manner-of-sale restrictions pursuant to Rule 144 and without the requirement for the Company to be in compliance with the current public information requirement under Rule 144, and (b) five years after the date of the Registration Rights Agreement. The Registration Rights Agreement also provides that the Company pay certain expenses of the securityholders and indemnify the applicable securityholders against certain liabilities.

The foregoing description of the Registration Rights Agreement does not purport to be complete and is qualified in its entirety by the full text of the Registration Rights Agreement, a copy of which is filed as Exhibit 4.2 to this Registration Statement.

2024 Registration Rights Agreement

On January 22, 2024, in connection with the 2024 Private Placement, the Company entered into the 2024 Registration Rights Agreement with the Selling Stockholders named therein, pursuant to which, among other things, the Company agreed to provide for the registration and resale of certain shares of Common Stock that are held by such Selling Stockholders from time to time, including the shares of Common Stock issuable upon exercise of the 2024 Pre-Funded Warrants.

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Pursuant to the 2024 Registration Rights Agreement, the Company agreed to prepare and file a registration statement with the SEC no later than the second business day following the later of (i) the filing date of the Company's Annual Report on Form 10-K for its fiscal year ending December 31, 2023 and (ii) the effectiveness date of this Registration Statement, and to use its commercially reasonable efforts to have the registration statement declared effective within 30 days thereafter, subject to certain exceptions and specified penalties if timely effectiveness is not achieved.

The Company has also agreed to, among other things, indemnify the Selling Stockholders named in the 2024 Registration Rights Agreement, their officers, directors, agents, partners, members, managers, stockholders, affiliates, investment advisers and employees under the registration statement from certain liabilities and pay all fees and expenses (excluding any legal fees of the selling holder(s), and any underwriting discounts and selling commissions) incident to the Company's obligations under the 2024 Registration Rights Agreement.

The foregoing description of the 2024 Registration Rights Agreement does not purport to be complete and is qualified in its entirety by the full text of the 2024 Registration Rights Agreement, a copy of which is filed as Exhibit 4.4 to this Registration Statement.

LEGAL MATTERS

Certain legal matters, including the legality of the securities offered, has been passed upon for us by Gibson, Dunn & Crutcher LLP, San Francisco, California. Additional legal matters may be passed upon for us or any underwriters, dealers or agents, by counsel that we will name in the applicable prospectus supplement.

EXPERTS

The financial statements of Dianthus Therapeutics, Inc. as of December 31, 2023 and 2022, and for each of the two years in the period ended December 31, 2023, included in this registration statement have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report. Such financial statements are included in reliance upon the report of such firm given their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Exchange Act and are required to file annual, quarterly and other reports, proxy statements and other information with the SEC. The SEC maintains an Internet website (<http://www.sec.gov>) that contains reports, proxy and information statements, and various other information about us.

Information about us is also available at our website at <http://www.dianhustx.com>. You may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. However, the information on our website is not a part of this prospectus and is not incorporated by reference into this prospectus.

We have filed a registration statement on [Form S-1](#) with the SEC relating to the securities covered by this prospectus. This prospectus is a part of the registration statement and does not contain all of the information in the registration statement. Whenever a reference is made in this prospectus to a contract or other document of ours please be aware that the reference is only a summary and that you should refer to the exhibits that are part of the registration statement for a copy of the contract or other document. You may review a copy of the registration statement through the SEC's website or our website.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Dianthus Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Dianthus Therapeutics, Inc. (the “Company”) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, changes in convertible preferred stock and stockholders’ equity/(deficit) and cash flows, for each of the two years in the period ended December 31, 2023 and 2022, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Research and Development Expenses related to contract research organizations and contract development and manufacturing organizations—*Refer to Note 2 to the financial statements*

Critical Audit Matter Description

The Company incurs certain research and development expenses from third-party contract research organizations (“CROs”) and contract development and manufacturing organizations (“CDMOs”). The Company may pay for

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services on a monthly, quarterly, project or other basis. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided by the service providers and vendors, whereas payments are dictated by the terms of each agreement. As such, depending on the timing of payment relative to the receipt of goods or services, management may record either prepaid expenses or accrued services.

We identified research and development expenses related to CROs and CDMOs as a critical audit matter because of the judgments necessary for the Company to estimate the extent of service performed and the associated expense incurred. A high degree of auditor judgment and an increased extent of effort was required when auditing the Company's estimates of the extent of services performed and expenses incurred and evaluating the results of those procedures.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to research and development expenses related to CROs and CDMOs included the following, among others:

- We tested the design and implementation of controls over the estimation of research and development expenses related to CROs and CDMOs.
- We evaluated the Company's overall estimation methodology and assumptions to estimate the research and development expenses related to CROs and CDMOs and evaluated management's conclusions compared to the evidence obtained.
- We made selections and tested on a sample basis the research and development expenses related to CROs and CDMOs by:
 - Obtaining and reading the related contracts to understand key provisions and agree them to the Company's analysis.
 - Obtaining and inspecting third-party documents such as service contracts, status reports, and other correspondence received from the vendors related to the services provided and comparing them to the Company's schedule of estimated expenses incurred to date.
 - Obtaining and inspecting confirmations from select vendors confirming the accuracy and completeness of the data and information provided to the Company.
 - Testing the mathematical accuracy of the underlying analyses used in the estimates of the services provided.
 - We examined subsequent invoices received from vendors and cash disbursements made subsequent to December 31, 2023 and inquired of individuals within the clinical and manufacturing operations of the Company to corroborate the applicable service period in order to evaluate completeness of the research and development expenses related to CROs and CDMOs.

Accounting for the Reverse Merger and Pre-Funded Warrants —Refer to Notes 1 and 3 to the financial statements

Critical Audit Matter Description

As further described in Notes 1 and 3 to the financial statements, on September 11, 2023, the Company completed a reverse merger with Magenta Therapeutics, Inc, with Dianthus Therapeutics, Inc. as the surviving entity. The reverse merger was accounted for as a reverse asset acquisition accounted for as a reverse recapitalization in accordance with U.S. GAAP with the Company as the accounting acquirer of Magenta. Concurrently with the execution and delivery of the reverse merger, the Company entered into a subscription agreement with certain investors pursuant to which the Company issued and sold and the investors purchased, (i) 2,873,988 shares of the Company's common stock and (ii) 210,320 pre-funded warrants exercisable for 210,320 shares of the Company's common stock.

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We identified the evaluation of the reverse merger with Magenta Therapeutics, Inc. as a critical audit matter. Evaluating the Company's accounting treatment of the reverse merger required a high degree of auditor judgment to evaluate the Company's (i) determination of the accounting acquirer, (ii) assessment of the transaction as a reverse recapitalization, and (iii) the classification of the pre-funded warrants.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the reverse merger and pre-funded warrants included the following, among others:

- We tested the design and implementation of controls related to the transaction, including controls over management's determination of the (i) reverse merger accounting acquirer, (ii) reverse merger accounting model, and (iii) classification of the pre-funded warrants.
- We evaluated the determination of the (i) reverse merger accounting acquirer, (ii) reverse merger accounting model, and (iii) classification of the pre-funded warrants with the assistance of our subject matter experts.
- We inspected minutes of board of directors' meetings, executed transaction agreements, and other information to assess the nature and structure of the reverse merger and pre-funded warrants in evaluating management's conclusions.

/s/ Deloitte & Touche LLP
Morristown, New Jersey
March 21, 2024

We have served as the Company's auditor since 2022.

DIANTHUS THERAPEUTICS, INC.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	\$132,325	\$ 15,365
Short-term investments	41,393	60,125
Receivable from related party	294	4,700
Unbilled receivable from related party	184	938
Prepaid expenses and other current assets	3,255	905
Total current assets	177,451	82,033
Property and equipment, net	185	142
Right-of-use operating lease assets	615	814
Other assets and restricted cash	1,154	121
Total assets	<u>\$179,405</u>	<u>\$ 83,110</u>
Liabilities, Convertible Preferred Stock and Stockholders' Equity/(Deficit)		
Current liabilities:		
Accounts payable	\$ 2,610	\$ 1,167
Accrued expenses	6,504	6,608
Current portion of deferred revenue—related party	100	100
Current portion of operating lease liabilities	417	350
Total current liabilities	9,631	8,225
Deferred revenue—related party	736	791
Long-term operating lease liabilities	168	438
Total liabilities	10,535	9,454
Commitments and contingencies (Note 16)		
Convertible preferred stock; \$0.0001 par value per share; authorized shares – none and 33,336,283 at December 31, 2023 and 2022, respectively; issued and outstanding – none and 33,336,282 at December 31, 2023 and 2022, respectively; liquidation preference – none and \$121,500 at December 31, 2023 and 2022, respectively	—	118,024
Stockholders' equity/(deficit):		
Preferred stock; \$0.001 par value per share; authorized shares – 10,000,000 and none at December 31, 2023 and 2022, respectively; issued and outstanding – none at December 31, 2023 and 2022	—	—
Common stock, par value per share—\$0.001 and \$0.0001 at December 31, 2023 and 2022, respectively; authorized shares – 150,000,000 and 8,722,279 at December 31, 2023 and 2022, respectively; issued and outstanding shares – 14,817,696 and 875,279 at December 31, 2023 and 2022, respectively	15	—
Additional paid-in capital	258,231	1,661
Accumulated deficit	(89,423)	(45,868)
Accumulated other comprehensive income/(loss)	47	(161)
Total stockholders' equity/(deficit)	168,870	(44,368)
Total liabilities, convertible preferred stock and stockholders' equity/(deficit)	<u>\$179,405</u>	<u>\$ 83,110</u>

The accompanying notes are an integral part of these consolidated financial statements.

DIANTHUS THERAPEUTICS, INC.**Consolidated Statements of Operations and Comprehensive Loss****(in thousands, except share and per share data)**

	Year Ended December 31,	
	2023	2022
Revenues:		
License revenue—related party	\$ 2,826	\$ 6,417
Operating expenses:		
Research and development	32,841	29,379
General and administrative	18,159	6,743
Total operating expenses	51,000	36,122
Loss from operations	(48,174)	(29,705)
Other income/(expense):		
Interest income	4,764	1,145
(Loss)/gain on currency exchange, net	(85)	136
Other expense	(60)	(52)
Total other income	4,619	1,229
Net loss	\$ (43,555)	\$ (28,476)
Net loss per share attributable to common stockholders, basic and diluted	\$ (8.45)	\$ (32.57)
Weighted-average number of shares of common stock outstanding, used in computing net loss per share of common stock, basic and diluted	5,153,423	874,234
Comprehensive loss:		
Net loss	\$ (43,555)	\$ (28,476)
Other comprehensive income/(loss):		
Change in unrealized gains/(losses) related to available-for-sale debt securities	208	(161)
Total other comprehensive income/(loss)	208	(161)
Total comprehensive loss	\$ (43,347)	\$ (28,637)

The accompanying notes are an integral part of these consolidated financial statements.

DIANTHUS THERAPEUTICS, INC.
Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Equity/(Deficit)

(in thousands, except share data)

	<u>Convertible Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Income/(Loss)</u>	<u>Total Stockholders' Equity/ (Deficit)</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>				
Balance, December 31, 2021	10,329,265	\$ 21,348	875,279	\$ —	\$ 143	\$ (17,392)	\$ —	\$ (17,249)
Issuance of convertible preferred stock, net of issuance costs of \$3,324	23,007,017	96,676	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	1,518	—	—	1,518
Net loss	—	—	—	—	—	(28,476)	—	(28,476)
Other comprehensive loss	—	—	—	—	—	—	(161)	(161)
Balance, December 31, 2022	33,336,282	\$ 118,024	875,279	\$ —	\$ 1,661	\$ (45,868)	\$ (161)	\$ (44,368)
Exercise of common stock options	—	—	2,798	1	4	—	—	5
Conversion of convertible preferred stock to common stock in connection with the Reverse Merger	(33,336,282)	(118,024)	7,269,183	1	118,023	—	—	118,024
Issuance of common stock and pre-funded warrants in the pre-closing financing, net of issuance costs of \$4,250	—	—	2,873,988	—	67,750	—	—	67,750
Issuance of common stock to former stockholders of Magenta Therapeutics, Inc. in connection with the Reverse Merger	—	—	3,796,448	—	71,825	—	—	71,825
Adjustment for change in common stock par value in connection with the Reverse Merger	—	—	—	13	(13)	—	—	—
Reverse recapitalization transaction costs	—	—	—	—	(3,919)	—	—	(3,919)
Stock-based compensation expense	—	—	—	—	2,900	—	—	2,900
Net loss	—	—	—	—	—	(43,555)	—	(43,555)
Other comprehensive income	—	—	—	—	—	—	208	208
Balance, December 31, 2023	—	\$ —	14,817,696	\$ 15	\$258,231	\$ (89,423)	\$ 47	\$ 168,870

The accompanying notes are an integral part of these consolidated financial statements.

DIANTHUS THERAPEUTICS, INC.

Consolidated Statements of Cash Flows

(in thousands)

	Year Ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (43,555)	\$ (28,476)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	67	30
Stock-based compensation expense	2,900	1,518
Accretion of discount on short-term investments	(1,423)	(606)
Amortization of right-of-use operating lease assets	288	117
Changes in operating assets and liabilities:		
Receivable from related party	4,406	(4,231)
Unbilled receivable from related party	754	69
Prepaid expenses and other current assets	123	(631)
Other assets	(1,027)	(31)
Accounts payable, accrued expenses and lease liabilities	661	2,280
Deferred revenue—related party	(55)	891
Net cash used in operating activities	<u>(36,861)</u>	<u>(29,070)</u>
Cash flows from investing activities:		
Capital expenditures	(110)	(139)
Purchases of short-term investments	(57,422)	(61,680)
Proceeds from maturities of short-term investments	77,785	2,000
Net cash provided by/(used in) investing activities	<u>20,253</u>	<u>(59,819)</u>
Cash flows from financing activities:		
Proceeds from exercise of stock options	5	—
Proceeds from the pre-closing financing	72,000	—
Payment of issuance costs in connection with the pre-closing financing	(4,250)	—
Cash acquired in connection with the reverse recapitalization	69,738	—
Payment of reverse recapitalization transaction costs	(3,919)	—
Proceeds from issuance of promissory notes payable to related party	377	—
Repayment of promissory notes payable to related party	(377)	—
Proceeds from issuance of Series A convertible preferred stock	—	100,000
Payment of issuance costs for Series A convertible preferred stock	—	(3,324)
Net cash provided by financing activities	<u>133,574</u>	<u>96,676</u>
Increase in cash, cash equivalents and restricted cash	116,966	7,787
Cash, cash equivalents and restricted cash, beginning of period	\$ 15,425	\$ 7,638
Cash, cash equivalents and restricted cash, end of period	<u>\$ 132,391</u>	<u>\$ 15,425</u>
Supplemental Disclosure		
Cash and cash equivalents	\$ 132,325	\$ 15,365
Restricted cash	\$ 66	\$ 60
Total cash, cash equivalents and restricted cash	<u>\$ 132,391</u>	<u>\$ 15,425</u>
Cash paid for interest	<u>\$ —</u>	<u>\$ —</u>
Cash paid for taxes	<u>\$ —</u>	<u>\$ —</u>
Conversion of convertible preferred stock into common stock	<u>\$ 118,024</u>	<u>\$ —</u>
Additions to right-of-use lease assets from new operating lease liabilities	<u>\$ 89</u>	<u>\$ 931</u>

The accompanying notes are an integral part of these consolidated financial statements.

DIANTHUS THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except share and per share data, unless otherwise stated)

1. Organization, Description of Business and Liquidity

Business

Dianthus Therapeutics, Inc. (formerly Magenta Therapeutics, Inc.) (the “Company” or “Dianthus”) is a clinical-stage biotechnology company focused on developing next-generation complement therapeutics for patients with severe autoimmune and inflammatory diseases. The Company’s corporate headquarters are in New York, New York.

Currently, the Company is devoting substantially all efforts and resources toward product research and development of its product candidates. The Company has incurred losses from operations and negative operating cash flows since its inception. There can be no assurance that its research and development programs will be successful, that products developed, if any, will obtain necessary regulatory approval, or that any approved product, if any, will be commercially viable. In addition, the Company operates in an environment of rapid technological change and is largely dependent on the services of its key employees, consultants, and advisors.

Reverse Merger and Pre-Closing Financing

On September 11, 2023, the Company completed its business combination with Dianthus Therapeutics, OpCo Inc. (formerly Dianthus Therapeutics, Inc.) (“Former Dianthus”) in accordance with the terms of the Agreement and Plan of Merger, dated as of May 2, 2023 (the “Merger Agreement”), by and among the Company, Dio Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company (“Merger Sub”), and Former Dianthus, pursuant to which, among other matters, Merger Sub merged with and into Former Dianthus, with Former Dianthus surviving as a wholly owned subsidiary of the Company (the “Reverse Merger”). In connection with the completion of the Reverse Merger, the Company changed its name from “Magenta Therapeutics, Inc.” to “Dianthus Therapeutics, Inc.,” and the business conducted by the Company became primarily the business conducted by Former Dianthus. Unless context otherwise requires, references herein to “Dianthus,” the “Company,” or the “combined company” refer to Dianthus Therapeutics, Inc. (formerly Magenta Therapeutics, Inc.) after completion of the Reverse Merger, the term “Former Dianthus” refers to Dianthus Therapeutics OpCo, Inc. (formerly Dianthus Therapeutics, Inc.), and the term “Magenta” refers to the Company prior to completion of the Reverse Merger. The Company was incorporated in June 2015 and Former Dianthus was incorporated in May 2019.

Immediately prior to the effective time of the Reverse Merger, the Company effected a 1-for-16 reverse stock split of its common stock (the “Reverse Stock Split”). Unless noted otherwise, all references herein to share and per share amounts reflect the Reverse Stock Split.

At the effective time of the Reverse Merger, the Company issued an aggregate of 11,021,248 shares of Company common stock to the Former Dianthus stockholders, based on the exchange ratio of approximately 0.2181 shares of Company common stock for each share of Former Dianthus common stock, including those shares of Former Dianthus common stock issued upon the conversion of Former Dianthus preferred stock and those shares of the Former Dianthus common stock issued in the pre-closing financing (as defined below), resulting in 14,817,696 shares of Company common stock being issued and outstanding following the effective time of the Reverse Merger.

At the effective time of the Reverse Merger, the Dianthus Therapeutics, Inc. 2019 Stock Plan (the “2019 Stock Plan”) (as discussed in Note 12) was assumed by the Company, and each outstanding and unexercised option to purchase shares of Former Dianthus common stock immediately prior to the effective time of the

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Reverse Merger was assumed by the Company and converted into an option to purchase shares of Company common stock, with necessary adjustments to the number of shares and exercise price to reflect the exchange ratio, and each outstanding and unexercised warrant to purchase shares of Former Dianthus common stock immediately prior to the effective time of the Reverse Merger (including the Former Dianthus pre-funded warrants sold in the pre-closing financing) was converted into a warrant to purchase shares of Company common stock, with necessary adjustments to the number of shares and exercise price to reflect the exchange ratio.

The Reverse Merger was accounted for as a reverse recapitalization in accordance with generally accepted accounting principles in the United States of America (“U.S. GAAP”). Under this method of accounting, Former Dianthus was deemed to be the accounting acquirer for financial reporting purposes. This determination was primarily based on the expectation that, immediately following the Reverse Merger: (i) Former Dianthus’ stockholders own a substantial majority of the voting rights in the combined company; (ii) Former Dianthus’ largest stockholders retain the largest interest in the combined company; (iii) Former Dianthus designated a majority (six of eight) of the initial members of the board of directors of the combined company; and (iv) Former Dianthus’ executive management team became the management team of the combined company. Accordingly, for accounting purposes: (i) the Reverse Merger was treated as the equivalent of Former Dianthus issuing stock to acquire the net assets of Magenta; (ii) the net assets of Magenta are recorded at their acquisition-date fair value in the consolidated financial statements of Former Dianthus and (iii) the reported historical operating results of the combined company prior to the Reverse Merger are those of Former Dianthus. Additional information regarding the Reverse Merger is included in Note 3. Historical common share figures of Former Dianthus have been retroactively restated based on the exchange ratio of approximately 0.2181.

On September 11, 2023, prior to the effective time of the Reverse Merger, the Company entered into a contingent value rights agreement (the “CVR Agreement”) with a rights agent, pursuant to which pre-Reverse Merger holders of Magenta common stock received one non-transferable contingent value right (each, a “CVR”) for each outstanding share of Magenta common stock held by such stockholder immediately prior to the effective time of the Reverse Merger on September 11, 2023. Subject to, and in accordance with, the terms and conditions of the CVR Agreement, each CVR represents the contractual right to receive a pro rata portion of the proceeds, if any, received by the Company as a result of (i) contingent payments made to the Company, such as milestone, royalty or earnout, when received under any pre-Reverse Merger disposition agreements related to Magenta’s pre-Reverse Merger assets and (ii) the Company’s sale of assets after the effective date of the Reverse Merger and prior to December 31, 2023, in each case, received within a three-year period following the closing of the Reverse Merger. As of December 31, 2023, no payments have been received under the CVR Agreement.

Concurrently with the execution and delivery of the Merger Agreement, and in order to provide Former Dianthus with additional capital for its development programs, Former Dianthus entered into a subscription agreement, as amended (the “Subscription Agreement”), with certain investors named therein (the “Investors”), pursuant to which, subject to the terms and conditions of the Subscription Agreement, immediately prior to the effective time of the Reverse Merger, Former Dianthus issued and sold, and the Investors purchased, (i) 2,873,988 shares of Former Dianthus common stock and (ii) 210,320 pre-funded warrants, exercisable for 210,320 shares of Former Dianthus common stock, at a purchase price of approximately \$23.34 per share or \$23.34 per warrant, for an aggregate purchase price of approximately \$72.0 million (the “pre-closing financing”).

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, uncertainty of product development and commercialization, lack of marketing and sales history, development by its competitors of new technological innovations, dependence on its key personnel, market acceptance of products, product liability, protection of proprietary technology, ability to raise additional financing and compliance with government regulations. If the Company does not successfully commercialize any of its product candidates, it will be unable to generate recurring product revenue or achieve profitability.

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The Company's lead product candidate that is in development and any future product candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure, and extensive compliance-reporting capabilities. Even if its product development efforts are successful, it is uncertain when, if ever, the Company will generate revenue from product sales.

Liquidity

In accordance with Accounting Standards Update No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* (Subtopic 205-40), the Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the accompanying consolidated financial statements were issued (the "issuance date"):

- Since its inception, the Company has funded its operations primarily with outside capital and has incurred significant recurring losses, including net losses of \$43.6 million and \$28.5 million for the years ended December 31, 2023 and 2022, respectively. In addition, the Company had an accumulated deficit of \$89.4 million as of December 31, 2023;
- The Company expects to continue to incur significant recurring losses and rely on outside capital to fund its operations for the foreseeable future; and
- As of the issuance date, the Company expects that its existing cash, cash equivalents and short-term investments on hand as of the issuance date will be sufficient to fund its obligations as they become due for at least twelve months beyond the issuance date. The Company expects that its research and development and general and administrative costs will continue to increase significantly, including in connection with conducting clinical trials and manufacturing for its existing product candidate and any future product candidates to support commercialization and providing general and administrative support for its operations, including the costs associated with operating as a public company.

In the event the Company is unable to secure additional outside capital, management will be required to seek other alternatives which may include, among others, a delay or termination of clinical trials or the development of its product candidates, temporary or permanent curtailment of the Company's operations, a sale of assets, or other alternatives with strategic or financial partners.

The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

2. Summary of Significant Accounting Policies

Basis of Presentation

The financial statements have been prepared in conformity with U.S. GAAP. Any reference in these notes to applicable guidance is meant to refer to authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results may differ materially from those estimates.

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Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates including the following: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Significant estimates are used in the following areas, among others: the recognition of research and development expense, stock-based compensation expense and revenue recognition.

Cash and Cash Equivalents

All short-term, highly liquid investments with original maturities of 90 days or less are considered to be cash and cash equivalents. The carrying amounts reported in the consolidated balance sheets for cash and cash equivalents are valued at cost, which approximates fair value.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and short-term investments. The Company regularly maintains deposits in accredited financial institutions in excess of federally insured limits. The Company invests its excess cash primarily in money market funds, U.S. treasury securities and U.S. government agency securities in accordance with the Company's investment policy. The Company's investment policy defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of its investments to preserve principal and maintain liquidity. The Company has not experienced any realized losses related to its cash, cash equivalents and short-term investments and management believes the Company is not exposed to significant risks of losses.

As of December 31, 2023 and 2022, the Company held cash deposits at Silicon Valley Bank ("SVB") in excess of government insured limits. On March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation was appointed as receiver. No losses were incurred by the Company on deposits that were held at SVB. Management believes that the Company is not currently exposed to significant credit risk as the vast majority of the Company's deposits were either owned directly by the Company and held in custody at a third-party financial institution or, subsequent to March 10, 2023, have been transferred to a third-party financial institution. The Company does not currently have any other significant relationships with SVB.

Short-term Investments

Short-term investments consist of investments in U.S. treasury and U.S. government agency securities. Management of the Company determines the appropriate classification of the securities at the time they are acquired and evaluates the appropriateness of such classifications at each balance sheet date. The Company classifies its short-term investments as available-for-sale pursuant to ASC 320, *Investments – Debt and Equity Securities*, and reports them at fair value in short-term investments with unrealized gains and losses reported as a component of accumulated other comprehensive income loss on the consolidated balance sheet. Realized gains and losses and declines in value judged to be other than temporary are included as a component of interest income based on the specific identification method.

Effective January 1, 2023, when the fair value is below the amortized cost of a marketable security, an estimate of expected credit losses is made in accordance with ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The credit-related impairment amount is recognized in the consolidated statements of operations and comprehensive loss. Credit losses are

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recognized through the use of an allowance for credit losses account in the consolidated balance sheet and subsequent improvements in expected credit losses are recognized as a reversal of an amount in the allowance account. If the Company has the intent to sell the security or it is more likely than not that the Company will be required to sell the security prior to recovery of its amortized cost basis, then the allowance for the credit loss is written-off and the excess of the amortized cost basis of the asset over its fair value is recorded in the consolidated statements of operations and comprehensive loss. There were no credit losses recorded during the year ended December 31, 2023.

Additional information regarding short-term investments is included in Note 4.

Receivable from Related Party and Unbilled Receivable from Related Party

The receivable from related party and unbilled receivable from related party results from option and license agreements with Zenas BioPharma Limited (“Zenas”), a related party. See Notes 13 and 17 for more information. The receivable represents amounts earned and billed to Zenas but not yet collected while unbilled receivable represents amounts earned but not yet billed to Zenas. The receivable and unbilled receivable are reported at net realizable value. The Company regularly evaluates the creditworthiness of Zenas and their financial condition and does not require collateral from Zenas. As of December 31, 2023 and 2022, no allowance for doubtful accounts was recorded as all accounts were considered collectible.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is provided using the straight-line method over estimated useful lives of three years for computer equipment and five years for furniture and fixtures. Expenditures for major renewals and betterments that extend the useful lives are capitalized. Expenditures for normal maintenance and repairs are expensed as incurred. The cost of assets sold or abandoned, and the related accumulated depreciation are eliminated from the accounts and any gains or losses are recognized in the accompanying consolidated statements of operations and comprehensive loss of the respective period.

Leases

Operating leases are accounted for in accordance with ASU 2016-02, *Leases*, as amended (“ASC 842”). Right-of-use lease assets represent the right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments arising from the lease. The measurement of lease liabilities is based on the present value of future lease payments over the lease term. As the Company’s leases do not provide an implicit rate, management used the Company’s incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future lease payments. The right-of-use asset is based on the measurement of the lease liability and includes any lease payments made prior to or on lease commencement and excludes lease incentives and initial direct costs incurred, as applicable. Rent expense for operating leases is recognized on a straight-line basis over the lease term. The Company does not have any leases classified as finance leases. Management have elected the practical expedient to exclude short-term leases from right-of-use assets and lease liabilities.

The Company’s leases do not have significant rent escalation, holidays, concessions, material residual value guarantees, material restrictive covenants or contingent rent provisions. The Company’s leases include both lease (e.g., fixed payments including rent, taxes, and insurance costs) and non-lease components (e.g., common-area or other maintenance costs), which are accounted for as a single lease component as management have elected the practical expedient to group lease and non-lease components for all leases.

Additional information and disclosures required under ASC 842 are included in Note 9.

Restricted Cash

In accordance with ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, restricted cash is included as a component of cash, cash equivalents and restricted cash in the accompanying consolidated statements of cash flows. Restricted cash serves as collateral for a letter of credit securing office space. Restricted cash is recorded within other assets and restricted cash line item in the accompanying consolidated balance sheet.

Fair Value Measurements

The Company calculates the fair value of assets and liabilities that qualify as financial instruments and includes additional information in the notes to the consolidated financial statements when the fair value is different than the carrying value of these financial instruments.

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. ASC Topic 820, *Fair Value Measurements and Disclosures* ("ASC 820"), defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. ASC 820 establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available.

Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect management's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality.

The three levels of the fair value hierarchy are described below:

- Level 1 - Quoted prices in active markets for identical assets or liabilities.
- Level 2 - Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets and liabilities. This includes certain pricing models, discounted cash flow methodologies and similar valuation techniques that use significant unobservable inputs.

To the extent that a valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by management in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Management has segregated all financial assets and liabilities that are measured at fair value on a recurring basis into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date in the table below. The Company's valuation techniques for its Level 2 financial assets included using quoted prices for similar assets in active markets and quoted prices for similar assets in markets that are not active.

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The estimated fair value of receivable from related party, unbilled receivable from related party, accounts payable and accrued expenses approximate their carrying amounts due to the relatively short maturity of these instruments.

Additional information regarding fair value measurements is included in Note 7.

Classification of Convertible Preferred Stock

Convertible preferred stock is recorded at its original issuance price, less direct and incremental offering costs, as stipulated by its terms. The Company has applied the guidance in ASC 480-10-S99, *Distinguishing Liabilities from Equity-Overall-SEC Materials*, and has therefore classified the convertible preferred stock outside of stockholders' equity/(deficit) in the accompanying consolidated balance sheet. In September 2023, all outstanding shares of convertible preferred stock were converted into common shares immediately prior to the effective time of the Reverse Merger. Additional information and disclosures are included in Note 11.

Segment Information

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources and in assessing performance. The Company's CODM is its Chief Executive Officer. The Company operates as a single operating segment and has one reportable segment.

License Revenue—Related Party

To date, the Company's only revenue has been attributable to an upfront payment and cost reimbursements under the Company's license agreement with Zenas. The Company has not generated any revenue from product sales and does not expect to generate any revenue from product sales for the foreseeable future.

The Company recognizes revenue pursuant to ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when the performance obligation is satisfied.

The Company evaluates the performance obligations promised in a contract that are based on goods and services that will be transferred to the customer and determine whether those obligations are both (i) capable of being distinct and (ii) distinct in the context of the contract. To the extent a contract includes multiple promised goods and services, the Company applies judgment to determine whether promised goods and services are both capable of being distinct and are distinct in the context of the contract. If these criteria are not met, the promised goods and services are accounted for as a combined performance obligation. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations.

The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration or variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of potential transaction price and the likelihood that the transaction price will be received. Variable

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consideration is included in the transaction price if, in management's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Any estimates, including the effect of the constraint on variable consideration, are evaluated at each reporting period for any changes. The Company then allocates the transaction price to each performance obligation and recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in the Company's consolidated balance sheets. If the related performance obligation is expected to be satisfied within the next twelve months this will be classified in current liabilities.

Additional information and disclosures required under ASC 606 are included in Note 13.

Research and Development Costs

Research and development expenses are recorded as expense, as incurred. Research and development expenses consists of (i) costs to engage contractors who specialize in the development activities of the Company; (ii) external research and development costs incurred under arrangements with third parties, such as contract research organizations and consultants; and (iii) costs associated with preclinical activities and regulatory operations.

The Company enters into consulting, research, and other agreements with commercial firms, researchers, and others for the provision of goods and services. Under such agreements, the Company may pay for services on a monthly, quarterly, project or other basis. Such arrangements are generally cancellable upon reasonable notice and payment of costs incurred. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided by the service providers and vendors, whereas payments are dictated by the terms of each agreement. As such, depending on the timing of payment relative to the receipt of goods or services, management may record either prepaid expenses or accrued services. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on behalf of the Company.

Patent Costs

Patent costs are expensed as incurred and recorded within general and administrative expenses.

Income Taxes

Income taxes are recorded in accordance with ASC 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities and for loss and credit carryforwards using enacted tax rates anticipated to be in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. As of December 31, 2023 and 2022, the Company did not have any material uncertain tax positions. The Company recognizes interest and penalties related to uncertain tax positions, if any exist, in income tax expense.

Stock-Based Compensation

The Company accounts for stock-based compensation awards in accordance with ASC Topic 718, *Compensation – Stock Compensation* (“ASC 718”). ASC 718 requires all stock-based payments, including grants of stock options and restricted stock, to be recognized in the consolidated statements of operations and comprehensive loss based on their fair values. All of the stock-based awards are subject only to service-based vesting conditions. Management estimates the fair value of the stock option awards using the Black-Scholes option pricing model, which requires the input of assumptions, including (a) the fair value of the Company’s common stock, (b) the expected stock price volatility, (c) the calculation of expected term of the award, (d) the risk-free interest rate and (e) expected dividends. Management estimates the fair value of the restricted stock awards using the fair value of the Company’s common stock. Forfeitures are recognized as they are incurred.

Prior to the Reverse Merger, management utilized valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately Held Company Equity Securities Issued as Compensation*, to estimate the fair value of Former Dianthus common stock. Each valuation methodology included estimates and assumptions that required management’s judgment. These estimates and assumptions included objective and subjective factors, including external market conditions, the prices at which Former Dianthus sold shares of convertible preferred stock, the superior rights and preferences of the convertible preferred stock senior to Former Dianthus common stock at the time, and a probability analysis of various liquidity events, such as a public offering or sale of Former Dianthus, under differing scenarios. Changes to the key assumptions used in the valuations could have resulted in materially different fair values of Former Dianthus common stock at each valuation date. Following the Reverse Merger, the fair value of the Company’s common stock is based on the closing stock price on the date of grant as reported on the Nasdaq Capital Market.

Due to a lack of company-specific historical and implied volatility data, management bases its estimate of expected volatility on the historical volatility of a representative group of companies with similar characteristics to the Company, including stage of product development and life science industry focus. Management believes the group selected has sufficiently similar economic and industry characteristics and includes companies that are most representative of the Company.

Management uses the simplified method, as prescribed by the SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term. The risk-free interest rate is based on observed interest rates appropriate for the term of the awards. The dividend yield assumption is based on history and expectation of paying no dividends.

Compensation expense related to stock-based awards is calculated on a straight-line basis by recognizing the grant date fair value, over the associated service period of the award, which is generally the vesting term.

Additional information regarding share-based compensation is included in Note 12.

Comprehensive Loss

The only component of comprehensive loss other than net loss is change in unrealized losses related to available-for-sale debt securities.

Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders are calculated in conformity with the two-class method required for participating securities. Convertible preferred stock is a participating security in distributions of the Company. The net loss attributable to common stockholders is not allocated to the convertible preferred shares as the holders of convertible preferred shares do not have a contractual obligation to

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share in losses. Under the two-class method, basic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during each period. The weighted-average number of shares of common stock outstanding used in the basic net loss per share calculation does not include unvested restricted common stock as these shares are considered contingently issuable shares until they vest.

Diluted net loss per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as convertible preferred stock, stock options and unvested restricted common stock, which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive. For all periods presented, basic and diluted net loss per share were the same, as any additional share equivalents would be anti-dilutive.

Additional information is included in Note 15.

Recently Issued Accounting Pronouncements

On January 1, 2023, the Company adopted ASU No. 2016-13 using the modified retrospective approach, and no cumulative effect adjustment to accumulated deficit was needed as of the adoption date. Additionally, no prior period amounts were adjusted. The new standard adjusts the accounting for assets held at amortized cost basis, including short-term investments accounted for as available-for-sale, and receivables. The standard eliminates the probable initial recognition threshold and requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. The adoption of this standard did not have a material impact on the Company's consolidated financial statements and related disclosures.

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. ASU 2023-07 expands annual and interim disclosure requirements for reportable segments, primarily through enhanced disclosures about significant segment expenses. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and for interim periods beginning after December 14, 2024, with early adoption permitted. The Company is currently evaluating the guidance and has not determined the impact this standard may have on the consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740), Improvements to Income Tax Disclosures*, to enhance the transparency and decision usefulness of income tax disclosures. The enhancement will provide information to better assess how an entity's operations and related tax risks and tax planning and operational opportunities affect its tax rate and prospects for future cash flows. Investors currently rely on the rate reconciliation table and other disclosures, including total income taxes paid, to evaluate income tax risks and opportunities. ASU No. 2023-09 is effective for fiscal years beginning after December 15, 2024 and early adoption is permitted. The Company is currently evaluating the impact ASU No. 2023-09 will have on its consolidated financial statements and related disclosures.

3. Reverse Merger

As described in Note 1, Merger Sub merged with and into Former Dianthus, with Former Dianthus surviving as a wholly owned subsidiary of the Company on September 11, 2023. The Reverse Merger was accounted for as a reverse asset acquisition accounted for as a reverse recapitalization in accordance with U.S. GAAP with Former Dianthus as the accounting acquirer of Magenta. At the effective time of the Reverse Merger, substantially all the assets of Magenta consisted of cash and cash equivalents, marketable securities, as well as other nominal non-operating assets. Under such reverse recapitalization accounting, the assets and liabilities of Magenta were recorded at their fair value in Magenta's financial statements at the effective time of the Merger, which approximated book value due to the short-

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term nature. No goodwill or intangible assets were recognized. Consequently, the consolidated financial statements of the Company reflect the operations of Former Dianthus for accounting purposes together with a deemed issuance of shares, equivalent to the shares held by the former stockholders of Magenta, the legal acquirer, and a recapitalization of the equity of Former Dianthus, the accounting acquirer.

As part of the recapitalization, the Company obtained the assets and liabilities listed below:

Cash and cash equivalents	\$69,738
Other current assets	2,473
Accrued liabilities	(386)
Net assets acquired	<u>\$71,825</u>

The Company incurred \$0.5 million in stock-based compensation expense, as a result of the acceleration of vesting of stock options and restricted stock units for certain former employees of Magenta at the time of the Reverse Merger. Of this amount, \$0.2 million was recorded in the research and development expenses line item and \$0.3 million was recorded in the general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss for the year ended December 31, 2023. Additionally, the Company incurred transaction costs of \$3.9 million, and this amount was recorded as a reduction to additional paid-in capital in the consolidated statements of convertible preferred stock and stockholders' equity/(deficit) for the year ended December 31, 2023.

With respect to the CVRs issued in connection with the Reverse Merger, the Company believes that the achievement of the milestones outlined in the CVR Agreement are highly susceptible to factors outside the Company's influence that are not expected to be resolved for a long period of time, if at all. In particular, these amounts are primarily influenced by the actions and judgments of third parties and the buyers of such assets and are based on the buyers of such assets progressing the in-process research and development assets into clinical trials, and in the case of one of the agreements, to a regulatory milestone. If the Company were to record a receivable for such contingent payments, it would also record a corresponding liability. As of December 31, 2023, no receivables are recorded on the consolidated balance sheet relating to such contingent payments.

4. Short-Term Investments

The table below provides a summary of short-term investments:

	December 31, 2023			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
<u>Available-for-sale, short-term investments:</u>				
U.S. treasury securities	\$ 36,370	\$ 48	\$ —	\$36,418
U.S. government agency securities	4,976	—	(1)	4,975
Total available-for-sale, short-term investments	<u>\$ 41,346</u>	<u>\$ 48</u>	<u>\$ (1)</u>	<u>\$41,393</u>
	December 31, 2022			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
<u>Available-for-sale, short-term investments:</u>				
U.S. treasury securities	\$ 47,630	\$ 3	\$ (122)	\$47,511
U.S. government agency securities	12,656	—	(42)	12,614
Total available-for-sale, short-term investments	<u>\$ 60,286</u>	<u>\$ 3</u>	<u>\$ (164)</u>	<u>\$60,125</u>

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5. Prepaid Expenses and Other Current Assets

The following table provides a summary of prepaid expenses and other current assets:

	December 31,	
	2023	2022
Prepaid materials, supplies and research and development services	\$2,155	\$820
Prepaid insurance	596	32
Prepaid subscriptions, software and other administrative services	504	53
Prepaid expenses and other current assets	<u>\$3,255</u>	<u>\$905</u>

6. Property and Equipment

The following table provides a summary of property and equipment:

	December 31,	
	2023	2022
Computer equipment	\$234	\$131
Furniture and fixtures	48	41
Subtotal	282	172
Less: accumulated depreciation	(97)	(30)
Property and equipment, net	<u>\$185</u>	<u>\$142</u>

Depreciation expense was \$67 and \$30 for the years ended December 31, 2023 and 2022, respectively.

7. Fair Value of Financial Instruments

The following table provides a summary of financial assets measured at fair value on a recurring basis:

Description	Fair Value at December 31, 2023	Level 1	Level 2	Level 3
Recurring Assets:				
Cash equivalents:				
Money market fund	\$ 131,193	\$131,193	\$ —	\$ —
Short-term investments:				
U.S. treasury securities	36,418	36,418	—	—
U.S. government agency securities	4,975	—	4,975	—
Total assets measured at fair value	<u>\$ 172,586</u>	<u>\$167,611</u>	<u>\$4,975</u>	<u>\$ —</u>

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<u>Description</u>	<u>Fair Value at December 31, 2022</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Recurring Assets:				
Cash equivalents:				
Money market fund	\$ 11,846	\$11,846	\$ —	\$ —
U.S. government agency securities	1,999	—	1,999	—
Short-term investments:				
U.S. treasury securities	20,775	20,775	—	—
U.S. government agency securities	39,350	26,736	12,614	—
Total assets measured at fair value	<u>\$ 73,970</u>	<u>\$59,357</u>	<u>\$14,613</u>	<u>\$ —</u>

There were no transfers between levels for the years ended December 31, 2023 or 2022.

8. Accrued Expenses

The following table provides a summary of accrued expenses:

	<u>December 31,</u>	
	<u>2023</u>	<u>2022</u>
Accrued compensation	\$5,361	\$2,084
Accrued external research and development	456	4,329
Accrued professional fees	422	162
Accrued other expenses	265	33
Accrued expenses	<u>\$6,504</u>	<u>\$6,608</u>

9. Leases

The Company leases space under operating leases for administrative offices in New York, New York, and Waltham, Massachusetts and wet laboratory space in Watertown, Massachusetts. The Company also leased office space under operating leases, which had a non-cancelable lease term of less than one year and, therefore, management elected the practical expedient to exclude these short-term leases from right-of-use assets and lease liabilities.

The following table provides a summary of the components of lease costs and rent:

	<u>Year Ended December 31,</u>	
	<u>2023</u>	<u>2022</u>
Operating lease cost	\$ 366	\$ 198
Variable lease cost	28	4
Short-term lease cost	—	34
Total operating lease costs	<u>\$ 394</u>	<u>\$ 236</u>

The Company recorded the operating lease costs of \$0.4 million and \$0.2 million within the general and administrative expenses line item in the consolidated statements of operations and comprehensive loss during the years ended December 31, 2023 and 2022, respectively. The Company recorded the operating lease costs of \$17 and nil within the research and development expenses line item in the consolidated statements of operations and comprehensive loss during the years ended December 31, 2023 and 2022, respectively.

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Maturities of operating lease liabilities, which do not include short-term leases, as of December 31, 2023, are as follows:

2024	\$417
2025	222
Total undiscounted operating lease payments	\$639
Less: imputed interest	(54)
Present value of operating lease liabilities	<u>\$585</u>
<u>Balance sheet classification:</u>	
Current portion of lease liabilities	\$417
Long-term lease liabilities	168
Total operating lease liabilities	<u>\$585</u>

The weighted-average remaining term of operating leases was 19 months and the weighted-average discount rate used to measure the present value of operating lease liabilities was 10.6% as of December 31, 2023.

10. Common Stock

At the effective time of the Reverse Merger on September 11, 2023, the Company issued an aggregate of 11,021,248 shares of Company common stock to the Former Dianthus stockholders, based on the exchange ratio of approximately 0.2181 shares of Company common stock for each share of Former Dianthus common stock, including those shares of Former Dianthus common stock issued upon the conversion of Former Dianthus preferred stock and those shares of the Former Dianthus common stock issued in the pre-closing financing, resulting in 14,817,696 shares of Company common stock being issued and outstanding immediately following the effective time of the Reverse Merger.

As of December 31, 2023 and 2022, the Company was authorized to issue up to 150,000,000 shares of \$0.001 par value of Company common stock and 8,722,279 shares of \$0.0001 par value of Company common stock, respectively. As of December 31, 2023 and 2022, the Company had issued and outstanding shares of 14,817,696 and 875,279, respectively.

Each share of Company common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Company's board of directors, if any. No dividends have been declared or paid by the Company through December 31, 2023.

The Company had the following shares of Company common stock reserved for future issuance as of December 31, 2023 and 2022:

	December 31,	
	2023	2022
Conversion of convertible preferred stock	—	7,269,183
Issuance of common stock upon exercise of stock options	1,749,475	1,273,454
Equity awards available for grant under stock awards	879,461	414,679
Shares available for issuance under the Employee Stock Purchase Plan	37,078	—
Issuance of common stock upon exercise of warrants	214,997	4,677
Total common stock reserved for future issuance	<u>2,881,011</u>	<u>8,961,993</u>

11. Preferred Stock and Convertible Preferred Stock

Preferred Stock

As of December 31, 2023, the Company was authorized to issue up to 10,000,000 shares of preferred stock at a par value of \$0.001. As of December 31, 2023, no shares of preferred stock were issued and outstanding.

Convertible Preferred Stock

On September 11, 2023, the Company completed the Reverse Merger with Former Dianthus in accordance with the Merger Agreement. Under the terms of the Merger Agreement, immediately prior to the effective time of the Reverse Merger, each share of Former Dianthus convertible preferred stock was converted into a share of Former Dianthus common stock. At closing of the Reverse Merger, the Company issued an aggregate of 7,269,183 shares of its common stock to Former Dianthus convertible preferred stockholders, based on the exchange ratio of approximately 0.2181 shares of Company common stock for each share of Former Dianthus common stock outstanding immediately prior to the Reverse Merger.

The authorized, issued and outstanding shares of the convertible preferred stock and liquidation preferences of Former Dianthus as of December 31, 2022 were as follows:

	<u>Issued Dates</u>	<u>Authorized Shares</u>	<u>Shares Issued and Outstanding</u>	<u>Per Share Liquidation Preference</u>	<u>Aggregate Liquidation Amount</u>	<u>Proceeds (Net of Issuance Costs)</u>
Series Seed 1 Convertible Preferred Stock	July 2019, April 2020 and December 2020	6,500,000	6,500,000	\$ 1.000	\$ 6,500	\$ 6,436
Series Seed 2 Convertible Preferred Stock	May 2021	3,829,266	3,829,265	\$ 3.9172	15,000	14,912
Series A Convertible Preferred Stock	April 2022	23,007,017	23,007,017	\$ 4.3465	100,000	96,676
Total Convertible Preferred Stock		<u>33,336,283</u>	<u>33,336,282</u>		<u>\$ 121,500</u>	<u>\$ 118,024</u>

12. Stock-Based Compensation

Stock Option and Incentive Plan

The Company grants stock-based awards under the Amended and Restated Dianthus Therapeutics, Inc. Stock Option and Incentive Plan (the "Incentive Plan"), which originally became effective on June 19, 2018 as the Magenta Therapeutics, Inc. 2018 Stock Option and Incentive Plan and was amended and restated in September 2023 and renamed the Amended and Restated Dianthus Therapeutics, Inc. Stock Option and Incentive Plan. The Incentive Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock units, unrestricted stock awards, cash-based awards, and dividend equivalent rights. In connection with the Reverse Merger, the Incentive Plan also provided for the assumption of shares remaining available for delivery under the 2019 Stock Plan (as defined below), and such shares will be available for the granting of awards under the Incentive Plan in accordance with applicable stock exchange requirements. The Company also has outstanding stock options under the Magenta Therapeutics, Inc. 2016 Stock Option and Grant Plan, as amended (the "2016 Plan"), but is no longer granting awards under the 2016 Plan.

As of December 31, 2023, the total number of shares reserved under the Incentive Plan was equal to 2,529,070 shares of the Company's common stock, of which 879,461 shares of the Company's common stock was available for future issuance. The Incentive Plan provides that the number of shares reserved under the Incentive Plan will automatically increase each January 1 beginning with January 1, 2024 by 4% of the

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outstanding number of shares of the Company's common stock on the immediately preceding December 31 or such lesser number of shares as determined by the Company's board of directors or compensation committee of the board of directors. This number is subject to adjustment in the event of a stock split, stock dividend or other change in capitalization. Shares of common stock underlying any awards under the Incentive Plan and the 2016 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) will be available for future awards under the Incentive Plan.

The Incentive Plan is administered by either the board of directors or the compensation committee of the board of directors. The exercise prices, vesting and other restrictions are determined at the discretion of the administrator, except that the term of stock options and stock appreciation rights may not be greater than ten years (or five years for certain incentive stock options). Awards typically vest over 12 months to four years. The exercise price for stock options granted may not be less than the fair value of common stock as of the date of grant (or 110% of the fair value of common stock for certain incentive stock options). The fair value of common stock is based on quoted market prices.

2019 Stock Plan

In July 2019, Former Dianthus' Board of Directors adopted, and the Former Dianthus' stockholders approved, the Dianthus Therapeutics, Inc. 2019 Stock Plan (the "2019 Stock Plan"). In connection with the Reverse Merger, the Company assumed options to purchase shares of Former Dianthus's common stock that were outstanding under the 2019 Stock Plan immediately prior to the Reverse Merger and such options were converted into options to purchase 1,273,454 shares of Company's common stock (the "Assumed Options"). No further awards will be made under the 2019 Stock Plan; however, the Assumed Options will remain outstanding under the 2019 Stock Plan in accordance with their terms, as adjusted to reflect the Reverse Merger.

2019 Employee Stock Purchase Plan

Employees may elect to participate in the Dianthus Therapeutics, Inc. 2019 Employee Stock Purchase Plan (the "ESPP"). The purchase price of common stock under the ESPP is equal to 85% of the lower of the fair market value of the common stock on the offering date or the exercise date. The six-month offering periods previously began in December and June of each year. Offerings under the ESPP were suspended in May 2023. During the year ended December 31, 2023, there were no shares of common stock purchased under the ESPP. During the year ended December 31, 2022, 7,501 shares of common stock were purchased under the ESPP at a purchase price per share of \$15.36. As of December 31, 2023, 37,078 shares remained available for issuance under the ESPP.

The ESPP provides that the number of shares reserved and available for issuance under the ESPP will automatically increase each January 1 through January 1, 2029, by the lesser of (i) 1% of the number of shares issued and outstanding on the immediately preceding December 31, (ii) 62,500 shares and (iii) such number of shares as determined by the Company's board of directors or its appointed administrator.

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Stock Options

The following table summarizes stock option activity for the year ended December 31, 2023:

	Number of stock options outstanding	Weighted average exercise price per share	Weighted average remaining contractual term (in years)	Aggregate intrinsic value
Balance at January 1, 2023	529,773	\$ 94.59	8.2	\$ —
Assumption of options in connection with the Reverse Merger	1,273,454	7.95		177
Options granted, fair value of \$10.30 per share	610,641	12.09		159
Options exercised	(2,798)	1.66		46
Options forfeited	(661,595)	74.14		456
Balance at December 31, 2023	<u>1,749,475</u>	<u>\$ 10.61</u>	<u>8.4</u>	<u>\$ 3,181</u>
Exercisable options at December 31, 2023	<u>650,557</u>	<u>\$ 11.74</u>	<u>7.7</u>	<u>\$ 1,506</u>
Unvested options at December 31, 2023	1,098,918	\$ 9.95	8.8	\$ 1,675

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the fair value of the common stock for those options that had exercise prices lower than the fair value of the common stock.

The weighted average grant-date fair value per share of stock options granted during the year ended December 31, 2023 was \$10.30 per share.

The table below summarizes the assumptions used to determine the grant-date fair value of stock options issued, presented on a weighted average basis during the years ended December 31, 2023 and 2022:

	December 31,	
	2023	2022
Risk-free interest rate	4.0%	2.5%
Expected term (in years)	6.0	5.9
Expected volatility	87.5%	81.2%
Expected dividend yield	0.0%	0.0%

Restricted Stock Units

The following table summarizes restricted stock unit activity for the year ended December 31, 2023:

	Number of units outstanding	Weighted average grant date fair value per share
Balance at January 1, 2023	16,084	\$ 70.09
Restricted stock units granted	7,696	8.80
Restricted stock units vested	(6,495)	68.96
Restricted stock units forfeited	(17,285)	43.22
Balance at December 31, 2023	<u>—</u>	<u>\$ —</u>

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Restricted Stock

In April 2020, Former Dianthus executed a restricted stock award agreement with a consultant to purchase 3,052 shares of common stock at an exercise price of \$0.14 per share. The restricted stock award vested over a four-year requisite service period, with 25% vesting on the first anniversary of the vesting commencement date and 2.0833% per month thereafter. The agreement contained restrictions on the ability to sell, assign or pledge the shares awarded. The restricted stock agreement contained a right of repurchase whereby, at the election of the Company, the Company may purchase back all unvested stock should the relationship between the recipient and the Company cease. The fair value of the restricted stock award on the date of the award was \$0.14 per share.

Former Dianthus has not issued any restricted stock since April 2020. As of December 31, 2023, the restricted stock award was fully vested.

Stock Warrants

In April 2021, Former Dianthus issued 4,677 warrants for the purchase of common stock at an exercise price of \$1.65 per share. The warrants vested on July 30, 2023 and have a grant date fair value of \$1.16 per warrant. Former Dianthus has not issued any warrants since April 2021. As of December 31, 2023, the warrants have a weighted average remaining contractual term of 7.3 years.

Stock-based Compensation Expense

The following table provides a summary of stock-based compensation expense related to stock options, restricted stock units, restricted stock, and warrants:

	Year Ended December 31,	
	2023	2022
Research and development	\$ 897	\$ 416
General and administrative	2,003	1,102
Total stock-based compensation expense	<u>\$ 2,900</u>	<u>\$ 1,518</u>

As of December 31, 2023, there was \$7.9 million of total unrecognized compensation cost related to granted stock options. The Company expects to recognize that cost over a remaining weighted-average period of 2.6 years.

13. License Revenue—Related Party

In September 2020, the Company entered into an Option Agreement with Zenas (“Zenas Option”), a related party (See Note 17). Through the Zenas Option, the Company provided Zenas an option to enter into an exclusive license agreement for the development and commercialization of products arising from its research of monoclonal antibody antagonists targeting certain specific complement proteins.

In September 2021, the Company notified Zenas that it had elected the first antibody sequence as a clinical candidate. In October 2021, Zenas notified the Company that it was exercising its option for such clinical candidate. The Zenas Option provided that upon the exercise of the option, the Company would negotiate in good faith a license agreement with Zenas pursuant to which it would grant Zenas the exclusive license with respect to the antibody sequences for the Zenas territory, which includes People’s Republic of China, including Hong Kong, Macau, and Taiwan. In accordance with Zenas Option, within 60 days following the execution of a license agreement, Zenas agreed to pay the Company a one-time payment of \$1.0 million for the exercise of the corresponding option. In addition, in connection with the exercise of the Zenas Option, Zenas was required to reimburse the Company for a portion of chemistry, manufacturing, and controls-related (“CMC”) costs and expenses from the date of delivery of its option exercise notice through the execution of a license agreement.

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In June 2022, the Company and Zenas executed the license agreement (“Zenas License”). The Zenas Option and Zenas License are collectively referred to as the “Zenas Agreements”. The Zenas License provides Zenas with a license in the People’s Republic of China, including Hong Kong, Macau, and Taiwan, for the development and commercialization of sequences and products under the first antibody sequence. The Company is also obligated to perform certain research and development and CMC services, and will also participate in a joint steering committee (“JSC”). Under the Zenas License, Zenas also has the right to exercise an option with respect to a second antibody sequence. If Zenas exercises the option and pays the Company the option exercise fee related to the second antibody sequence, the Company will grant Zenas an exclusive license to the sequences and products under this second antibody sequence.

Since the Zenas Agreements were negotiated with a single commercial objective, they are treated as a combined contract for accounting purposes. The Company assessed the Zenas Agreements in accordance with ASC 606 and concluded that it represents a contract with a customer and is within the scope of ASC 606. The Company determined that there is one combined performance obligation that consists of the license and data transfer, the research and development and CMC services, and the participation in the JSC. The Company determined that Zenas’ right to exercise an option with respect to a second antibody sequence does not represent a material right.

The consideration under the Zenas Agreements includes the following payments by Zenas to the Company: (i) a \$1 million upfront payment upon execution of the Zenas License; (ii) an approximate \$1.1 million payment representing reimbursement for a portion of development costs previously incurred by the Company; (iii) reimbursement of a portion of all CMC-related costs and expenses for the first antibody sequence through the manufacture of the first two batches of drug product; (iv) reimbursement of a portion of all non-CMC-related costs and expenses for the development of the first antibody sequence through the first regulatory approval; (v) development milestones totaling up to \$11.0 million; and (vi) royalties on net sales ranging from the mid-single digits to the low teens.

The Company determined that the combined performance obligation is satisfied over time; therefore, the Company will recognize the transaction price from the license agreement over the Company’s estimated period to complete its activities. The Company concluded that it will utilize a cost-based input method to measure its progress toward completion of its performance obligation and to calculate the corresponding amount of revenue to recognize each period. The Company believes this is the best measure of progress because other measures do not reflect how the Company transfers its performance obligation to Zenas. In applying the cost-based input method of revenue recognition, the Company uses actual costs incurred relative to budgeted costs expected to be incurred for the combined performance obligation. These costs consist primarily of third-party contract costs. Revenue will be recognized based on the level of costs incurred relative to the total budgeted costs for the combined performance obligation. A cost-based input method of revenue recognition requires management to make estimates of costs to complete the Company’s performance obligation. In making such estimates, judgment is required to evaluate assumptions related to cost estimates.

The Company also determined that the milestone payments of \$11.0 million are variable consideration under ASC 606 which need to be added to the transaction price when it is probable that a significant revenue reversal will not occur. Based on the nature of the milestones, such as the regulatory approvals which are generally not within the Company’s control, the Company will not consider achievement of this milestone to be probable until the uncertainty associated with such milestone has been resolved. When it is probable that a significant reversal of revenue will not occur, the milestone payment will be added to the transaction price for which the Company recognizes revenue. As of December 31, 2023, no milestones had been achieved.

There is a sales or usage-based royalty exception within ASC 606 that applies when a license of intellectual property is the predominant item to which the royalty relates. In accordance with this royalty exception, the Company will recognize royalty revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). We have not recorded any royalty revenue to date.

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For the years ended December 31, 2023 and 2022, the Company recognized related party license revenue totaling \$2.8 million and \$6.4 million, respectively, associated with the Zenas Agreements. As of December 31, 2023, the Company recorded a related party receivable of \$0.3 million, unbilled related party receivable of \$0.2 million, current deferred related party revenue of \$0.1 million and noncurrent deferred related party revenue of \$0.7 million on its consolidated balance sheet. As of December 31, 2022, the Company recorded a related party receivable of \$4.7 million, unbilled related party receivable of \$0.9 million, current deferred related party revenue of \$0.1 million and noncurrent deferred related party revenue of \$0.8 million on its consolidated balance sheet.

14. Income Taxes

For the years ended December 31, 2023 and 2022, the Company recorded no current or deferred income tax expenses or benefits as it has incurred losses since inception and has provided a full valuation allowance against its deferred tax assets.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2023	2022
Federal statutory income tax rate	21.0%	21.0%
State taxes, net of federal benefit	2.1%	2.2%
Research tax credits	34.5%	2.2%
Tax attributes acquired as part of reverse merger	201.1%	—
Other	(1.7)%	(3.0)%
Increase in deferred tax asset valuation allowance	(257.0)%	(22.4)%
Effective income tax rate	<u>0.0%</u>	<u>0.0%</u>

The following table provides a summary of net deferred tax assets:

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	\$ 73,580	\$ 5,383
Capitalized research and development costs	22,446	4,315
Tax credit carryforwards	16,147	1,120
Lease liabilities	14,063	183
Share-based compensation	6,462	273
Amortization of license fees	3,209	—
Accrued expenses	795	484
Other	59	4
Gross deferred tax assets	<u>136,761</u>	<u>11,762</u>
Valuation allowance	<u>(123,452)</u>	<u>(11,566)</u>
Total deferred tax assets	13,309	196
Deferred tax liabilities:		
Right-of-use lease assets	(12,499)	(189)
Depreciation and amortization	(810)	—
Other	—	(7)
Total deferred tax liabilities	<u>(13,309)</u>	<u>(196)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

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As of December 31, 2023, the Company had federal net operating loss carryforwards of approximately \$320.7 million, all of which can be carried forward indefinitely. As of December 31, 2023, the Company had state tax net operating loss carryforwards of approximately \$299.1 million, which begin to expire in 2035. As of December 31, 2023, the Company also had available research and orphan drug tax credit carryforwards for federal and state income tax purposes of \$14.8 million and \$3.5 million, respectively, which begin to expire in 2035 and 2030, respectively.

In assessing the realizability of the net deferred tax assets, management considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the net operating loss carryforwards. Management believes that it is more likely than not that the Company's deferred income tax assets will not be realized.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2023 and 2022 related primarily to the increase in net operating loss carryforwards, capitalized research and development expenses and research tax credit carryforwards. During the years ended December 31, 2023 and 2022, capitalized research and development expenses increased pursuant to Section 174 of the Internal Revenue Code of 1986, as amended (the "Code"). The changes in the valuation allowance for the years ended December 31, 2023 and 2022 were as follows:

	<u>Year Ended December 31,</u>	
	<u>2023</u>	<u>2022</u>
Valuation allowance as of beginning of year	\$ 11,566	\$ 5,194
Net increases recorded to income tax provision	111,886	6,372
Valuation allowance as of end of year	<u>\$ 123,452</u>	<u>\$ 11,566</u>

Net operating loss carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50% as defined under Sections 382 and 383 in the Code, which could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the Company's value immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has not yet conducted a study to determine if any such changes have occurred that could limit the ability to use the net operating loss carryforwards. However, the Reverse Merger is expected to result in an ownership change. Therefore, the Company does not expect to be able to utilize a material portion of the net operating losses and research and orphan drug tax credit carryforwards.

The Company has not recorded any liabilities for unrecognized tax benefits as of December 31, 2023 or 2022. The Company will recognize interest and penalties related to uncertain tax positions, if any, in income tax expense. As of December 31, 2023 and 2022, the Company had no accrued interest or penalties related to uncertain tax positions.

15. Net Loss Per Share

Basic and diluted net loss per share of common stock were calculated as follows:

	Year Ended December 31,	
	2023	2022
Numerator:		
Net loss	\$ (43,555)	\$ (28,476)
Denominator:		
Weighted-average shares of common stock outstanding	5,153,711	875,279
Less: weighted-average unvested restricted shares of common stock	(288)	(1,045)
Weighted-average shares used to compute net loss per share of common stock, basic and diluted	5,153,423	874,234
Net loss per share attributable to common stockholders, basic and diluted	\$ (8.45)	\$ (32.57)

The Company's potential dilutive securities, which include convertible preferred stock, stock options, unvested restricted shares of common stock, and warrants for the purchase of common stock, have been excluded from the computation of diluted net loss per share as the effect would be antidilutive. Therefore, the weighted-average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share is the same. The following potential dilutive securities, presented on an as converted basis, were excluded from the calculation of net loss per share due to their anti-dilutive effect:

	Year Ended December 31,	
	2023	2022
Convertible preferred stock (as converted)	—	7,269,183
Stock options outstanding	1,749,475	1,273,454
Unvested restricted shares of common stock	—	635
Warrants for the purchase of common stock	214,997	4,677
Total	1,964,472	8,547,949

16. Commitments and Contingencies

Alloy Therapeutics, LLC:

In August 2019, the Company entered into a license agreement with Alloy Therapeutics, LLC ("Alloy"). The license agreement was amended in October 2022. The license agreement with Alloy grants to the Company the following:

- A worldwide, non-exclusive license to use the Alloy technology solely to generate Alloy antibodies and platform assisted antibodies for internal, non-clinical research purposes, and
- With respect to Alloy antibodies and platform assisted antibodies that are selected by the Company for inclusion into a partnered antibody program, a worldwide, assignable license to make, have made, use, offer for sale, sell, import, develop, manufacture, and commercialize products comprising partnered antibody programs selected from Alloy antibodies and platform assisted antibodies in any field of use.

The Company pays annual license fees and annual partnered antibody program fees totaling \$0.1 million to Alloy. The Company is also obligated to pay a \$0.1 million fee to Alloy if the Company sublicenses a product

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developed with Alloy antibodies or platform assisted antibodies. Upon the achievement, with the first selected antibody for products developed with Alloy, of (i) certain development milestones and (ii) certain commercial milestones, the Company is obligated to make additional payments to Alloy of up to \$1.8 million and \$11.0 million, respectively. Upon the achievement, with the second selected antibody for products developed with Alloy, of (i) certain development milestones and (ii) certain commercial milestones, the Company is obligated to make additional payments to Alloy of up to \$3.1 million and \$15.0 million, respectively. The Company recorded \$0.1 million and \$0.5 million for amounts owed under the Alloy license agreement within the research and development expenses line item in the consolidated statements of operations and comprehensive loss during the years ended December 31, 2023 and 2022, respectively.

OmniAb, Inc.:

In September 2022, the Company entered into a commercial platform license agreement and services agreement with two subsidiaries of Ligand Pharmaceuticals Incorporated. In November 2022, Ligand spun-off these subsidiaries into a separate legal entity, OmniAb, Inc. (“OmniAb”). The platform license agreement and services agreement with OmniAb grants to the Company the following:

- A worldwide, non-exclusive, non-sublicensable license under the OmniAb technology to use chicken animals (solely at OmniAb’s facilities and through OmniAb personnel) for generation of OmniAb antibodies for research purposes.
- A worldwide, non-exclusive license under the OmniAb technology to use rodent animals (solely at approved contract research organization (“CRO”) facilities and through approved CRO personnel) for generation of OmniAb antibodies for research purposes. Such license is non-sublicensable except to an approved CRO.

Upon the achievement of certain development milestones, the Company is obligated to make additional payments to OmniAb of up to \$12.2 million. Upon the achievement of certain commercial milestones, the Company is obligated to make royalty payments in the low to mid-single digits. The Company has recorded \$0.3 and \$0.1 million for amounts owed under the OmniAb license agreement within research and development expenses line item in the consolidated statements of operations and comprehensive loss during the years ended December 31, 2023 and 2022, respectively.

IONTAS Limited:

In July 2020, the Company entered into a collaborative research agreement with IONTAS Limited (“IONTAS”) to perform certain milestone-based research and development activities for the Company under its first development program. This agreement was amended in January 2023 to extend their services to additional development programs. IONTAS provides dedicated resources to perform the research and development activities and receives compensation for those resources as well as success-based milestone payments.

Upon the achievement, with the first development program with IONTAS, of (i) certain development milestones and (ii) certain commercial milestones, the Company is obligated to make additional payments to IONTAS of up to £3.1 million and £2.3 million, respectively. Upon the achievement, with the second development program with IONTAS, of certain development milestones, the Company is obligated to make additional payments to IONTAS of up to £2.5 million. The Company has recorded \$2.1 million and \$1.7 million for amounts owed under the IONTAS collaborative research license agreement within the research and development expenses line item in the consolidated statements of operations and comprehensive loss during the years ended December 31, 2023 and 2022, respectively.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to employees, consultants, vendors, business partners and other parties with respect to certain matters including, but

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not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. To date, the Company has not incurred any material costs as a result of such indemnification agreements. The Company is not aware of any indemnification arrangements that could have a material effect on its financial position, results of operations or cash flows, and has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2023 or 2022.

Litigation

From time to time, the Company may be exposed to litigation relating to potential products and operations. The Company is not currently engaged in any legal proceedings that are expected, individually or in the aggregate, to have a material adverse effect on its financial condition, results of operations or cash flows.

Other

As of December 31, 2023 and 2022, the Company had standing agreements with consultants, contractors or service providers whose terms do not yield material long-term commitments.

17. Related Party Transactions

Zenas BioPharma Limited:

The Company is a party to option and license agreements with Zenas, a related party. The Company considers Zenas to be a related party because (i) Tellus BioVentures LLC (“Tellus”), whose sole member is a significant shareholder in the Company and serves as Chairman of the Board of Directors of the Company, is also a significant shareholder in Zenas and serves as Chief Executive Officer and Chairman of the Board of Directors of Zenas and (ii) Fairmount Healthcare Fund LP and Fairmount Healthcare Fund II LP (together, the “Fairmount Funds”), who are significant shareholders in the Company and have a seat on the Board of Directors of the Company, are also significant shareholders in Zenas and have a seat on the Board of Directors of Zenas. As of December 31, 2023, Tellus and affiliated entities owned approximately 10%, and the Fairmount Funds and affiliated entities owned approximately 13% of the Company’s outstanding shares. See Note 13 for more information. In connection with these agreements, the Company recognized \$2.8 million and \$6.4 million within the license revenue – related party line item in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, the Company recorded a related party receivable of \$0.3 million, unbilled related party receivable of \$0.2 million, current deferred related party revenue of \$0.1 million and noncurrent deferred related party revenue of \$0.7 million on its consolidated balance sheet. As of December 31, 2022, the Company recorded a related party receivable of \$4.7 million, unbilled related party receivable of \$0.9 million, current deferred related party revenue of \$0.1 million and noncurrent deferred related party revenue of \$0.8 million on its consolidated balance sheet.

In 2020, Zenas issued 156,848 common shares to the Company in exchange for the Zenas Option. The Company determined that the fair value on the date of issuance and as of December 31, 2023 and 2022, respectively, was not material to its consolidated financial statements. The Company used the measurement alternative as the measurement attribute for accounting for the Zenas common shares which does not require it to assess the fair value of the common stock at each reporting period as the fair value of the Zenas common shares is not readily determinable nor is there a reliable source for observable transactions from which the Company could determine a fair value. In addition, the Company does not have ready access to significant events occurring at Zenas. If the Company does identify observable price changes in orderly transactions for the identical or similar common shares of Zenas, the Company will measure the common shares at fair value as of the date that the observable transaction occurred.

On March 13, 2023, the Fairmount Funds issued promissory notes in the aggregate principal amount of \$377 thousand to Former Dianthus at an interest rate of 4.5% per annum. On March 15, 2023, Former Dianthus repaid principal and interest in the amount of \$377 thousand to the Fairmount Funds in satisfaction of its obligations under the promissory notes.

18. Subsequent Events

The Company evaluated subsequent events from December 31, 2023, the date of these consolidated financial statements, through March 21, 2024, which represents the date the consolidated financial statements were issued, for events requiring recording or disclosure in the consolidated financial statements for the year ended December 31, 2023. The Company concluded that no events have occurred that would require recognition or disclosure in the consolidated financial statements except as noted below.

On January 22, 2024, the Company entered into a securities purchase agreement for a private placement with certain institutional and accredited investors. At the closing of the private placement on January 24, 2024, the Company sold and issued 14,500,500 shares of common stock at a price per share of \$12.00, and pre-funded warrants to purchase 4,666,332 shares of common stock at a purchase price of \$11.999 per pre-funded warrant, which represents the per share purchase price of the common stock less the \$0.001 per share exercise price for each pre-funded warrant, for an aggregate purchase price of approximately \$230 million. The pre-funded warrants are exercisable at any time after the date of issuance. A holder of pre-funded warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. A holder of pre-funded warrants may increase or decrease this percentage to a percentage not in excess of 19.99% by providing at least 61 days' prior notice to the Company.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The expenses payable by us in connection with the issuance and distribution of the securities being registered hereunder on Form S-1 (other than underwriting discounts and commissions, if any) are set forth below. The Selling Stockholders will not bear any portion of such expenses. Each item listed is estimated, except for the SEC registration fee:

SEC registration fee	\$ 59,626.26
Legal fees and expenses	\$ 150,000.00
Accounting fees and expenses	\$ 195,000.00
Printing and miscellaneous expenses	\$ 237,000.00
Total	\$ 641,626.26

Item 14. Indemnification of Officers and Directors

Section 145 of the DGCL authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

Dianthus has adopted provisions in its charter that limit or eliminate the personal liability of Dianthus' directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to Dianthus or its stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to Dianthus or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

Dianthus' bylaws provide that:

- Dianthus will indemnify its directors, officers and, in the discretion of its board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and

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- Dianthus will advance expenses, including attorneys' fees, to its directors and, in the discretion of its board of directors, to its officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of Dianthus, subject to limited exceptions.

Dianthus has entered into indemnification agreements with its directors and executive officers. These agreements provide that Dianthus will indemnify each of its directors and executive officers to the fullest extent permitted by Delaware law. Dianthus will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director or executive officer in connection with any proceeding in which indemnification is available and Dianthus will indemnify its directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of Dianthus or in furtherance of Dianthus' rights. Additionally, certain of Dianthus' directors may have certain rights to indemnification, advancement of expenses or insurance provided by their affiliates or other third parties, which indemnification relates to and might apply to the same proceedings arising out of such director's services as a director referenced herein. Nonetheless, Dianthus has agreed in the indemnification agreements that Dianthus' obligations to those same directors are primary and any obligation of such affiliates or other third parties to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

Dianthus also maintains general liability insurance which covers certain liabilities of its directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act.

Item 15. Recent Sales of Unregistered Securities

On January 24, 2024, in order to provide us with additional capital for our development programs, we completed a private placement of shares of Common Stock and the 2024 Pre-Funded Warrants pursuant to the Securities Purchase Agreement. Pursuant to and subject to the terms and conditions of the Securities Purchase Agreement, Dianthus issued and sold, and Selling Stockholders named in the Securities Purchase Agreement purchased 14,500,500 shares of Common Stock and 4,666,332 2024 Pre-Funded Warrants, exercisable for 4,666,332 shares of Common Stock, at a purchase price of \$12.00 per share or \$11.999 per 2024 Pre-Funded Warrant, which represents the per share purchase price of the Common Stock less the \$0.001 per share exercise price for each 2024 Pre-Funded Warrant, for an aggregate purchase price of approximately \$230.0 million. The issuance was made in a transaction not involving a public offering pursuant to an exemption from the registration requirements of the Securities Act, in reliance upon Section 4(a)(2) of the Securities Act and/or Rule 506 of Regulation D promulgated thereunder, or under any state securities laws.

On May 2, 2023, concurrently with the execution and delivery of the Merger Agreement, and in order to provide Former Dianthus with additional capital for its development programs, Former Dianthus entered into Subscription Agreement with the Investors. Pursuant to and subject to the terms and conditions of the Subscription Agreement, immediately prior to the effective time of the Merger, Former Dianthus issued and sold, and the Investors purchased, 2,873,988 shares of Former Dianthus common stock and 210,320 pre-funded warrants, exercisable for 210,320 shares of Former Dianthus common stock, at a purchase price of approximately \$23.34 per share or \$23.34 per warrant, for an aggregate purchase price of approximately \$72.0 million. The issuance was made in a transaction not involving a public offering pursuant to an exemption from the registration requirements of the Securities Act, in reliance upon Section 4(a)(2) of the Securities Act.

On May 12, 2021, Magenta entered into a securities purchase agreement with certain purchasers pursuant to which Magenta agreed to sell and issue to the purchasers in a private placement shares of common stock of Magenta. At the closing of the private placement on May 14, 2021, Magenta sold and issued to the selling stockholders 9,599,998 shares of its common stock at a purchase price of \$9.00 per share. The total purchase price paid by the selling stockholders at the closing was approximately \$86.4 million. Magenta issued the shares in reliance on the exemption from registration provided for under Section 4(a)(2) of the Securities Act. Magenta

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relied on this exemption from registration for private placements based in part on the representations made by the purchasers, including the representations with respect to each purchaser's investment intent. The offer and sale of the shares was not registered under the Securities Act. Magenta filed a resale registration statement with the SEC on June 25, 2021 to register the resale of the shares. Such information has not been adjusted to reflect the effects of the Reverse Stock Split.

Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
2.1†	<u>Agreement and Plan of Merger, dated as of May 2, 2023, by and among Magenta Therapeutics, Inc., Dio Merger Sub, Inc. and Dianthus Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Registration Statement on Form S-4 filed with the SEC on July 31, 2023).</u>
3.1	<u>Fifth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 12, 2023).</u>
3.2	<u>Third Amended and Restated By-laws (incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 21, 2024).</u>
4.1	<u>Form of Pre-Funded Warrant of Dianthus Therapeutics, Inc. (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 12, 2023).</u>
4.2	<u>Registration Rights Agreement, dated September 11, 2023, by and among Dianthus Therapeutics, Inc., Dianthus Therapeutics OpCo, Inc. and certain parties thereto (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed with the SEC on September 12, 2023).</u>
4.3	<u>Form of Pre-Funded Warrant of Dianthus Therapeutics, Inc. (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on January 22, 2024).</u>
4.4	<u>Registration Rights Agreement, dated January 22, 2024, by and among Dianthus Therapeutics, Inc. and certain parties thereto (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on January 22, 2024).</u>
5.1*	<u>Opinion of Gibson, Dunn & Crutcher LLP.</u>
10.1	<u>Contingent Value Rights Agreement, dated September 11, 2023, by and between Dianthus Therapeutics, Inc. and the Rights Agent (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 12, 2023).</u>
10.2#	<u>Form of Lock-Up Agreement (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the SEC on May 3, 2023).</u>
10.3#	<u>Form of Indemnification Agreements for Directors of the Company (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on September 12, 2023).</u>
10.4#	<u>Form of Indemnification Agreements for Officers of the Company (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the SEC on September 12, 2023).</u>
10.5#	<u>Amended and Restated Dianthus Therapeutics, Inc. Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed with the SEC on September 12, 2023).</u>
10.6#	<u>Dianthus Therapeutics, Inc. 2019 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 21, 2024).</u>

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<u>Exhibit Number</u>	<u>Description</u>
10.7#	<u>Form of Stock Option Agreement for Directors under the Amended and Restated Dianthus Therapeutics, Inc. Stock Option and Incentive Plan (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 filed with the SEC on October 4, 2023).</u>
10.8#	<u>Form of Stock Option Agreement for Executives under the Amended and Restated Dianthus Therapeutics, Inc. Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 21, 2024).</u>
10.9#	<u>Dianthus Therapeutics, Inc. 2019 Stock Plan (incorporated by reference to Exhibit 10.17 to Amendment No. 1 to the Registrant's Registration Statement on Form S-4 filed with the SEC on June 22, 2023).</u>
10.10#	<u>Form of Nonstatutory Stock Option Agreement under the Dianthus Therapeutics, Inc. 2019 Stock Plan (incorporated by reference to Exhibit 10.18 to Amendment No. 1 to the Registrant's Registration Statement on Form S-4 filed with the SEC on June 22, 2023).</u>
10.11#	<u>Form of Incentive Stock Option Agreement under the Dianthus Therapeutics, Inc. 2019 Stock Plan (incorporated by reference to Exhibit 10.19 to Amendment No. 1 to the Registrant's Registration Statement on Form S-4 filed with the SEC on June 22, 2023).</u>
10.12#	<u>Employment Agreement, dated October 23, 2021, by and between Dianthus Therapeutics, Inc. and Marino Garcia (incorporated by reference to Exhibit 10.13 to Amendment No. 1 to the Registrant's Registration Statement on Form S-4 filed with the SEC on June 22, 2023).</u>
10.13#	<u>Amendment to Offer Letter, dated September 11, 2023, by and between Dianthus Therapeutics OpCo, Inc. and Marino Garcia (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed with the SEC on September 12, 2023).</u>
10.14#	<u>Offer Letter, as amended, dated March 11, 2022, by and between Dianthus Therapeutics, Inc. and Simrat Randhawa (incorporated by reference to Exhibit 10.14 to Amendment No. 1 to the Registrant's Registration Statement on Form S-4 filed with the SEC on June 22, 2023).</u>
10.15#	<u>Amendment to Offer Letter, dated September 11, 2023, by and between Dianthus Therapeutics OpCo, Inc. and Simrat Randhawa (incorporated by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 21, 2024).</u>
10.16#	<u>Offer Letter, dated January 18, 2022, by and between Dianthus Therapeutics, Inc. and Ryan Savitz (incorporated by reference to Exhibit 10.15 to Amendment No. 1 to the Registrant's Registration Statement on Form S-4 filed with the SEC on June 22, 2023).</u>
10.17#	<u>Amendment to Offer Letter, dated September 11, 2023, by and between Dianthus Therapeutics OpCo, Inc. and Ryan Savitz (incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K filed with the SEC on September 12, 2023).</u>
10.18#	<u>Director Compensation Letter, dated May 6, 2022, by and between Dianthus Therapeutics, Inc. and Paula Soteropoulos (incorporated by reference to Exhibit 10.16 to Amendment No. 1 to the Registrant's Registration Statement on Form S-4 filed with the SEC on June 22, 2023).</u>
10.19#	<u>Separation Agreement, dated February 7, 2023, by and between Magenta Therapeutics, Inc. and Jason Gardner (incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 21, 2024).</u>
10.20#	<u>Separation Agreement, dated May 12, 2023, by and between Magenta Therapeutics, Inc. and Lisa Olson (incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 21, 2024).</u>
10.21#	<u>Separation Agreement, dated September 11, 2023, by and between Magenta Therapeutics, Inc. and Stephen Mahoney (incorporated by reference to Exhibit 10.12 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2023).</u>

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<u>Exhibit Number</u>	<u>Description</u>
10.22#	Separation Agreement, dated September 11, 2023, by and between Magenta Therapeutics, Inc. and Thomas Beetham (incorporated by reference to Exhibit 10.22 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 21, 2024).
10.23††	Biologics Master Services Agreement, dated as of March 22, 2021, by and between Dianthus Therapeutics, Inc. and WuXi Biologics (Hong Kong) Limited (incorporated by reference to Exhibit 10.24 to Amendment No. 2 to the Registrant's Registration Statement on Form S-4 filed with the SEC on July 17, 2023).
10.24††	Cell Line License Agreement, dated as of March 22, 2021, by and between Dianthus Therapeutics, Inc. and WuXi Biologics (Hong Kong) Limited (incorporated by reference to Exhibit 10.25 to Amendment No. 2 to the Registrant's Registration Statement on Form S-4 filed with the SEC on July 17, 2023).
10.25	Securities Purchase Agreement, dated as of January 22, 2024, by and between the Company and each purchaser identified in Annex A thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on January 22, 2024).
16.1	Letter from KPMG LLP, dated September 12, 2023 (incorporated by reference to Exhibit 16.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 12, 2023).
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 21, 2024).
23.1*	Consent of Deloitte & Touche LLP, independent registered public accounting firm of Dianthus Therapeutics, Inc.
23.2*	Consent of Gibson, Dunn & Crutcher LLP (included in Exhibit 5.1).
24.1	Power of Attorney (included on the signature page to the registration statement on Form S-3 filed with the SEC on October 4, 2023).
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).
107*	Filing Fee Table.
*	Filed herewith.
†	The annexes, schedules and certain exhibits to the Merger Agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Dianthus Therapeutics, Inc. hereby agrees to furnish supplementally a copy of any omitted annex, schedule or exhibit to the SEC upon request.
††	Portions of this exhibit (indicated by asterisks) have been omitted in accordance with the rules of the Securities and Exchange Commission.
#	Management contract or compensatory plan or arrangement.

(b) Financial statement schedules

None.

Item 17. Undertakings

(a) The undersigned Registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) to include any prospectus required by Section 10(a)(3) of the Securities Act;
 - (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Filing Fee Table" in the effective registration statement; and
 - (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;
- (2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the Offering.
- (4) That, for the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- (5) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer, or controlling person of the Registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on March 21, 2024.

DIANTHUS THERAPEUTICS, INC.

By: /s/ Ryan Savitz
Ryan Savitz
Chief Financial Officer

Pursuant to the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ Marino Garcia</u> Marino Garcia	President, Chief Executive Officer and Director (<i>Principal Executive Officer</i>)	March 21, 2024
<u>/s/ Ryan Savitz</u> Ryan Savitz	Chief Financial Officer (<i>Principal Financial Officer</i>)	March 21, 2024
<u>/s/ Edward Carr</u> Edward Carr	Chief Accounting Officer (<i>Principal Accounting Officer</i>)	March 21, 2024
<u>/s/ *</u> Leon O. Moulder, Jr.	Director and Chair of the Board	March 21, 2024
<u>/s/ *</u> Tomas Kiselak	Director	March 21, 2024
<u>/s/ *</u> Lei Meng	Director	March 21, 2024
<u>/s/ *</u> Paula Soteropoulos	Director	March 21, 2024
<u>/s/ *</u> Jonathan Violin, Ph.D.	Director	March 21, 2024
<u>/s/ *</u> Alison F. Lawton	Director	March 21, 2024
<u>/s/ *</u> Anne McGeorge	Director	March 21, 2024

*By: /s/ Ryan Savitz
Ryan Savitz, Attorney-in-fact

GIBSON DUNN

Gibson, Dunn & Crutcher LLP

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Client: 23553.00001

March 21, 2024

Dianthus Therapeutics, Inc.
7 Times Square, 43rd Floor
New York, New York 10036

Re: Dianthus Therapeutics, Inc.
Registration Statement on Form S-1

Ladies and Gentlemen:

We have acted as counsel to Dianthus Therapeutics, Inc., a Delaware corporation (the "Company"), in connection with the preparation and filing with the Securities and Exchange Commission (the "Commission") of a Registration Statement on Form S-1 (the "Registration Statement") pursuant to the Securities Act of 1933, as amended (the "Securities Act"), relating to the resale from time to time by the selling stockholders named therein of up to 21,326,988 shares of the Company's common stock, par value \$0.001 per share (the "Shares").

In arriving at the opinion expressed below, we have examined originals, or copies certified or otherwise identified to our satisfaction as being true and complete copies of the originals, of the specimen common stock certificates and such other documents, corporate records, certificates of officers of the Company and of public officials and other instruments as we have deemed necessary or advisable to enable us to render these opinions. In our examination, we have assumed the genuineness of all signatures, the legal capacity and competency of all natural persons, the authenticity of all documents submitted to us as originals and the conformity to original documents of all documents submitted to us as copies.

Based on the foregoing, and subject to the assumptions, exceptions, qualifications and limitations set forth herein, we are of the opinion that the Shares, when issued against payment therefor as set forth in the Registration Statement, will be validly issued, fully paid and non-assessable.

We consent to the filing of this opinion as an exhibit to the Registration Statement, and we further consent to the use of our name under the caption "Legal Matters" in the Registration Statement and the prospectus that forms a part thereof. In giving these consents, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission.

GIBSON DUNN

Very truly yours,

/s/ Gibson, Dunn & Crutcher LLP

Abu Dhabi • Beijing • Brussels • Century City • Dallas • Denver • Dubai • Frankfurt • Hong Kong • Houston • London •
Los Angeles • Munich • New York • Orange County • Palo Alto • Paris • Riyadh • San Francisco • Singapore • Washington, D.C.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use in this Registration Statement No. 333-274863 on Form S-1 of our report dated March 21, 2024, relating to the financial statements of Dianthus Therapeutics, Inc. We also consent to the reference to us under the heading “Experts” in such Registration Statement.

/s/ Deloitte & Touche LLP

Morristown, New Jersey

March 21, 2024

Calculation of Filing Fee Tables
FORM S-1
(Form Type)

Dianthus Therapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

	Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee	Carry Forward Form Type	Carry Forward File Number	Carry Forward Initial effective date	Filing Fee Previously Paid In Connection with Unsold Securities to be Carried Forward
Newly Registered Securities												
Fees to Be Paid	Equity	Common stock, par value \$0.001 per share ⁽¹⁾	Other	19,166,832 ⁽²⁾	\$19.5664 ⁽³⁾	\$375,025,901.6448 ⁽³⁾	0.00014760	\$55,353.82	—	—	—	—
Fees Previously Paid	Equity	Common stock, par value \$0.001 per share ⁽¹⁾	Other	2,160,156 ⁽⁴⁾	\$13.40 ⁽⁵⁾	\$28,946,090.40 ⁽⁵⁾	0.00014760	\$4,272.44	—	—	—	—
Carry Forward Securities												
Carry Forward Securities	N/A	N/A	N/A	N/A		N/A			N/A	N/A	N/A	N/A
	Total Offering Amounts					\$403,971,992.0448		\$59,626.26				
	Total Fees Previously Paid							\$59,626.26				
	Total Fee Offsets							—				
	Net Fee Due							\$—				

- (1) Pursuant to Rule 416 under the Securities Act of 1933, as amended (the “**Securities Act**”), this registration statement also covers such an indeterminate amount of shares of common stock of the registrant as may become issuable to prevent dilution resulting from stock splits, stock dividends and similar events.
- (2) The amount registered consists of (i) 14,500,500 shares of common stock of the registrant held by certain selling stockholders for which a registration fee was previously paid and (ii) 4,666,332 shares of common stock of the registrant issuable upon the exercise of 4,666,332 pre-funded warrants of the registrant held by certain selling stockholders for which a registration fee was previously paid.
- (3) Estimated solely for the purpose of calculating the registration fee, based on the average of the high and low prices of the shares of common stock of the registrant on The Nasdaq Capital Market on February 2, 2024 (such date being within five business days of the date that this registration statement was first filed with the U.S. Securities and Exchange Commission, in accordance with Rule 457(c) under the Securities Act).
- (4) The amount registered consists of (i) 1,949,836 shares of common stock of the registrant held by certain selling stockholders for which a registration fee was previously paid and (ii) 210,320 shares of common stock of the registrant issuable upon the exercise of 210,320 pre-funded warrants of the registrant held by certain selling stockholders for which a registration fee was previously paid.
- (5) Estimated solely for the purpose of calculating the registration fee, based on the average of the high and low prices of the shares of common stock of the registrant on The Nasdaq Capital Market on October 2, 2023 (such date being within five business days of the date that this registration statement was first filed with the U.S. Securities and Exchange Commission, in accordance with Rule 457(c) under the Securities Act).