UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K/A
(Amendment No. 1)

CURRENT REPORT
Pursuant to Section 13 OR 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 11, 2023

DIANTHUS THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38541**	**81-0724163**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

7 Times Square, 43rd Floor New York, New York	**10036**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (929) 999-4055

Magenta Therapeutics, Inc.
300 Technology Square, 8th Floor
Cambridge, Massachusetts
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value	DNTH	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 13(a) of the Exchange Act. ☐

Explanatory Note

This Amendment No. 1 on Form 8-K/A (this "***Amendment***") amends the Current Report on Form 8-K filed by Dianthus Therapeutics, Inc. (formerly Magenta Therapeutics, Inc.) (the "***Company***") with the U.S. Securities and Exchange Commission on September 12, 2023 (the "***Original Report***"), in which the Company reported, among other things, the completion of its previously announced business combination, pursuant to which Dio Merger Sub, Inc. merged with and into Dianthus Therapeutics OpCo, Inc. (formerly Dianthus Therapeutics, Inc.) ("***OpCo***"), with OpCo surviving as a wholly owned subsidiary of the Company.

This Amendment includes (i) the unaudited condensed financial statements of OpCo for the six months ended June 30, 2023 and 2022, (ii) the audited financial statements of OpCo for the years ended December 31, 2022 and 2021, (iii) the unaudited pro forma condensed combined financial information of the Company and OpCo as of June 30, 2023 and for the six months ended June 30, 2023 and for the year ended December 31, 2022, (iv) Management's Discussion and Analysis of Financial Condition and Results of Operations of OpCo for the six months ended June 30, 2023 and 2022, (v) Management's Discussion and Analysis of Financial Condition and Results of Operations of OpCo for the years ended December 31, 2022 and 2021, (vi) the Company's Risk Factors, (vii) the Company's Business Section and (viii) clarifications regarding the terms of the Class I, Class II and Class III directors of the board of directors of the Company (the "***Board***") and the amount of shares of common stock outstanding.

Except as described above, this Amendment does not amend or modify any other Item of the Original Report. Except as otherwise indicated herein, this Amendment does not purport to provide an update or a discussion of any developments at the Company or its subsidiaries subsequent to the filing date of the Original Report. The information previously reported in or filed with the Original Report is hereby incorporated by reference to this Amendment. The historical audited and unaudited financial statements of OpCo and the unaudited pro forma condensed combined financial information of the Company and OpCo included herein was excluded from the Original Report in reliance on Items 9.01(a) and 9.01(b).

Item 2.02. Results of Operations and Financial Condition.

The unaudited condensed financial statements of OpCo for the six months ended June 30, 2023 and 2022 and the related notes thereto are attached hereto as Exhibit 99.4 and are incorporated herein by reference.

Management's Discussion and Analysis of Financial Condition and Results of Operations of OpCo for the six months ended June 30, 2023 and 2022 is contained in Exhibit 99.3 attached hereto and is incorporated herein by reference.

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Appointment of Directors

As previously disclosed, on September 11, 2023, Marino Garcia and Paula Soteropoulos were appointed as Class I directors of the Board, Tomas Kiselak and Jonathan Violin, Ph.D., were appointed as Class II directors of the Board and Leon O. Moulder, Jr. and Lei Meng were appointed as Class III directors of the Board. Anne McGeorge and Alison F. Lawton continued as Class II and Class III directors of the Board, respectively. The terms of the Class I directors expire at the Company's 2025 annual meeting, the terms of the Class II directors expire at the Company's 2026 annual meeting and the terms of the Class III directors expire at the Company's 2024 annual meeting.

Item 8.01. Other Events.

The Company's Risk Factors and Business Section are attached hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference.

Management's Discussion and Analysis of Financial Condition and Results of Operations of OpCo for the years ended December 31, 2022 and 2021 is contained in Exhibit 99.3 attached hereto and is incorporated herein by reference.

As of September 21, 2023, the Company had 14,813,295 shares of common stock issued and outstanding.

Item 9.01. Financial Statements and Exhibits.

(a) *Financial Statements of Businesses Acquired.*

The unaudited condensed financial statements of OpCo for the six months ended June 30, 2023 and 2022 and the related notes thereto are attached hereto as Exhibit 99.4 and are incorporated herein by reference.

The audited financial statements of OpCo for the years ended December 31, 2022 and 2021 and the related notes thereto are attached hereto as Exhibit 99.5 and are incorporated herein by reference.

(b) *Pro Forma Financial Information.*

The unaudited pro forma condensed combined financial information of the Company and OpCo as of June 30, 2023 and for the six months ended June 30, 2023 and for the year ended December 31, 2022 and the related notes thereto are attached hereto as Exhibit 99.6 and are incorporated herein by reference.

(d) *Exhibits*

Exhibit No.	Description
23.1	Consent of Deloitte & Touche LLP, independent registered public accounting firm of Dianthus Therapeutics OpCo, Inc. (formerly Dianthus Therapeutics, Inc.)
99.1	Risk Factors of Dianthus Therapeutics, Inc.
99.2	Business Section of Dianthus Therapeutics, Inc.
99.3	Management's Discussion and Analysis of Financial Condition and Results of Operations of Dianthus Therapeutics OpCo, Inc. (formerly Dianthus Therapeutics, Inc.) for the six months ended June 30, 2023 and 2022 and for the years ended December 31, 2022 and 2021.
99.4	Unaudited condensed financial statements of Dianthus Therapeutics OpCo, Inc. (formerly Dianthus Therapeutics, Inc.) for the six months ended June 30, 2023 and 2022.
99.5	Audited financial statements of Dianthus Therapeutics OpCo, Inc. (formerly Dianthus Therapeutics, Inc.) for the years ended December 31, 2022 and 2021.
99.6	Unaudited pro forma condensed combined financial information of Dianthus Therapeutics, Inc. and Dianthus Therapeutics OpCo, Inc. (formerly Dianthus Therapeutics, Inc.) as of June 30, 2023 and for the six months ended June 30, 2023 and for the year ended December 31, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DIANTHUS THERAPEUTICS, INC.

Date: September 21, 2023

By: /s/ Ryan Savitz
Name: Ryan Savitz
Title: Chief Financial Officer

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-257381 and 333-266511 on Form S-3 and Registration Statements Nos. 333-225838, 333-230387, 333-233125, 333-236853, 333-253815 and 333-263358 on Form S-8 of Magenta Therapeutics, Inc. of our report dated May 15, 2023, relating to the financial statements of Dianthus Therapeutics, Inc. appearing in this Current Report on Form 8-K/A dated September 20, 2023.

/s/ Deloitte & Touche LLP

Morristown, New Jersey
September 20, 2023

RISK FACTORS

Investing in Dianthus Therapeutics, Inc., or Dianthus, securities involves a high degree of risk. You should carefully consider the risk factors set forth below and under "Risk Factors" in Dianthus' Annual Report on Form 10-K for the year ended December 31, 2022 as updated by subsequent filings under the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act, before deciding whether to purchase Dianthus securities. The risks and uncertainties described below and in the documents mentioned above are not the only ones Dianthus faces. Additional risks and uncertainties not presently known to Dianthus could adversely affect its business, operating results and financial condition, as well as adversely affect the value of an investment in Dianthus securities, and the occurrence of any of these risks might cause you to lose all or part of your investment. Terms not defined herein shall have the meanings ascribed to them in Dianthus' definitive proxy statement/prospectus filed with by the U.S. Securities and Exchange Commission on August 1, 2023 (the "Definitive Proxy Statement/Prospectus").

Summary of Risk Factors

- Dianthus has a limited operating history, has not completed any clinical trials and has no products approved for commercial sale, which may make it difficult for you to evaluate its current business and likelihood of success and viability;
- Dianthus will require substantial additional capital to finance its operations in the future. If Dianthus is unable to raise such capital when needed, or on acceptable terms, Dianthus may be forced to delay, reduce or eliminate clinical trials, product development programs or future commercialization efforts;
- OpCo has incurred significant losses since inception, and Dianthus expects to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. Dianthus has no products for sale, has not generated any product revenue and may never generate product revenue or become profitable;
- Dianthus faces competition from entities that have developed or may develop programs for the diseases it plans to address with DNTH103 or other product candidates;
- DNTH103 and Dianthus' 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 Dianthus or its current or future collaborators are unable to complete development of, or commercialize, Dianthus' product candidates, or experience significant delays in doing so, its business will be materially harmed;
- Dianthus is substantially dependent on the success of its most advanced product candidate, DNTH103, and its anticipated clinical trials of such candidate may not be successful;
- If Dianthus does not achieve its projected development goals in the time frames Dianthus announces and expects, the commercialization of DNTH103 or any other product candidates may be delayed;
- Dianthus' approach to the discovery and development of product candidates is unproven, and Dianthus may not be successful in its 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 Dianthus' preclinical studies and clinical trials are not sufficient to support regulatory approval of any of its product candidates, Dianthus may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate;
- If Dianthus encounters difficulties enrolling patients in its future clinical trials, its clinical development activities could be delayed or otherwise adversely affected;
- Dianthus has collaborations with third parties, including its existing license and development collaboration with Zenas BioPharma. If Dianthus is unable to maintain these collaborations, or if these collaborations are not successful, segments of its business could be adversely affected;

- Dianthus has identified material weaknesses in its internal control over financial reporting which, if not corrected, could affect the reliability of its financial statements and have other adverse consequences;
- In order to successfully implement its plans and strategies, Dianthus will need to grow the size of its organization and Dianthus may experience difficulties in managing this growth;
- Dianthus' ability to protect its patents and other proprietary rights is uncertain, exposing Dianthus 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 Dianthus is not able to obtain, or if there are delays in obtaining, required regulatory approvals for its product candidates, Dianthus will not be able to commercialize, or will be delayed in commercializing, such product candidates, and its ability to generate revenue will be materially impaired;
- Dianthus may not be able to meet requirements for the chemistry, manufacturing and control of its product candidates;
- Dianthus' product candidates for which it intends to seek approval as biologics may face competition sooner than anticipated;
- The market price of Dianthus' common stock is expected to be volatile, the market price of the common stock may drop, and active trading market for Dianthus' common stock may not be sustained and its stockholders may not be able to sell their shares of common stock for a profit, if at all;
- Dianthus may be unable to integrate successfully the businesses of Dianthus and OpCo and realize the anticipated benefits of the merger;
- Provisions in Dianthus' certificate of incorporation and bylaws and under Delaware law could make an acquisition of Dianthus more difficult and may discourage any takeover attempts which stockholders may consider favorable, and may lead to entrenchment of management; and
- Dianthus will incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.

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

Dianthus has a limited operating history, has not completed any clinical trials and has no products approved for commercial sale, which may make it difficult for you to evaluate its current business and likelihood of success and viability.

Dianthus is a clinical-stage biotechnology company with limited operating history that has incurred significant operating losses and has utilized substantially all of its resources to conduct research and development activities (including with respect to its DNTH103 program) and undertake preclinical studies of product candidates, conducting a clinical trial of Dianthus' most advanced product candidate and the manufacturing of the product candidates, business planning, developing and maintaining its intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these activities. Dianthus has limited experience as a company in initiating, conducting or completing clinical trials. In part because of this lack of experience, Dianthus cannot be certain that its current and planned clinical trials will begin or be completed on time, if at all. In addition, while Dianthus is evaluating DNTH103 in an ongoing Phase 1 clinical trial, Dianthus has not completed a clinical trial for any product candidate, has no products approved for commercial sale and has not yet demonstrated its ability to successfully complete 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 its behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Additionally, Dianthus expects its 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 its control. Consequently, any predictions made about Dianthus' future success or viability may not be as accurate as they could be if Dianthus had a longer operating history.

In addition, as its business grows, Dianthus may encounter unforeseen expenses, restrictions, difficulties, complications, delays and other known and unknown factors. Dianthus 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. Dianthus may not be successful in such a transition.

Dianthus will require substantial additional capital to finance its operations in the future. If Dianthus is unable to raise such capital when needed, or on acceptable terms, Dianthus 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 its inception, OpCo has funded its operations primarily through private financings and has incurred significant recurring losses, including net losses of $18.2 million for the six months ended June 30, 2023 and $28.5 million and $13.1 million for the years ended December 31, 2022 and 2021, respectively. Dianthus expects its expenses to increase in connection with its ongoing activities, particularly as Dianthus conducts its ongoing Phase 1 clinical trial of DNTH103, prepares for an investigational new drug application ("IND") and other regulatory filings, initiates additional clinical trials, and continues to research, develop and conduct preclinical studies of its other potential product candidates. In addition, if Dianthus obtains regulatory approval for any product candidate for commercial sale, including DNTH103, Dianthus anticipates incurring significant commercialization expenses related to product manufacturing, marketing, sales and distribution activities to launch any such product. Dianthus' expenses could increase beyond expectations if Dianthus is required by the FDA or other regulatory agencies to perform preclinical studies or clinical trials in addition to those that Dianthus currently anticipates. Because the design and outcome of its current, planned and anticipated clinical trials are highly uncertain, Dianthus cannot reasonably estimate the actual amount of funding that will be necessary to successfully complete the development and commercialization of any product candidate Dianthus develops. Dianthus' future capital requirements depend on many factors, including factors that are not within its control.

Dianthus will also incur additional costs associated with operating as a public company that OpCo did not incur as a private company. Accordingly, Dianthus will require substantial additional funding to continue its operations. Based on its current operating plan, Dianthus believes that its existing cash, cash equivalents and short-term investments should be sufficient to fund its operations into the second quarter of 2026. This estimate is based on assumptions that may prove to be materially wrong, and Dianthus could use its available capital resources sooner than it currently expects. Dianthus' 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 Dianthus pursues;
- its 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 Dianthus encounters any serious adverse events in its 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 Dianthus establishes 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;
- its arrangements with its 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 its planned clinical trials and for commercial launch;
- the impact of any business interruptions to its operations or to those of the third parties with whom Dianthus works, particularly in light of the current COVID-19 pandemic environment; and
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights.

Dianthus does not have any committed external sources of funds and adequate additional financing may not be available to it on acceptable terms, or at all. Dianthus 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 its stockholders or the failure to obtain such financing may restrict its operating activities. Any additional fundraising efforts may divert Dianthus' management from their day-to-day activities, which may adversely affect its business. To the extent that Dianthus raises 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 Dianthus' business. If Dianthus raises additional funds through upfront payments or milestone payments pursuant to future collaborations with third parties, Dianthus may have to relinquish valuable rights to product development programs, or grant licenses on terms that are not favorable to it. Dianthus' 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 Dianthus may have no or little control. Dianthus' failure to raise capital as and when needed or on acceptable terms would have a negative impact on its financial condition and its ability to pursue its business strategy, and Dianthus may have to delay, reduce the scope of, suspend or eliminate clinical trials, product development programs or future commercialization efforts.

OpCo has incurred significant losses since inception, and Dianthus expects to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. Dianthus has no products for sale, has 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. Dianthus has no products approved for commercial sale, Dianthus has not generated any revenue from product sales to date, and Dianthus continues to incur significant research and development and other expenses related to its ongoing operations. Dianthus does not expect to generate product revenue unless or until Dianthus successfully completes clinical development and obtains regulatory approval of, and then successfully commercializes, at least one product candidate. Dianthus may never succeed in these activities and, even if Dianthus does, may never generate product revenue or revenues that are significant or large enough to achieve profitability. If Dianthus is unable to generate sufficient revenue through the sale of any approved products, Dianthus may be unable to continue operations without additional funding.

OpCo has incurred significant net losses in each period since it commenced operations in 2019. Dianthus' net loss was $18.2 million for the six months ended June 30, 2023 and $28.5 million for the year ended December 31, 2022. Dianthus expects to continue to incur significant losses for the foreseeable future. Dianthus' operating expenses and net losses may fluctuate significantly from quarter to quarter and year to year. Dianthus anticipates that its expenses will increase substantially if and as Dianthus:

- advances its existing and future programs through preclinical and clinical development, including expansion into additional indications;
- seeks to identify additional programs and additional product candidates;
- maintains, expands, enforces, defends and protects its intellectual property portfolio;
- seeks regulatory and marketing approvals for product candidates;
- seeks to identify, establish and maintain additional collaborations and license agreements;
- ultimately establishes a sales, marketing and distribution infrastructure to commercialize any drug products for which Dianthus may obtain marketing approval, either by itself or in collaboration with others;
- generates revenue from commercial sales of products for which Dianthus receives marketing approval;
- hires additional personnel including research and development, clinical and commercial;
- adds operational, financial and management information systems and personnel, including personnel to support product development;
- acquires or in-licenses products, intellectual property and technologies; and
- establishes commercial-scale current good manufacturing practices ("cGMP") capabilities through a third-party or its own manufacturing facility.

In addition, Dianthus' expenses will increase if, among other things, it is required by the U.S. Food and Drug Administration (the "FDA") or other regulatory authorities to perform trials or studies in addition to, or different than, those that Dianthus currently anticipates, there are any delays in completing its clinical trials or the development of any product candidates, or there are any third-party challenges to its intellectual property or Dianthus needs to defend against any intellectual property-related claim.

Even if Dianthus obtains marketing approval for, and is successful in commercializing, one or more product candidates, Dianthus expects 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. Dianthus may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect its business. The size of its future net losses will depend, in part, on the rate of future growth of its expenses and its ability to generate revenue.

Dianthus' failure to become profitable would decrease the value of the company and could impair its ability to raise capital, maintain its research and development efforts, expand its business and/or continue its operations. A decline in the value of the company could also cause you to lose all or part of your investment.

In addition, management of OpCo have previously evaluated adverse conditions and events that raised substantial doubt about OpCo's ability to continue as a going concern, and its independent registered public accounting firm included an explanatory paragraph in its report on its financial statements as of and for the year ended December 31, 2022 included elsewhere herein with respect to this uncertainty. This substantial doubt about OpCo's ability to continue as a going concern could materially limit Dianthus' ability to raise additional funds through the issuance of new debt or equity securities or otherwise. Future reports on its financial statements may include an explanatory paragraph with respect to its ability to continue as a going concern.

There is no assurance that adequate additional financing needed to allow Dianthus to continue as a going concern will be available to Dianthus on acceptable terms, or at all. The perception that Dianthus may not be able to continue as a going concern may cause others to choose not to do business with Dianthus due to concerns about its ability to meet its contractual obligations.

Risks Related to Discovery, Development and Commercialization

Dianthus faces competition from entities that have developed or may develop programs for the diseases it plans 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 Dianthus' failure to effectively compete may prevent it from achieving significant market penetration. Dianthus competes 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 Dianthus is 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 Dianthus does. Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of its competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with Dianthus 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.

Dianthus' 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. Dianthus' success will depend partially on its ability to develop and commercialize products that have a competitive safety, efficacy, dosing and/or presentation profile. Dianthus' 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 Dianthus may develop, if any, or if competitors develop competing products or if biosimilars enter the market more quickly than Dianthus is able to, if at all, and are able to gain market acceptance.

DNTH103 and Dianthus' 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 Dianthus or its current or future collaborators are unable to complete development of, or commercialize, Dianthus' product candidates, or experience significant delays in doing so, its business will be materially harmed.

Dianthus has no products on the market and DNTH103 and Dianthus' other programs are in early stages of development. As a result, Dianthus expects it will be many years before it commercializes any product candidate, if any. Dianthus' 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 Dianthus cannot guarantee that it will ever obtain regulatory approval for any product candidates. Dianthus has 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. Dianthus has also not yet demonstrated its ability to obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on its behalf, or conduct sales and marketing activities necessary for successful product commercialization. Before obtaining regulatory approval for the commercial distribution of product candidates, Dianthus 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.

Dianthus or its collaborators may experience delays in initiating or completing clinical trials.

Dianthus or its collaborators also may experience numerous unforeseen events during, or as a result of, any current or future clinical trials that Dianthus could conduct that could delay or prevent its ability to receive marketing approval or commercialize DNTH103 or any other product candidates, including:

- regulators or institutional review boards ("IRBs"), the FDA or ethics committees may not authorize Dianthus or its investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- Dianthus 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 Dianthus may decide, or regulators may require Dianthus, to conduct additional preclinical studies or clinical trials or Dianthus may decide to abandon product development programs;
- the number of subjects required for clinical trials of any Dianthus' product candidates may be larger than it anticipates, especially if regulatory bodies require completion of non-inferiority or superiority trials, enrollment in these clinical trials may be slower than Dianthus anticipates or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than Dianthus anticipates;
- Dianthus' third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to Dianthus 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 Dianthus add new clinical trial sites or investigators;
- Dianthus may elect to, or regulators, IRBs or ethics committees may require that Dianthus or its investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in its trials are being exposed to unacceptable health risks;
- the cost of clinical trials of any of Dianthus' product candidates may be greater than it anticipates;
- the quality of Dianthus' product candidates or other materials necessary to conduct clinical trials of its product candidates may be inadequate to initiate or complete a given clinical trial;
- Dianthus' inability to manufacture sufficient quantities of its product candidates for use in clinical trials;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about its product candidates;
- Dianthus' 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 its product candidates; and
- the FDA or other regulatory authorities may require Dianthus to submit additional data such as long- term toxicology studies, or impose other requirements before permitting Dianthus to initiate a clinical trial.

Commencing clinical trials in the United States is subject to acceptance by the FDA of an IND or similar application and finalizing the trial design. In the event that the FDA requires Dianthus to complete additional preclinical studies or Dianthus is required to satisfy other FDA requests prior to commencing clinical trials, the start of its clinical trials may be delayed. Even after Dianthus receives and incorporates guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that Dianthus has satisfied their requirements to commence any clinical trial or change their position on the acceptability of its trial design or the clinical endpoints selected, which may require Dianthus to complete additional preclinical studies or clinical trials, delay the enrollment of its clinical trials or impose stricter approval conditions than Dianthus currently expects. There are equivalent processes and risks applicable to clinical trial applications in other countries, including countries in the European Union.

Dianthus may not have the financial resources to continue development of, or to modify existing or enter into new collaborations for, a product candidate if Dianthus experiences any issues that delay or prevent regulatory approval of, or its ability to commercialize, DNTH103 or any other product candidates. Dianthus or its 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 its business, financial condition, results of operations, cash flows, and prospects.

Dianthus is substantially dependent on the success of its most advanced product candidate, DNTH103, and its anticipated clinical trials of such candidate may not be successful.

Dianthus' future success is substantially dependent on its ability to timely obtain marketing approval for, and then successfully commercialize, its most advanced product candidate, DNTH103. Dianthus is investing a majority of its efforts and financial resources into the research and development of this candidate. Dianthus recently reported positive topline results from its Phase 1 clinical trial in healthy volunteers of DNTH103, and pending clearance of any IND or CTA that Dianthus plans to submit, Dianthus anticipates initiating a Phase 2 clinical trial in the first quarter 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 Dianthus plans 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 Dianthus generates any revenues from product sales, if any. Dianthus is not permitted to market or promote this product candidate, or any other product candidates, before it receives marketing approval from the FDA and/or comparable foreign regulatory authorities, and Dianthus may never receive such marketing approvals.

The success of DNTH103 will depend on a variety of factors. Dianthus does not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to its intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. Accordingly, Dianthus cannot guarantee that it will ever be able to generate revenue through the sale of this candidate, even if approved. If Dianthus is not successful in commercializing DNTH103, or is significantly delayed in doing so, its business will be materially harmed.

If Dianthus does not achieve its projected development goals in the time frames Dianthus announces and expects, the commercialization of DNTH103 or any other product candidates may be delayed.

From time to time, Dianthus estimates the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which Dianthus 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. From time to time, Dianthus may 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 its estimates, in some cases for reasons beyond its control. If Dianthus does 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.

Dianthus' approach to the discovery and development of product candidates is unproven, and Dianthus may not be successful in its efforts to build a pipeline of product candidates with commercial value.

Dianthus' 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 its 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.

Dianthus may ultimately discover that its technologies for its specific targets and indications and DNTH103 or any product candidates resulting therefrom do not possess certain properties required for therapeutic effectiveness. Dianthus currently has only preclinical and limited preliminary data from its ongoing Phase 1 clinical trial regarding properties of DNTH103 and the same results may not be seen in patients. 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 possibly harmful ways.

In addition, Dianthus may in the future seek to discover and develop product candidates that are based on novel targets and technologies that are unproven. If its discovery activities fail to identify novel targets or technologies for drug discovery, or such targets prove to be unsuitable for treating human disease, Dianthus may not be able to develop viable additional product candidates. Dianthus and its existing or future collaborators may never receive approval to market and commercialize DNTH103 or any other product candidates. Even if Dianthus 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 Dianthus 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, Dianthus' product candidates and pipeline may have little, if any, value, which may have a material and adverse effect on its 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 Dianthus' preclinical studies and clinical trials are not sufficient to support regulatory approval of any of its product candidates, Dianthus 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, Dianthus must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of its product candidate in humans. Dianthus' 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, Dianthus depends on the availability of non-human primates ("NHPs") to conduct certain preclinical studies that Dianthus is required to complete prior to submitting an IND 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 its future preclinical studies to increase significantly and, if the shortage continues, could also result in delays to Dianthus' 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, Dianthus expects 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 its 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.

Dianthus cannot be sure that the FDA or comparable foreign regulatory authorities will agree with its clinical development plan.

Dianthus plans to use the data from its ongoing Phase 1 clinical trial of DNTH103 in healthy volunteers to support Phase 2 clinical trials in generalized Myasthenia gravis ("gMG"), multifocal motor neuropathy ("MMN"), chronic inflammatory demyelinating polyneuropathy ("CIDP") and other indications. If the FDA or comparable regulatory authorities require Dianthus to conduct additional trials or enroll additional patients, its development timelines may be delayed. Dianthus cannot be sure that submission of an IND, a Clinical Trial Application ("CTA") or similar application will result in the FDA or comparable foreign regulatory authorities, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Events that may prevent successful or timely initiation or completion of clinical trials include: inability to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials; delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials; delays or failure in obtaining regulatory authorization to commence a trial; delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; delays in identifying, recruiting and training suitable clinical investigators; delays in obtaining required IRB approval at each clinical trial site; difficulties in patient enrollment in Dianthus' clinical trials for a variety of reasons; delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of its product candidates for use in clinical trials or the inability to do any of the foregoing; failure by its CROs, other third parties or Dianthus 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 its CDMOs or Dianthus to make any necessary changes to such manufacturing process; and third parties being unwilling or unable to satisfy their contractual obligations to Dianthus.

Dianthus could also encounter delays if a clinical trial is placed on clinical hold, suspended or terminated by Dianthus, 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 ("DSMB") or equivalent body for such trial, or on account of changes to federal, state, or local laws. If Dianthus is required to conduct additional clinical trials or other testing of DNTH103 or any other product candidates beyond those that Dianthus contemplates, if Dianthus is 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, its business and results of operations may be adversely affected and Dianthus may incur significant additional costs.

Dianthus may not be successful in its efforts to identify or discover additional product candidates in the future.

A key part of Dianthus' business strategy is to identify and develop additional product candidates. Its 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, Dianthus may be unable to identify or design additional product candidates with the pharmacological and pharmacokinetic drug properties that Dianthus desires, 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 Dianthus is unable to identify suitable active selective complement targets for preclinical and clinical development, Dianthus may not be able to successfully implement its business strategy, and may have to delay, reduce the scope of, suspend or eliminate one or more of its product candidates, clinical trials or future commercialization efforts, which would negatively impact its financial condition.

If Dianthus encounters difficulties enrolling patients in its future clinical trials, its clinical development activities could be delayed or otherwise adversely affected.

Dianthus may experience difficulties in patient enrollment in its future clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on its 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 its competitors have ongoing clinical trials for product candidates that are under development for the same indications as Dianthus' 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 Dianthus anticipates, especially if regulatory bodies require the completion of non-inferiority or superiority trials. Even if Dianthus is able to enroll a sufficient number of patients for its future clinical trials, Dianthus may have difficulty maintaining patients in its clinical trials. Its 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 Dianthus to abandon one or more clinical trials altogether.

Preliminary, "topline" or interim data from its clinical trials that Dianthus announces or publishes from time to time may change as more patient data becomes available and are subject to audit and verification procedures.

From time to time, Dianthus may publicly disclose preliminary or topline data from its 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. Dianthus also makes assumptions, estimations, calculations and conclusions as part of its analyses of these data without the opportunity to fully and carefully evaluate complete data. As a result, the preliminary or topline results that Dianthus 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. From time to time, Dianthus may also disclose interim data from its 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 its clinical trials continue other treatments. Further, others, including regulatory agencies, may not accept or agree with its 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 Dianthus in general. In addition, the information Dianthus chooses 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 Dianthus determines is material or otherwise appropriate information to include in its disclosure. If the preliminary, topline or interim data that Dianthus reports differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, Dianthus' ability to obtain approval for, and commercialize, DNTH103 or any other product candidate may be harmed, which could harm its business, financial condition, results of operations, cash flows, and prospects.

Dianthus' current or future clinical trials or those of its future collaborators may reveal significant adverse events or undesirable side effects not seen in its 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 Dianthus' clinical trials could reveal a high and unacceptable severity and prevalence of side effects, adverse events or unexpected characteristics. While its completed preclinical studies in NHPs and its ongoing Phase 1 clinical trial in humans have not shown any such characteristics to date, Dianthus has not yet completed its clinical trial in humans.

If significant adverse events or other side effects are observed in any of its current or future clinical trials, Dianthus may have difficulty recruiting patients to such trials, patients may drop out of its trials, patients may be harmed, or Dianthus may be required to abandon the trials or its development efforts of one or more product candidates altogether, including DNTH103. Dianthus, 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 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 its clinical trials or could result in potential product liability claims. Potential side effects associated with DNTH103 or any other product candidates may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from DNTH103 or any other product candidates may not be normally encountered in the general patient population and by medical personnel. Any of these occurrences could harm Dianthus' business, financial condition, results of operations, cash flows, and prospects significantly.

In addition, even if Dianthus successfully advances 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, Dianthus 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 Dianthus' 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, Dianthus' entire pipeline could be affected, which would have a material adverse effect on its business, financial condition, results of operations, cash flows, and prospects.

Dianthus may expend its 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 Dianthus has limited financial and managerial resources, Dianthus intends to focus its research and development efforts on certain selected product candidates. For example, Dianthus is initially focused on its most advanced product candidate, DNTH103. As a result, Dianthus may forgo or delay pursuit of opportunities with other potential candidates that may later prove to have greater commercial potential. Dianthus' resource allocation decisions may cause Dianthus to fail to capitalize on viable commercial products or profitable market opportunities. Dianthus' spending on current and future research and development programs for specific indications may not yield any commercially viable product candidates. If Dianthus does not accurately evaluate the commercial potential or target market for a particular product candidate, Dianthus 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 Dianthus 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 Dianthus 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. Dianthus 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 Dianthus 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 Dianthus or its existing or future collaborators. Market acceptance of DNTH103 or any other product candidates will depend on many factors, including factors that are not within its control.

Sales of products also depend on the willingness of clinicians to prescribe the treatment. Dianthus cannot predict whether clinicians, clinicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that any of its 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, Dianthus may not generate or derive sufficient revenue from that product and may not become or remain profitable.

Dianthus has never commercialized a product candidate and may lack the necessary expertise, personnel and resources to successfully commercialize a product candidate on its own or together with suitable collaborators.

Dianthus has never commercialized a product candidate, and Dianthus currently has no sales force, marketing or distribution capabilities. To achieve commercial success for a product candidate, which Dianthus may license to others, Dianthus may rely on the assistance and guidance of those collaborators. For a product candidate for which Dianthus retains commercialization rights and marketing approval, Dianthus will have to develop its own sales, marketing and supply organization or outsource these activities to a third party. Factors that may affect its ability to commercialize a product candidate, if approved, on its own include recruiting and retaining adequate numbers of effective sales and marketing personnel, developing adequate educational and marketing programs to increase public acceptance of its approved product candidate, ensuring regulatory compliance of Dianthus, 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. Dianthus may not be able to build an effective sales and marketing organization. If Dianthus is unable to build its own distribution and marketing capabilities or to find suitable partners for the commercialization of an approved product candidate, Dianthus may not generate revenues from them or be able to reach or sustain profitability.

Dianthus has never completed any late-stage clinical trials and Dianthus may not be able to file an IND, a CTA or other applications for regulatory approval to commence additional clinical trials on the timelines Dianthus expects, and, even if Dianthus is able to, the FDA, EMA or comparable foreign regulatory authorities may not permit Dianthus to proceed and could also suspend/terminate the trial after it has been initiated.

Dianthus is early in its 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 its product candidates. Carrying out clinical trials and the submission of a successful IND or CTA is a complicated process. As an organization, Dianthus has not yet completed a Phase 1 clinical trial and has limited experience as a company in preparing, submitting and prosecuting regulatory filings. Since the announcement of positive topline results from its Phase 1 clinical trial of DNTH103, to support the initiation of a global Phase 2 clinical trial in gMG, Dianthus intends to submit an IND in the United States in the fourth quarter of 2023 and, subsequently, a CTA in the European Union in the first quarter of 2024. However, Dianthus may not be able to file the IND or CTA in accordance with its desired timelines. For example, Dianthus 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 Dianthus depends.

Moreover, Dianthus 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 Dianthus to suspend or terminate clinical trials. For example, upon submission of its IND or CTA for a Phase 2 clinical trial of DNTH103, the FDA or EMA may recommend changes to its proposed study designs, including the number and size of registrational clinical trials required to be conducted in such Phase 2 programs. Consequently, Dianthus may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of its 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 its trials may prevent Dianthus from completing its clinical trials or commercializing its products on a timely basis, if at all. Dianthus is subject to similar risks related to the review and authorization of its protocols and amendments by comparable foreign regulatory authorities.

Risks Related to Its Reliance on Third Parties

Dianthus currently relies 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 Dianthus may rely on third parties to produce and process its products, if approved. Dianthus' business could be adversely affected if it is unable to use third-party manufacturing suites or if the third-party manufacturers encounter difficulties in production.

Dianthus does not currently lease or own any facility that may be used as its clinical-scale manufacturing and processing facility and currently relies on a CDMO, WuXi Biologics (as defined below), to manufacture Dianthus' product candidate used in its Phase 1 clinical trial. Dianthus currently has a sole source relationship with WuXi Biologics for its supply of DNTH103 (see the section titled "*Dianthus' Business—Collaboration, License and Services Agreements*" in Exhibit 99.2 of Dianthus' Current Report on Form 8-K/A filed with the SEC on September 21, 2023 (the "Current Report on Form 8-K/A") of which this Exhibit 99.1 is a part for additional information on Dianthus' relationship with WuXi Biologics). If there should be any disruption in such supply arrangement, including any adverse events affecting Dianthus' sole supplier, Wuxi Biologics, it could have a negative effect on the clinical development of Dianthus' product candidates and other operations while Dianthus works to identify and qualify an alternate supply source. Dianthus may not control the manufacturing process of, and may be completely dependent on, its 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. Dianthus performs periodic audits of each CDMO facility that supports its supply of DNTH103 and reviews/approves all DNTH103 cGMP-related documentation. Dianthus also has a quality agreement with WuXi Biologics that documents its mutual agreement on compliance with cGMPs and expectations on quality-required communications to Dianthus. Beyond this, Dianthus has no control over the ability of its 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, Dianthus may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and materially and adversely affect Dianthus' ability to develop, obtain regulatory approval for or market such product candidate, if approved. Similarly, Dianthus' failure, or the failure of its CDMO, to comply with applicable regulations could result in sanctions being imposed on Dianthus, 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 Dianthus' business and results of operations. In addition, Dianthus has not yet caused any product candidates to be manufactured on a commercial scale and may not be able to do so for any of its product candidates, if approved.

Moreover, Dianthus' 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 conflict between Russian and Ukraine, may affect Dianthus' third-party vendors and cause delays. Furthermore, since Dianthus has engaged WuXi Biologics, a manufacturer located in China, Dianthus is 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 Dianthus is required to change manufacturers for any reason, Dianthus 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 Dianthus needs to transfer from WuXi Biologics, which is Dianthus' sole manufacturing source for DNTH103, Dianthus anticipates 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 Dianthus is able to identify an alternative source, could negatively affect Dianthus' ability to supply product candidates, including DNTH103, in a timely manner or within budget. If any CDMO on which Dianthus will rely fails to manufacture quantities of a product candidate at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows Dianthus to achieve profitability, Dianthus' business, financial condition, cash flows, and prospects could be materially and adversely affected. In addition, Dianthus' 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, Dianthus' integrity and purity specifications. Dianthus and its CDMO may also face product seizure or detention or refusal to permit the import or export of products. Dianthus' business could be materially adversely affected by business disruptions to its third-party providers that could materially adversely affect its anticipated timelines, potential future revenue and financial condition and increase Dianthus' costs and expenses. Each of these risks could delay or prevent the completion of Dianthus' preclinical studies and clinical trials or the approval of any of its product candidates by the FDA, result in higher costs or adversely impact commercialization of Dianthus' products.

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

Dianthus works closely with its 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. Dianthus' 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 Dianthus' clinical trials. Further, while Dianthus works with its 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 Dianthus' ability to manufacture its product candidates in a timely or cost-effective manner and could delay completion of Dianthus' clinical trials, product testing, and potential regulatory approval of Dianthus' product candidates.

Dianthus currently relies, and plans to rely in the future, on third parties to conduct and support its preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, Dianthus may not be able to obtain regulatory approval of or commercialize its product candidates.

Dianthus utilizes and plans 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 its preclinical studies and clinical trials under agreements with Dianthus. Dianthus will rely heavily on these third parties over the course of its preclinical studies and clinical trials, and Dianthus controls only certain aspects of their activities. As a result, Dianthus 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 Dianthus were relying entirely upon its own staff.

Nevertheless, Dianthus is responsible for ensuring that each of its studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and its reliance on these third parties does not relieve Dianthus of its regulatory responsibilities. Dianthus and its 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 Dianthus or any of these third parties fail to comply with applicable GCP guidelines, the clinical data generated in its clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require Dianthus to perform additional clinical trials before approving its marketing applications. Dianthus cannot provide assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of its clinical trials comply with GCP regulations. In addition, its clinical trials must be conducted with product generated under cGMP regulations. Dianthus' failure to comply with these regulations may require it to repeat clinical trials, which would delay the regulatory approval process. Moreover, its 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 Dianthus' clinical trials will not be its employees and, except for remedies available to Dianthus under its agreements with such third parties, Dianthus cannot control whether they devote sufficient time and resources to its product candidates. These third parties may be involved in acquisitions or similar transactions and may have relationships with other commercial entities, including its competitors, for whom they may also be conducting clinical trials or other product development activities, which could negatively affect their performance on its behalf and the timing thereof and could lead to products that compete directly or indirectly with its 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 its clinical protocols or regulatory requirements or for other reasons, its clinical trials may be extended, delayed or terminated and Dianthus may not be able to complete development of, obtain regulatory approval of or successfully commercialize DNTH103 or other product candidates.

Dianthus has collaborations with third parties, including its existing license and development collaboration with Zenas BioPharma. If Dianthus is unable to maintain these collaborations, or if these collaborations are not successful, segments of its business could be adversely affected.

Dianthus has various collaboration and license arrangements, including with Zenas BioPharma for the development and commercialization of DNTH103 in the greater area of China, and Dianthus currently holds an exclusive license for worldwide (excluding the greater area of China) development and commercialization rights for certain potential product candidates. Further, Dianthus may in the future form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that Dianthus believes will complement or augment its development and commercialization efforts with respect to its product candidates. Collaborations or licensing arrangements that Dianthus enters into may not be successful, and any success will depend heavily on the efforts and activities of such collaborators or licensors. If any of Dianthus' collaborators, licensors or licensees experience delays in performance of, or fail to perform their obligations under, their applicable agreements with Dianthus, disagree with its interpretation of the terms of such agreement or terminate their agreement with Dianthus, its pipeline of product candidates would be adversely affected. If Dianthus fails to comply with any of the obligations under its collaborations or license agreements, including payment terms and diligence terms, its collaborators, licensors or licensees may have the right to terminate its agreements, in which event Dianthus 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 its agreements. Dianthus' collaborators, licensors or licensees may also fail to properly maintain or defend the intellectual property Dianthus has licensed from, if required by its agreement with them, or even infringe upon its intellectual property rights, leading to the potential invalidation of its intellectual property or subjecting Dianthus to litigation or arbitration, any of which would be time-consuming and expensive and could harm its ability to commercialize its product candidates. Further, any of these relationships may require Dianthus to increase its near and long-term expenditures, issue securities that dilute its existing stockholders or disrupt its management and business. In addition, collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with its 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 Dianthus'.

As part of its strategy, Dianthus plans to evaluate additional opportunities to enhance its capabilities and expand its development pipeline or provide development or commercialization capabilities that complement its own. Dianthus may not realize the benefits of such collaborations, alliances or licensing arrangements. Any of these relationships may require Dianthus to incur non-recurring and other charges, increase its near and long- term expenditures, issue securities that dilute its existing stockholders or disrupt its management and business.

Dianthus 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 Dianthus considers attractive. These companies may have a competitive advantage over Dianthus due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive Dianthus to be a competitor may be unwilling to assign or license rights to Dianthus. Whether Dianthus reaches a definitive agreement for a collaboration will depend, among other things, upon its 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. Dianthus may not be able to negotiate additional collaborations on a timely basis, on acceptable terms or at all. If Dianthus fails to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, Dianthus may not be able to further develop its product candidates or bring them to market.

Risks Related to Dianthus' Business and Operations

In order to successfully implement its plans and strategies, Dianthus will need to grow the size of its organization and it may experience difficulties in managing this growth.

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

Dianthus is highly dependent on its key personnel and anticipates hiring new key personnel. If Dianthus is not successful in attracting and retaining highly qualified personnel, it may not be able to successfully implement its business strategy.

Dianthus' ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon its ability to attract and retain highly qualified managerial, scientific and medical personnel. Dianthus is highly dependent on its managerial, scientific and medical personnel, including its Chief Executive Officer, Chief Medical Officer, Chief Financial Officer, Chief Accounting Officer and other members of its leadership team. Although Dianthus has entered into employment agreements with its executive officers, each of them may terminate their employment with Dianthus at any time. Dianthus does not maintain "key person" insurance for any of its executives or other employees. The loss of the services of its executive officers or other key employees could impede the achievement of its research, development and commercialization objectives and seriously harm its ability to successfully implement its business strategy. Furthermore, replacing executive officers and key personnel may be difficult and may take an extended period of time. If Dianthus does not succeed in attracting and retaining qualified personnel, it could materially and adversely affect its business, financial condition, cash flows, and results of operations. Dianthus could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources on its employee recruitment and retention efforts.

Its future growth may depend, in part, on its ability to operate in foreign markets, where Dianthus would be subject to additional regulatory burdens and other risks and uncertainties.

Its future growth may depend, in part, on its ability to develop and commercialize DNTH103 or other product candidates in foreign markets for which Dianthus may rely on collaboration with third parties. Dianthus is not permitted to market or promote any product candidates before Dianthus receives regulatory approval from the applicable foreign regulatory authority, and may never receive such regulatory approval for any product candidates. To obtain separate regulatory approval in many other countries, Dianthus 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 Dianthus cannot predict success in these jurisdictions. If Dianthus fails to comply with the regulatory requirements in international markets or to receive applicable marketing approvals, its target market will be reduced and its ability to realize the full market potential of DNTH103 or other product candidates will be harmed and its business will be adversely affected. Moreover, even if Dianthus obtains approval of DNTH103 or other product candidates and ultimately commercialize such product candidates in foreign markets, Dianthus 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.

Dianthus' 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.

Dianthus is exposed to the risk that its employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CDMOs, suppliers and vendors acting for or on its 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 Dianthus takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting Dianthus from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

Dianthus' internal computer systems, or those of any of its 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 its proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to its brand and material disruption of its operations.

Despite the implementation of security measures in an effort to protect systems that store its information, given their size and complexity and the increasing amounts of information maintained on its internal information technology systems and those of its third-party CROs, CDMOs, other contractors (including sites performing its 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 its employees, contractors, consultants, business partners and/or other third parties, or from cyber-attacks by malicious third parties, which may compromise its system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, its data. To the extent that any disruption or security breach were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, Dianthus' data or applications, or for it to be believed or reported that any of these occurred, Dianthus could incur liability and reputational damage and the development and commercialization of DNTH103 or other product candidates could be delayed.

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

While Dianthus has implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. Dianthus may be unable in the future to detect vulnerabilities in its 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, Dianthus may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require Dianthus 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.

Dianthus relies on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts. Its 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 its third-party service providers experience a security incident or other interruption, Dianthus could experience adverse consequences. While Dianthus may be entitled to damages if its third-party service providers fail to satisfy their privacy or security-related obligations to Dianthus, any award may be insufficient to cover its damages, or Dianthus may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and Dianthus cannot guarantee that third parties' infrastructure in its supply chain or its third-party partners' supply chains have not been compromised.

If Dianthus (or a third party upon whom Dianthus relies) experiences a security incident or are perceived to have experienced a security incident, Dianthus 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 its 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 its platform, deter new customers from products, and negatively impact its ability to grow and operate its business.

Dianthus' contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in its contracts are sufficient to protect Dianthus from liabilities, damages, or claims related to its data privacy and security obligations. Dianthus cannot be sure that its insurance coverage will be adequate or sufficient to protect Dianthus from or to mitigate liabilities arising out of its privacy and security practices or from disruptions in, or failure or security breach of, its systems or third-party systems where information important to its 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.

Dianthus is 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 its operating results and business.

Dianthus, and third parties with whom Dianthus works, 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. Dianthus is or may become subject to the terms of contractual obligations related to privacy, data protection, and data security. Dianthus' obligations may also change or expand as its business grows. The actual or perceived failure by Dianthus or third parties related to Dianthus to comply with such laws, regulations and obligations could increase its compliance and operational costs, expose Dianthus 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 its business, financial condition, cash flows, and results of operations. See the sections titled "*Dianthus' Business—Government Regulation—Data Privacy and Security*" and "*—Other Government Regulation Outside of the United States*" in Exhibit 99.2 of the Current Report on Form 8-K/A of which this Exhibit 99.1 is a part for a more detailed description of the laws that may affect its ability to operate.

If Dianthus fails to comply with environmental, health and safety laws and regulations, Dianthus could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of its business.

Dianthus is 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. Its operations may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. In addition, Dianthus 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 Dianthus' research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Dianthus may acquire businesses or products, or form strategic alliances, in the future, and may not realize the benefits of such acquisitions.

Dianthus may acquire additional businesses or products, form strategic alliances, or create joint ventures with third parties that Dianthus believes will complement or augment its existing business. If Dianthus acquires businesses with promising markets or technologies, Dianthus may not be able to realize the benefit of acquiring such businesses if Dianthus is unable to successfully integrate them with its existing operations and company culture. Dianthus 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 Dianthus from realizing their expected benefits or enhancing its business. There is no assurance that, following any such acquisition, Dianthus will achieve the synergies expected in order to justify the transaction, which could result in a material adverse effect on its business and prospects.

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

Dianthus' 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, Dianthus 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, OpCo could not access its assets held in its account with Silicon Valley Bank for a period in March 2023, which required OpCo to obtain a short-term loan to fund its operations (see "*Certain Relationships and Related Party Transactions of the Combined Company—Dianthus Transactions—Promissory Notes*" in the Definitive Proxy Statement/Prospectus for information on the short-term loan). Any material loss that Dianthus may experience in the future or inability for a material time period to access its cash and cash equivalents could have an adverse effect on its ability to pay its operational expenses or make other payments, which could adversely affect its business.

Dianthus has identified material weaknesses in its internal control over financial reporting which, if not corrected, could affect the reliability of its 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.

Dianthus has identified material weaknesses in its internal control over financial reporting that it is currently working to remediate, which relate to: (a) Dianthus' 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) Dianthus' accounting software system has certain system limitations that do not allow for an effective control environment.

Dianthus' management has concluded that these material weaknesses in its internal control over financial reporting are due to the fact that Dianthus is a company with limited resources and does not have the necessary business processes and related internal controls formally designed and implemented coupled with the appropriate resources to oversee Dianthus' business processes and controls.

Dianthus' management is in the process of developing a remediation plan. The material weaknesses will be considered remediated when Dianthus' 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. Dianthus' management will monitor the effectiveness of its remediation plans and will make changes management determines to be appropriate.

If not remediated, these material weaknesses could result in material misstatements to Dianthus' 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 Dianthus is unable to assert that its internal control over financial reporting is effective, or, if required in the future, its 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 Dianthus' financial reports, the market price of Dianthus' common stock could be adversely affected and Dianthus 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

Dianthus' ability to protect its patents and other proprietary rights is uncertain, exposing Dianthus to the possible loss of competitive advantage.

Dianthus relies or may rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to its product candidates and technologies and to prevent third parties from competing with it. Dianthus' success depends in large part on its 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. Dianthus owns five pending patent applications, and it expects to continue to file patent applications in the United States and abroad related to discoveries and technologies that are important to its business. However, Dianthus may not be able to protect its 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 Dianthus' intellectual property rights in some foreign jurisdictions may be less extensive than those in the United States. As such, Dianthus does not have patents in all countries or all major markets and may not be able to obtain patents in all jurisdictions even if it applies for them. Competitors may operate in countries where Dianthus does not have patent protection and could then freely use Dianthus' 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.

Dianthus' intellectual property portfolio is at an early stage and does not currently own or in-license any issued patents. Dianthus' pending and future patent applications may not result in patents being issued.

Any issued patents may not afford sufficient protection of Dianthus 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 may be licensed or are owned covering Dianthus 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 Dianthus encounters delays in any clinical trials or delays in obtaining regulatory approval, the period of time during which Dianthus could market product candidates under patent protection would be reduced. Thus, the patents that Dianthus may own or license may not afford any meaningful competitive advantage.

In addition to seeking patents for some of its technology and product candidates, Dianthus may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain its competitive position. Any disclosure, either intentional or unintentional, by its employees, the employees of third parties with whom Dianthus shares facilities or third-party consultants and vendors that Dianthus engages to perform researches, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of its trade secrets or proprietary information could enable competitors to duplicate or surpass Dianthus' technological achievements, thus eroding its competitive position in the market. In order to protect its proprietary technology and processes, Dianthus relies 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. Dianthus may need to share its 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 Dianthus undertakes efforts to protect its trade secrets and other confidential information from disclosure, others may independently discover trade secrets and proprietary information, and, in such cases, Dianthus 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 its proprietary rights and failure to obtain or maintain trade secret protection could adversely affect Dianthus' competitive business position.

Lastly, if Dianthus' trademarks and trade names are not registered or adequately protected, then Dianthus may not be able to build name recognition in markets of interest and its business may be adversely affected.

Dianthus may not be successful in obtaining or maintaining necessary rights to product candidates through acquisitions and in-licenses.

Because Dianthus' development programs may in the future require the use of proprietary rights held by third parties, the growth of its business may depend in part on Dianthus' ability to acquire, in-license, or use these third-party proprietary rights. Dianthus 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 it identifies as necessary for 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 Dianthus may consider attractive or necessary. These established companies may have a competitive advantage over Dianthus due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive Dianthus to be a competitor may be unwilling to assign or license rights to Dianthus. Dianthus also may be unable to license or acquire third-party intellectual property rights on terms that would allow it to make an appropriate return on investment or at all. If Dianthus is unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights Dianthus has, it may have to abandon development of the relevant product candidate, which could have a material adverse effect on Dianthus' business, financial condition, results of operations, cash flows, and prospects.

While Dianthus 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 Dianthus' business, including by payment of all applicable fees for patents covering a product candidate, Dianthus could lose rights to the intellectual property or exclusivity with respect to those rights, Dianthus' ability to develop and commercialize such candidate may be adversely affected and it may not be able to prevent competitors from making, using and selling competing products. In addition, even where Dianthus has the right to control patent prosecution of patents and patent applications which may be licensed to and from third parties, Dianthus 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 Dianthus assumed control over patent prosecution.

Dianthus' 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 Dianthus in-licenses. If other third parties have ownership rights to future in-licensed patents, they may be able to license such patents to Dianthus' competitors, and the competitors could market competing products and technology. This could have a material adverse effect on Dianthus' competitive position, business, financial conditions, results of operations, cash flows, and prospects.

It is possible that Dianthus may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. Even if Dianthus is able to obtain a license, it may be non-exclusive, thereby giving competitors access to the same technologies licensed to Dianthus. In that event, Dianthus may be required to expend significant time and resources to redesign its 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 Dianthus is unable to do so, it may be unable to develop or commercialize the affected product candidates, which could harm Dianthus' business, financial condition, results of operations, cash flows, and prospects significantly. Dianthus cannot provide any assurances that third-party patents do not exist which might be enforced against Dianthus' current technology or manufacturing methods, its 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 Dianthus' part to pay royalties and/or other forms of compensation to third parties, which could be significant. For example, Dianthus is 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 Dianthus does not believe that this is a valid patent, this patent could be construed to cover its anti-C1s antibodies.

Disputes may arise between Dianthus and its 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 Dianthus' technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; Dianthus' right to sublicense patents and other rights to third parties; Dianthus' 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 Dianthus and/or its partners; and the priority date of an invention of patented technology.

Dianthus may be subject to patent infringement claims or may need to file claims to protect its intellectual property, which could result in substantial costs and liability and prevent it from commercializing potential products.

Because the intellectual property landscape in the biotechnology industry is rapidly evolving and interdisciplinary, it is difficult to conclusively assess Dianthus' freedom to operate and guarantee that it can operate without infringing on or violating third party rights. If certain of Dianthus' 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 Dianthus, Dianthus 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 Dianthus, whether or not successful, may cause Dianthus to incur significant legal expenses and divert the attention of Dianthus' management and key personnel from other business concerns. Dianthus cannot be certain that patents owned or licensed by it will not be challenged by others in the course of litigation. Some of competitors may be able to sustain the costs of complex intellectual property litigation more effectively than Dianthus 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 Dianthus' ability to raise funds and on the market price of Dianthus' common stock.

Competitors may infringe or otherwise violate Dianthus' patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, Dianthus may be required to file claims, which can be expensive and time-consuming. Any such claims could provoke these parties to assert counterclaims against Dianthus, 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 Dianthus asserts 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 Dianthus' patents do not cover the technology. Similarly, if Dianthus asserts trademark infringement claims, a court or administrative body may determine that the marks asserted are invalid or unenforceable or that the party against whom Dianthus has asserted trademark infringement has superior rights to the marks in question. In such a case, Dianthus could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if Dianthus is successful, any award of monetary damages or other remedy received may not be commercially valuable.

Further, Dianthus may be required to protect its 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, Dianthus' patent rights, which could adversely affect its 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 Dianthus' product candidates are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against Dianthus' future licensees and other parties with whom it has business relationships and Dianthus may be required to indemnify those parties for any damages they suffer as a result of these claims, which may require Dianthus 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, Dianthus 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 Dianthus' intellectual property rights, there is a risk that some of Dianthus' confidential information could be compromised by disclosure during this type of litigation or other proceedings.

Dianthus may be subject to claims that it has 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 Dianthus' employees, Dianthus engages and may engage in the services of consultants to assist in the development of its product candidates. Many of these consultants, and many of Dianthus' 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 Dianthus' competitors or potential competitors. Dianthus could in the future be subject to claims that it or its employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors.

Although Dianthus tries to ensure that its employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for Dianthus, Dianthus may become subject to claims that it caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that Dianthus 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 Dianthus may litigate to defend itself against these claims, even if Dianthus is successful, litigation could result in substantial costs and could be a distraction to management. If Dianthus' defenses to these claims fail, in addition to requiring Dianthus to pay monetary damages, a court could prohibit it from using technologies or features that are essential to Dianthus' 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 Dianthus' reputation, its ability to form strategic alliances or sublicense Dianthus' rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on Dianthus' business, results of operations, financial condition and prospects.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing Dianthus' ability to protect its 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 Dianthus' owned and any future in-licensed patent applications and the maintenance, enforcement or defense of Dianthus 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 Dianthus' patent applications and the enforcement or defense of Dianthus' issued patents, all of which could have a material adverse effect on Dianthus' 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. 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 and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on Dianthus' patent rights and its ability to protect, defend and enforce Dianthus' 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 Dianthus' 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, Dianthus would not be able to prevent third parties from practicing its inventions in Russia or from selling or importing products made using its inventions in and into Russia. Accordingly, Dianthus' competitive position may be impaired, and its 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 will be a common patent court to hear patent infringement and revocation proceedings effective for member states of the European Union. This could enable third parties to seek revocation of 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 OpCo does not currently own any European patents or applications, if Dianthus obtains such patents and applications in the future, any such revocation and loss of patent protection could have a material adverse impact on Dianthus' business and its ability to commercialize or license its technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect Dianthus' ability to enforce or defend the validity of any European patents obtained. Dianthus may decide to opt out from the UPC for any future European patent applications that it may file and any patents it 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. Dianthus cannot be certain that future European patents and patent applications will avoid falling under the jurisdiction of the UPC, if Dianthus decides 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 Dianthus' 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 Dianthus fails to maintain the patents and patent applications covering its product candidates, Dianthus' competitive position would be adversely affected.

Dianthus 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 Dianthus' ability to develop and market its products.

Dianthus cannot guarantee that any of its 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 Dianthus be certain that it has 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 its 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. Dianthus' interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, Dianthus may incorrectly determine that its 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. Dianthus' determination of the expiration date of any patent in the United States or abroad that it considers relevant may be incorrect. Dianthus' failure to identify and correctly interpret relevant patents may negatively impact its ability to develop and market Dianthus' 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, Dianthus cannot be certain that others have not filed patent applications for technology covered by Dianthus' pending applications or any future issued patents, or that Dianthus was the first to invent the technology. Dianthus' competitors may have filed, and may in the future file, patent applications covering its products or technology similar to Dianthus'. Any such patent application may have priority over Dianthus' patent applications or patents, which could require Dianthus to obtain rights to issued patents covering such technologies.

Dianthus may become subject to claims challenging the inventorship or ownership of its patents and other intellectual property.

Dianthus may be subject to claims that former employees, collaborators or other third parties have an interest in Dianthus' 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 Dianthus' 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, Dianthus may enter into agreements to clarify the scope of its rights in such intellectual property. If Dianthus fails in defending any such claims, in addition to paying monetary damages, Dianthus 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 Dianthus' business. Even if Dianthus is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Dianthus' 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 its licensors are not the sole and exclusive owners of the patents Dianthus in-licensed. If other third parties have ownership rights or other rights to Dianthus' in-licensed patents, they may be able to license such patents to Dianthus' competitors, and its competitors could market competing products and technology. This could have a material adverse effect on Dianthus' competitive position, business, financial conditions, results of operations, cash flows, and prospects.

Patent terms may be inadequate to protect Dianthus' competitive position on its 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 Dianthus' product candidates are obtained, once the patent life has expired, Dianthus 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, Dianthus' owned and future licensed patent portfolio may not provide it with sufficient rights to exclude others from commercializing products similar or identical to Dianthus'.

Dianthus' technology licensed from various third parties may be subject to retained rights.

Dianthus' future licensors may retain certain rights under the relevant agreements with Dianthus, 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 Dianthus' licensors limit their use of the technology to these uses, and Dianthus could incur substantial expenses to enforce its 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. Dianthus may in the future collaborate with academic institutions to accelerate Dianthus' preclinical research or development. While it is Dianthus' policy to avoid engaging university partners in projects in which there is a risk that federal funds may be commingled, Dianthus 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, Dianthus co-owns or licenses in-technology which is critical to its business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, Dianthus' 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 Dianthus is not able to obtain, or if there are delays in obtaining, required regulatory approvals for its product candidates, Dianthus will not be able to commercialize, or will be delayed in commercializing, such product candidates, and its 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. Dianthus cannot commercialize product candidates in the United States without first obtaining regulatory approval from the FDA. Similarly, Dianthus 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 its product candidates, including its most advanced product candidate, DNTH103, Dianthus 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 its 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 its data are 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 its clinical trials; Dianthus 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 its clinical trials or by individuals using drugs similar to a product candidate; Dianthus 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 its 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 biologics license application ("BLA") or other submission or to obtain regulatory approval in the United States or elsewhere, and Dianthus 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 Dianthus 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 Dianthus' clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in Dianthus failing to obtain regulatory approval to market DNTH103 or other product candidates, which would significantly harm its business, results of operations and prospects. If Dianthus were to obtain approval, regulatory authorities may approve any such product candidate for fewer or more limited indications than Dianthus 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 Dianthus is not able to obtain, or if there are delays in obtaining, required regulatory approvals for a product candidate, Dianthus will not be able to commercialize, or will be delayed in commercializing, such product candidate and its ability to generate revenue may be materially impaired.

Disruptions at the FDA and other government agencies could negatively affect the review of Dianthus' regulatory submissions, which could negatively impact its 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 its regulatory submissions, which could have a material adverse effect on Dianthus' business.

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

In order to receive approval of its products by the FDA and comparable foreign regulatory authorities, Dianthus must show that Dianthus and its contract manufacturing partners are able to characterize, control and manufacture its 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, and demonstrating that its drug products meet stability requirements. Meeting these chemistry, manufacturing and control ("CMC") requirements is a complex task that requires specialized expertise. If Dianthus is not able to meet the CMC requirements, Dianthus may not be successful in getting its products approved.

Dianthus intends to deliver its product candidates via a drug delivery device that will have its own regulatory, development, supply and other risks.

Dianthus intends to deliver its 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. Dianthus' 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. Dianthus 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, Dianthus 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.

Dianthus currently and may in the future conduct clinical trials for its product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

Dianthus' Phase 1 clinical trial for DNTH103 is currently being conducted in New Zealand, and Dianthus may in the future choose to conduct more of its clinical trials outside the United States. Dianthus currently intends to conduct its Phase 2 clinical trial 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 Dianthus conducts 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 its development of the applicable product candidates. Even if the FDA accepted such data, it could require Dianthus to modify its 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 its ability to conduct its 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.

Dianthus' product candidates for which it intends 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.

Dianthus' 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 Dianthus receives regulatory approval of DNTH103 or other product candidates, Dianthus will be subject to extensive ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and Dianthus may be subject to penalties if Dianthus fails to comply with regulatory requirements or experience unanticipated problems with its product candidates.

Any regulatory approvals that Dianthus 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 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 Dianthus 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 Dianthus 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 Dianthus, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, restrictions on its 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 Dianthus' ability to commercialize DNTH103 or other product candidates and generate revenue and could require Dianthus to expend significant time and resources in response and could generate negative publicity.

Dianthus 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. Dianthus 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 Dianthus is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if Dianthus is not able to maintain regulatory compliance, Dianthus may lose any marketing approval that Dianthus may have obtained and Dianthus may not achieve or sustain profitability. See the section titled "*Dianthus' Business—Government Regulation—Healthcare Reform*" in Exhibit 99.2 of the Current Report on Form 8-K/A of which this Exhibit 99.1 is a part for a more detailed description of healthcare reforms measures that may prevent Dianthus from being able to generate revenue, attain profitability, or commercialize product candidates.

Dianthus' 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 Dianthus to penalties.

Dianthus' business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose Dianthus 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 Dianthus conducts its operations, including how Dianthus researches, markets, sells and distributes its product candidates, if approved. See the section titled "*Dianthus' Business—Government Regulation—Other Healthcare Laws and Compliance Requirements*" in Exhibit 99.2 of the Current Report on Form 8-K/A of which this Exhibit 99.1 is a part for a more detailed description of the laws that may affect its ability to operate.

Ensuring that its internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. If Dianthus' operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to it, Dianthus 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 its operations. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Therefore, even if Dianthus is successful in defending against any such actions that may be brought against Dianthus, its business may be impaired.

Even if Dianthus is able to commercialize DNTH103 or other product candidates, due to unfavorable pricing regulations and/or third-party coverage and reimbursement policies, Dianthus may not be able to offer such products at competitive prices which would seriously harm its business.

Dianthus intends to seek approval to market DNTH103 and other product candidates in both the United States and in selected foreign jurisdictions. If Dianthus obtains approval in one or more foreign jurisdictions for such product candidates, Dianthus will be subject to rules and regulations in those jurisdictions. Its ability to successfully commercialize any product candidates that Dianthus 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 its products in an attempt to reduce their costs, which may reduce its commercial opportunity. Additionally, if any of its product candidates are approved and Dianthus is found to have improperly promoted off-label uses of those programs, Dianthus may become subject to significant liability, which would materially adversely affect its business and financial condition. See the sections titled "*Dianthus' Business—Government Regulation—Coverage and Reimbursement*" and "*—Regulation in the European Union*" in Exhibit 99.2 of the Current Report on Form 8-K/A of which this Exhibit 99.1 is a part for a more detailed description of the government regulations and third-party payor practices that may affect Dianthus' ability to commercialize its product candidates.

Dianthus is subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Dianthus can face criminal liability and other serious consequences for violations, which can harm its business.

Dianthus is 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 Dianthus conducts 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.

Dianthus 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. Dianthus has direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. Dianthus can be held liable for the corrupt or other illegal activities of its employees, agents, contractors, and other collaborators, even if Dianthus does 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 Dianthus' 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, Dianthus 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, its 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, Dianthus could face significant new costs.

If Dianthus decides 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.

Dianthus may seek Fast Track Designation or Orphan Drug Designation for one or more product candidates. The FDA has broad discretion whether or not to grant such designations, so even if Dianthus believes a particular product candidate is eligible for such designations, it cannot guarantee you that the FDA would decide to grant it. Even if Dianthus does receive Fast Track Designation or Orphan Drug Designation, it 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 "*Dianthus' Business—Government Regulation—Expedited Development and Review Programs*" in Exhibit 99.2 of the Current Report on Form 8-K/A of which this Exhibit 99.1 is a part for a more detailed description of the process for seeking Fast Track Designation or Orphan Drug Designation.

General Risk Factors

Dianthus' estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which Dianthus compete achieve the forecasted growth, its business may not grow at similar rates, or at all.

Dianthus' 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. Its estimates and forecasts relating to size and expected growth of its target market may prove to be inaccurate. Even if the markets in which Dianthus competes meet its size estimates and growth forecasts, its business may not grow at similar rates, or at all. Dianthus' growth is subject to many factors, including its success in implementing its business strategy, which is subject to many risks and uncertainties.

Dianthus' revenue will be dependent, in part, upon the size of the markets in the territories for which Dianthus gains regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement and whether Dianthus owns the commercial rights for that territory. If the number of its addressable patients is not as significant as Dianthus estimates, the indication approved by regulatory authorities is narrower than Dianthus expects or the treatment population is narrowed by competition, physician choice or treatment guidelines, Dianthus may not generate significant revenue from sales of such products, even if approved.

Dianthus may become exposed to costly and damaging liability claims, either when testing a product candidate in the clinical or at the commercial stage, and its product liability insurance may not cover all damages from such claims.

Dianthus is exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. While Dianthus currently has 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 Dianthus 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 Dianthus, regardless of their merit, could be difficult and costly to defend and could materially and adversely affect the market for its products or any prospects for commercialization of its products. Although Dianthus believes it currently maintains adequate product liability insurance for DNTH103 and other product candidates, it is possible that its liabilities could exceed its insurance coverage or that in the future Dianthus 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 Dianthus for uninsured liabilities or in excess of insured liabilities, its assets may not be sufficient to cover such claims and its business operations could be impaired.

Litigation costs and the outcome of litigation could have a material adverse effect on Dianthus' business.

From time to time Dianthus may be subject to litigation claims through the ordinary course of its business operations regarding, but not limited to, employment matters, security of patient and employee personal information, contractual relations with collaborators and intellectual property rights. Litigation to defend itself against claims by third parties, or to enforce any rights that Dianthus may have against third parties, may continue to be necessary, which could result in substantial costs and diversion of its resources, causing a material adverse effect on its business, financial condition, results of operations, cash flows, and prospects.

Dianthus' 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 conflict between Russia and Ukraine, or other macroeconomic conditions, which could have a material and adverse effect on its 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, the ongoing military conflict between Russia and Ukraine and rising tensions with China have created extreme 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 its business or the third parties on whom Dianthus relies.

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 Dianthus by increasing its costs, including labor and employee benefit costs.

Dianthus 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 its results of operations and financial condition.

The market price of Dianthus' common stock is expected to be volatile, and the market price of the common stock may drop.

The market price of Dianthus' 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 Dianthus' common stock to fluctuate include:

- results of clinical trials and preclinical studies of Dianthus' product candidates, or those of Dianthus' competitors or Dianthus' existing or future collaborators;
- failure to meet or exceed financial and development projections Dianthus may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- if Dianthus does 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 Dianthus or its competitors;
- actions taken by regulatory agencies with respect to Dianthus' product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and Dianthus' ability to obtain patent protection for its 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 Dianthus' business, or if they issue adverse or misleading opinions regarding its 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 Dianthus or its securityholders in the future;
- if Dianthus fails to raise an adequate amount of capital to fund its operations or continued development of its product candidates;
- trading volume of Dianthus' common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets;
- the introduction of technological innovations or new therapies that compete with the products and services of Dianthus'; and

- period-to-period fluctuations in Dianthus' 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 Dianthus' common stock. In addition, a recession, depression or other sustained adverse market event could materially and adversely affect Dianthus' business and the value of its 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 Dianthus experiences a market valuation that activists believe is not reflective of its intrinsic value. Activist campaigns that contest or conflict with Dianthus' strategic direction or seek changes in the composition of its board of directors could have an adverse effect on its operating results, financial condition and cash flows.

Dianthus may be unable to integrate successfully the businesses of Dianthus and OpCo and realize the anticipated benefits of the merger.

The merger involved the combination of two companies which operated as independent companies. Dianthus will be required to devote significant management attention and resources to integrating its business practices and operations. Dianthus may fail to realize some or all of the anticipated benefits of the merger if the integration process takes longer than expected or is more costly than expected. Potential difficulties Dianthus may encounter in the integration process include the following:

- the inability to successfully combine the businesses of Dianthus and OpCo in a manner that permits Dianthus to achieve the anticipated benefits from the merger, which would result in the anticipated benefits of the merger not being realized partly or wholly in the time frame currently anticipated or at all;
- creation of uniform standards, controls, procedures, policies and information systems; and
- potential unknown liabilities and unforeseen increased expenses, delays or regulatory conditions associated with the merger.

In addition, prior to the completion of the merger, Dianthus and OpCo operated independently. It is possible that the integration process also could result in the diversion of each company's management's attention, the disruption or interruption of, or the loss of momentum in, each company's ongoing businesses or inconsistencies in standards, controls, procedures and policies, any of which could adversely affect Dianthus' ability to maintain its business relationships or the ability to achieve the anticipated benefits of the merger, or could otherwise adversely affect the business and financial results of Dianthus.

Dianthus will incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.

Dianthus will incur significant legal, accounting and other expenses as a public company that OpCo did not incur as a private company, including costs associated with public company reporting obligations under the Exchange Act. Dianthus' management team will consist of the executive officers of OpCo prior to the merger, 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 Dianthus complies with all of these requirements. Any changes Dianthus makes to comply with these obligations may not be sufficient to allow it to satisfy its 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 Dianthus 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.

Once Dianthus is no longer an emerging growth company, a smaller reporting company or otherwise no longer qualifies for applicable exemptions, Dianthus will be subject to additional laws and regulations affecting public companies that will increase its costs and the demands on management and could harm the its operating results and cash flows.

Dianthus is subject to the reporting requirements of the Exchange Act, which requires, among other things, that Dianthus file with the SEC, annual, quarterly and current reports with respect to its business and financial condition as well as other disclosure and corporate governance requirements. However, as an emerging growth company, Dianthus may take advantage of exemptions from various requirements such as an exemption from the requirement to have its independent auditors attest to Dianthus' internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002 as well as an exemption from the "say on pay" voting requirements pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. Dianthus will no longer qualify as an emerging growth company after December 31, 2023. After Dianthus no longer qualifies as an emerging growth company, Dianthus expects to still 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 it 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 the Definitive Proxy Statement/Prospectus and in its periodic reports and proxy statements. Once Dianthus is no longer an emerging growth company or a smaller reporting company or otherwise no longer qualifies for these exemptions, Dianthus will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If Dianthus is not able to comply with the requirements in a timely manner or at all, Dianthus' financial condition or the market price of its common stock may be harmed.

If Dianthus fails to maintain proper and effective internal controls, its ability to produce accurate financial statements on a timely basis could be impaired.

Dianthus is 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 Dianthus maintain effective disclosure controls and procedures and internal control over financial reporting. Dianthus must perform system and process evaluation and testing of its internal control over financial reporting to allow management to report on the effectiveness of its internal controls over financial reporting in its Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. As a private company, OpCo has never been required to test its internal controls within a specified period. This will require that Dianthus incur substantial professional fees and internal costs to expand its accounting and finance functions and that it expends significant management efforts. Dianthus may experience difficulty in meeting these reporting requirements in a timely manner. For additional information related to the risks and uncertainties of Dianthus' compliance with the Sarbanes-Oxley Act, see the section above titled "*Risks Related to Dianthus' Business and Operations—Dianthus has identified material weaknesses in its internal control over financial reporting which, if not corrected, could affect the reliability of its financial statements and have other adverse consequences.*"

In addition to the material weaknesses described above, Dianthus may discover additional weaknesses in its system of internal financial and accounting controls and procedures that could result in a material misstatement of its financial statements. Dianthus' 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 Dianthus is not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if it is unable to maintain proper and effective internal controls, Dianthus may not be able to produce timely and accurate financial statements. If that were to happen, the market price of its common stock could decline and it could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

Dianthus' certificate of incorporation and bylaws and provisions under Delaware law could make an acquisition of Dianthus more difficult and may prevent attempts by its stockholders to replace or remove its management.

Provisions of Dianthus' certificate of incorporation and bylaws may discourage, delay or prevent a merger, acquisition or other change in control of Dianthus that stockholders may consider favorable, including transactions in which its 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 Dianthus' common stock, thereby depressing the market price of its common stock. In addition, because Dianthus' board of directors will be responsible for appointing the members of Dianthus' management team, these provisions may frustrate or prevent any attempts by Dianthus' stockholders to replace or remove its current management by making it more difficult for stockholders to replace members of Dianthus' 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 Dianthus' directors to be changed only by resolution of its board of directors;
- limit the manner in which stockholders can remove directors from the board;
- 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 its stockholders by written consent;
- limit who may call a special meeting of stockholders;
- authorize Dianthus' 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 Dianthus' board of directors; and
- require the approval of the holders of at least 66.67% of the votes that all its stockholders would be entitled to cast to amend or repeal certain provisions of Dianthus' charter or bylaws.

Moreover, because Dianthus is incorporated in Delaware, it is governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of the outstanding Dianthus voting stock from merging or combining with Dianthus. Although Dianthus believes these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with its 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 Dianthus' 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.

The bylaws of Dianthus provide that, unless Dianthus consents in writing to the selection of an alternative forum, certain designated courts will be the sole and exclusive forum for certain legal actions between Dianthus and its stockholders, which could limit its stockholders' ability to obtain a favorable judicial forum for disputes with Dianthus or its directors, officers, employees or agents.

The bylaws of Dianthus provide that, unless it consents 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 its behalf, (ii) any action asserting a claim of or based on a breach of a fiduciary duty owed by any of its current or former directors, officers, or other employees to Dianthus or its stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, its charter or its 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. The bylaws of Dianthus will further provide that, unless it consents 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, the bylaws of Dianthus provide that any person or entity purchasing or otherwise acquiring any interest in shares of its 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 stockholders of Dianthus 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 the bylaws of Dianthus may limit its stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with Dianthus or its directors, officers or employees, which may discourage such lawsuits against Dianthus and its directors, officers and employees even though an action, if successful, might benefit its stockholders.

Dianthus does not anticipate paying any cash dividends in the foreseeable future.

The current expectation is that Dianthus will retain its future earnings, if any, to fund the growth of its business as opposed to paying dividends. As a result, capital appreciation, if any, of the common stock of Dianthus will be your sole source of gain, if any, for the foreseeable future.

An active trading market for Dianthus' common stock may not be sustained and its stockholders may not be able to sell their shares of common stock for a profit, if at all.

Prior to the merger, there had been no public market for shares of OpCo capital stock. An active trading market for Dianthus' shares of common stock may not be sustained. If an active market for Dianthus' common stock is not sustained, it may be difficult for its stockholders to sell their shares at an attractive price or at all.

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

If securityholders sell, or indicate an intention to sell, substantial amounts of Dianthus' common stock in the public market after legal restrictions on resale discussed in the Definitive Proxy Statement/Prospectus lapse, the trading price of the common stock of Dianthus could decline. As of September 21, 2023, Dianthus had 14,813,295 shares of common stock issued and outstanding. Of the shares of Dianthus common stock outstanding, approximately 5,727,550 will be available for sale in the public market beginning 180 days after the closing of the merger as a result of the expiration of lock-up agreements between Dianthus and OpCo on the one hand and certain securityholders of Dianthus and OpCo on the other hand (and without giving effect to any restrictions on resale under securities laws). All other outstanding shares of common stock, other than shares held by affiliates of Dianthus, shares of Dianthus common stock issued in exchange for shares of OpCo common stock issued in the OpCo pre-closing financing (as defined in Dianthus' Current Report on Form 8-K filed with the SEC on September 12, 2023) and shares of Dianthus common stock issuable upon the exercise of the pre-funded warrants issued in exchange for the OpCo pre-funded warrants issued in the OpCo pre-closing financing, are freely tradable, without restriction, in the public market (other than restrictions under applicable securities laws). In addition, shares of common stock that are subject to outstanding options or warrants of Dianthus (excluding the pre-funded warrants issued in exchange for the OpCo pre-funded warrants issued in the OpCo pre-closing financing) are or will become 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. In addition, Dianthus intends to file a registration statement covering outstanding shares of Dianthus common stock held by certain affiliates, shares of Dianthus common stock issued in exchange for shares of OpCo common stock issued in the OpCo pre-closing financing and shares of Dianthus common stock issuable upon the exercise of the pre-funded warrants issued in exchange for the OpCo pre-funded warrants issued in the OpCo pre-closing financing. Dianthus also intends to register shares of its common stock that it may issue under its equity compensation plans. Upon registration, such shares of common stock are expected to be freely tradable, without restriction, in the public market (other than restrictions under applicable securities laws and subject to the lock-up agreements). If any of the foregoing shares of common stock are sold, the trading price of Dianthus' common stock could decline.

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

Dianthus' executive officers, directors and principal stockholders will, in the aggregate, beneficially own approximately 77.0% of Dianthus' outstanding shares of common stock. 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 Dianthus stockholders for approval, as well as Dianthus' 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 Dianthus' assets. This concentration of voting power could delay or prevent an acquisition of Dianthus on terms that other stockholders may desire.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about Dianthus, its business or its market, its stock price and trading volume could decline.

The trading market for Dianthus' common stock will be influenced by the research and reports that equity research analysts publish about it and its business. Equity research analysts may elect to not provide research coverage of Dianthus' common stock, and such lack of research coverage may adversely affect the market price of its common stock. In the event Dianthus does have equity research analyst coverage, it will not have any control over the analysts or the content and opinions included in their reports. The price of Dianthus' common stock could decline if one or more equity research analysts downgrade its stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of Dianthus or fails to publish reports on it regularly, demand for its common stock could decrease, which in turn could cause its stock price or trading volume to decline.

Dianthus has broad discretion in the use of its cash and cash equivalents and the proceeds from the OpCo pre-closing financing 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.

Dianthus has broad discretion over the use of its cash and cash equivalents and the proceeds from the OpCo pre-closing financing. You may not agree with Dianthus' decisions, and its use of the proceeds may not yield any return on your investment. Dianthus' failure to apply these resources effectively could compromise its ability to pursue its growth strategy and Dianthus might not be able to yield a significant return, if any, on its investment of these net proceeds. You will not have the opportunity to influence Dianthus decisions on how to use Dianthus' cash resources.

Dianthus may be subject to adverse legislative or regulatory tax changes that could negatively impact its 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 Dianthus or its stockholders. Dianthus will assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where Dianthus has operations to determine the potential effect on its business and any assumptions it will make about its future taxable income. Dianthus 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 its 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 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 its effective tax rate, results of operation and general business condition.

The ability of Dianthus to utilize its net operating loss carryforwards and certain other tax attributes is expected to be limited.

Dianthus' ability to utilize its net operating loss carryforwards and certain other tax attributes to offset future taxable income or tax liabilities is expected to be limited. If the Dianthus earns taxable income, such limitations could result in increased future income tax liability to Dianthus, and Dianthus' future cash flows could be adversely affected.

In general, Dianthus' ability to use its federal and state net operating loss and credits carryforwards to reduce future taxable liabilities is dependent upon its generation of future taxable income, and Dianthus cannot predict with certainty when, or whether, it will generate sufficient taxable income or tax liabilities to use all of its 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 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, Dianthus' tax carryforwards will be attributable to both the historic pre-merger net operating losses of OpCo and the historic pre-merger net operating losses and credits of Dianthus.

As of December 31, 2022, OpCo had net operating loss carryforwards for federal and state income tax purposes of $24.5 million and $20.1 million, respectively. The federal net operating losses will not be subject to expiration and can be carried forward indefinitely, subject to the limitations described above. The state net operating losses begin to expire in 2038. In addition, as discussed above, under Sections 382 of the Code, an ownership change for OpCo may limit the amount of its net operating loss carryforwards that could be utilized annually to offset its future taxable income, if any. OpCo has not performed an analysis to determine whether there has been such an ownership change pursuant to Sections 382 of the Code, or whether such an ownership change resulted from the merger. Any such limitation would significantly reduce its ability to utilize its net operating loss carryforwards before they expire and could have a material adverse effect on its results of operations in future years.

Prior to the merger, as of December 31, 2022, Dianthus had federal net operating loss carryforwards of $272.9 million, of which $17.5 million begin to expire in 2035 and $255.4 million can be carried forward indefinitely, subject to the limitations described above. As of December 31, 2022, Dianthus had state net operating loss carryforwards of $272.6 million, which begin to expire in 2035. As of December 31, 2022, Dianthus also had available research and orphan drug tax credit carryforwards for federal and state income tax purposes of $12.9 million and $3.4 million, respectively, which begin to expire in 2035 and 2030, respectively. Dianthus has 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 of Dianthus. For these reasons, Dianthus does not expect to be able to utilize a material portion of the net operating losses and research and orphan drug tax credit carryforwards.

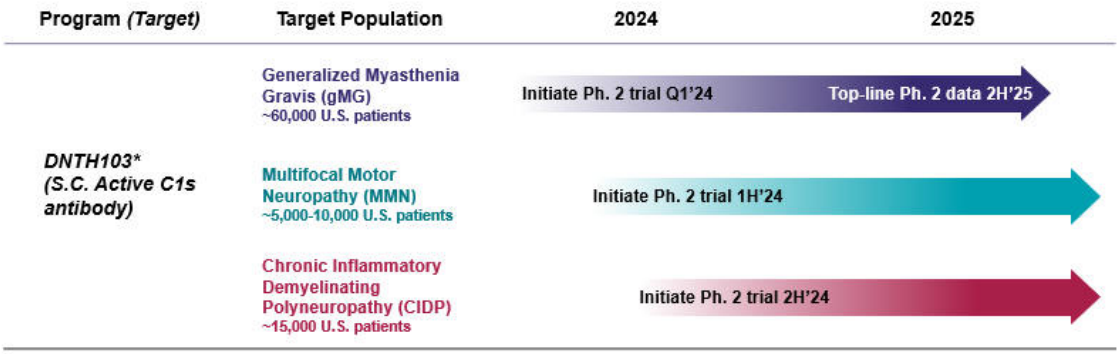
DIANTHUS' BUSINESS

Terms not defined herein shall have the meanings ascribed to them in Dianthus' definitive proxy statement/prospectus filed with the U.S. Securities and Exchange Commission on August 1, 2023.

Overview

Dianthus Therapeutics, Inc., or Dianthus, is a clinical-stage biotechnology company focused on developing next-generation complement therapeutics for patients living with severe autoimmune and inflammatory diseases. Dianthus believes its 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. Dianthus has 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, Dianthus aims to reduce the amount of drug required for a therapeutic effect. Dianthus intends to deliver its product candidates through a lower dose, less frequent, self-administered, convenient subcutaneous ("S.C.") injection suitable for a pre-filled pen.

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



* Dianthus holds world-wide rights excluding rights to Greater China, which are outlicensed to Zenas BioPharma LLC ("Zenas BioPharma").

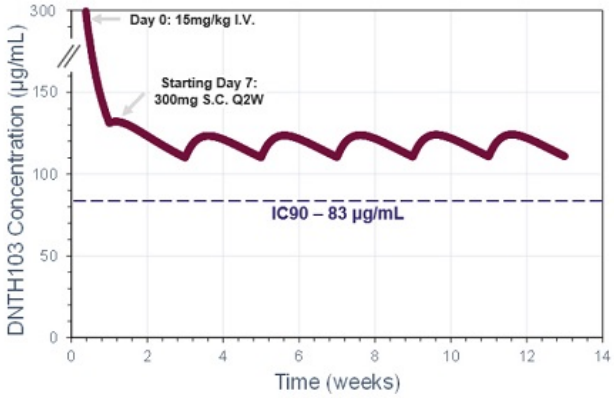
DNTH103

Dianthus' most advanced product candidate, DNTH103, is a clinical-stage, highly potent, highly selective and fully human monoclonal immunoglobulin G4 ("IgG4") with picomolar binding affinity that is designed to selectively bind only to the active form of the C1s complement protein ("C1s"). 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 with YTE 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. Data reported in August of 2023 from DNTH103's ongoing Phase 1 clinical trial in 52 healthy volunteers across seven dose cohorts validates the extended half-life and potent classical pathway inhibition and supports a potentially differentiated safety profile of DNTH103. The top-line 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 of 83ug/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 a U.S. Food and Drug Administration, or FDA, Boxed Warning and associated Risk Evaluation and Mitigation Strategy ("REMS"). Dianthus believes 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.

DNTH103 was designed to achieve the following target product profile across multiple indications:

- *Lower dose for convenient S.C. self-administration*: Reduce the amount of drug required for a therapeutic effect by selectively targeting only the active form of C1s and deliver 300mg in a single 2mL S.C. injection suitable for a pre-filled pen;
- *Less frequent administration*: Lower the frequency of administration by incorporating the YTE half-life extension technology and deliver DNTH103 through a single S.C. injection Q2W; and
- *Lower risk of infection from encapsulated bacteria*: By inhibiting only the classical pathway and leaving the lectin and alternative pathways intact, provide a therapeutic option with a superior safety profile as compared to terminal pathway inhibitors approved or in development for conditions such as gMG and reduce the potential for a serious bacterial infection and an FDA Boxed Warning and associated REMS program.

DNTH103 is currently being evaluated in a first-in-human Phase 1 single and multiple ascending dose ("MAD") clinical trial in New Zealand to explore the safety, tolerability, PK, and pharmacodynamics ("PD") of DNTH103 in healthy volunteers. DNTH103 has completed the dose cohorts that are required to progress into Phase 2 clinical trials, pending regulatory authorizations. In August of 2023, Dianthus reported data from 52 healthy volunteers that have been dosed across seven cohorts, including five single ascending dose ("SAD") cohorts: 1mg/kg intravenous ("I.V."), 10mg/kg I.V., 30mg/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 52 healthy volunteers, DNTH103 has a half-life of approximately 60 days. With these data, Dianthus conducted a PK simulation (as shown below) 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 83ug/mL. Dianthus believes, based on published scientific literature related to other complement therapies, that the IC90 will be sufficient to achieve clinical activity in patients with generalized Myasthenia Gravis ("gMG").



DNTH103 was also studied in a validated functional in vitro experiment simulating the neuromuscular junction in patients with AChR antibody positive MG with the objective of evaluating the impact of DNTH103 on muscle fatigue, a composite measure of neurotransmission and muscle contraction.

In AChR antibody positive MG, IgG1 or IgG3 autoantibodies to the acetylcholine receptor induce local classical pathway activation and MAC formation, resulting in neuromuscular junction damage and subsequent disruption of neurotransmission and muscle contraction. Similar functional in vitro studies from Hesperos, Inc., have been published in peer-reviewed journals and used to support IND submissions for other neuromuscular conditions such as MMN and CIDP.

In this experiment, the nerve cells are continuously stimulated for two minutes and measurements of the muscle contractions are collected. The impact of the addition of serum from three different AChR antibody positive MG patients to the simulated neuromuscular junction was then assessed, causing muscle contraction to become weaker and fatigue due to neurotransmission impairment. The percent change in muscle fatigue index to baseline was then examined following the introduction of 1.0 µM of a tested recombinantly-generated form (in-vitro synthesized molecules whose molecular structure is predicted to be identical based on amino acid sequences from patent filings) of ravulizumab, and two concentrations of DNTH103, 1.0 µM and 0.1 µM. The results demonstrate that ravulizumab reduced muscle fatigue in AChR antibody positive MG patient samples, as expected. DNTH103 also reduced muscle fatigue in AChR antibody positive MG patient samples, indicating an improvement in neurotransmission and muscle contraction. The results provide further scientific rationale for DNTH103 in gMG.

Dianthus intends to submit an Investigational New Drug application (“IND”) in the United States in the fourth quarter of 2023, and subsequently, a Clinical Trial Application (“CTA”) in the European Union to support the initiation of a global Phase 2 clinical trial in gMG in the first quarter of 2024.

Myasthenia gravis (“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.

Dianthus believes 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.

Dianthus plans 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 multifocal motor neuropathy ("MMN"), and chronic inflammatory demyelinating polyneuropathy ("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. Dianthus plans to start Phase 2 trials in these additional indications in 2024, subject to IND clearances or other regulatory authorizations. Dianthus continues to evaluate other indications where the classical pathway plays a significant role in the disease pathology and DNTH103 could address unmet medical needs.

Discovery Programs

Dianthus has a dedicated team of scientists with extensive complement and antibody experience focused on expanding its pipeline of next-generation complement therapeutics targeting the active form of complement proteins. Dianthus expects its ongoing discovery efforts to nominate a new development candidate for an additional complement target in the second half of 2024.

Dianthus' Team and Investors

Dianthus Therapeutics OpCo, Inc., or OpCo, was founded in 2019 by a group of leading entrepreneurial scientists and investors with extensive monoclonal antibody experience. Its scientific founders' discoveries have also led to the creation of other successful biotechnology companies, including Apogee Therapeutics, Inc., Astria Therapeutics, Inc., Cogent Biosciences, Inc., Spyre Therapeutics, Inc., and Viridian Therapeutics, Inc. Dianthus is led by a strong management team and scientists with diverse backgrounds and significant experience in developing novel treatments for patients at biopharmaceutical companies such as Alexion Pharmaceuticals, Inc., Aspreva Pharmaceuticals Corp., Aurinia Pharmaceuticals Inc., Ra Pharmaceuticals, Inc., and UCB S.A. Together, its team has a proven track record in the discovery, development and commercialization of numerous approved complement and autoimmune and inflammatory therapeutics.

Since its inception and prior to the completion of the Merger, OpCo had raised approximately $121 million of capital from premier life science investors, including 5AM Ventures, Avidity Partners, Fairmount Funds Management LLC ("Fairmount"), Fidelity Management & Research Company, Tellus BioVentures, LLC ("Tellus BioVentures") and Venrock Healthcare Capital Partners.

On September 11, 2023, in connection with the completion of the Merger, OpCo completed a $72 million private investment in its common stock and pre-funded warrants from a syndicate of healthcare investors led by Fidelity Management & Research Company, Catalio Capital Management, 5AM Ventures, Avidity Partners, Wedbush Healthcare Partners and founding investors Fairmount, Tellus BioVentures and Venrock Healthcare Capital Partners.

Dianthus' Strategy

Dianthus' 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 its strategy are:

- **Rapidly advance DNTH103 into a global Phase 2 clinical trial in gMG.** DNTH103 has completed the Phase 1 healthy volunteer dose cohorts that are required to progress into Phase 2 clinical trials, pending regulatory approvals. Dianthus intends to submit an IND in the U.S. in the fourth quarter of 2023, followed by a CTA filing in the EU thereafter, to support a global Phase 2 clinical trial in gMG. Data from DNTH103's ongoing Phase 1 clinical trial in 52 healthy volunteers across seven 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. Dianthus aims 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. Dianthus believes 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, Dianthus is evaluating diseases in which the classical pathway plays a significant role in the disease pathology, such as MMN and CIDP. Dianthus expects to progress DNTH103 into Phase 2 clinical trials in these additional indications in 2024, starting with MMN in the first half 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.** Dianthus is 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. Dianthus has a dedicated team of scientists with extensive complement and antibody experience working to expand its pipeline of investigational complement therapeutic candidates to develop and deliver novel and highly differentiated therapies for underserved patients. Dianthus expects to nominate a new development candidate for an additional complement target in the second half of 2024.
- **Collaborate strategically to maximize the value of Dianthus' product candidates.** In June 2022, Dianthus licensed development and commercialization rights to Zenas BioPharma for DNTH103 in greater China. Aside from greater China, Dianthus currently holds worldwide development and commercialization rights, including through exclusive licenses, to all of its product candidates. Dianthus intends to pursue independent development and commercialization in select indications and markets where it can maximize shareholder value with a focused commercial organization. Dianthus may opportunistically explore licensing agreements, collaborations or partnerships to enhance its development efforts, develop its product candidates in larger market indications or commercialize its products where it could create more value for patients and shareholders by utilizing the resources of larger or better positioned biopharmaceutical companies.

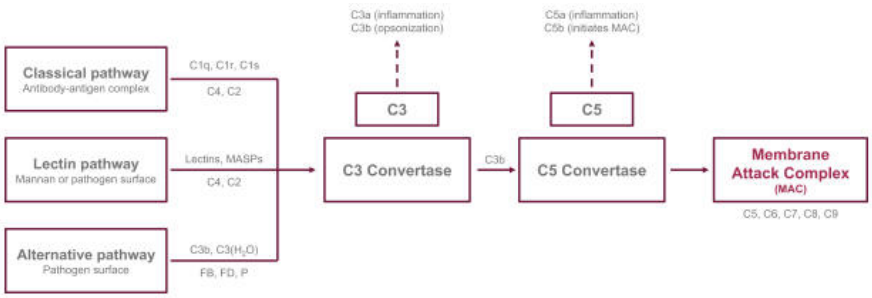
Overview of the Complement System

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:

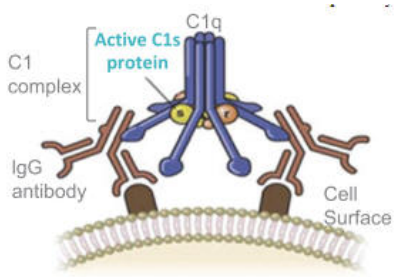
- *Classical Pathway*: Activated primarily by immune complexes.
- *Lectin Pathway*: Activated by mannose binding lectin interaction with sugars on the surface of pathogens or injured cells.
- *Alternative Pathway*: Automatically activated in a conformational, non-enzymatic process that leads to amplification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



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 membrane attack complex ("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 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.

Dianthus' First Product Candidate, DNTH103

Summary

DNTH103 is a highly selective and potent fully human monoclonal IgG4 antibody that is designed to bind selectively to the active form of C1s and inhibits further progression of the classical pathway cascade. DNTH103 is designed to support less frequent, lower volume, self-administration as a convenient S.C. injection. Based on preclinical and available clinical data to date, Dianthus believes DNTH103 has the following potential advantages:

- ***High selectivity and potency with picomolar binding affinity.*** DNTH103 is a potent and selective antibody designed to bind with high affinity to the active form of C1s. In preclinical studies, DNTH103 has been observed to have a greater than 10,000-fold binding affinity versus proC1s and inhibits further progression of the classical pathway cascade. By targeting active C1s, the much less abundant form found in peripheral blood at approximately 39-fold less active C1s than proC1s on a molar basis, Dianthus may be able to lower the effective dose required to treat a range of autoimmune and inflammatory diseases. A currently approved therapy binds to both the inactive (or proC1s) and active forms of C1s, thus requiring relatively high doses to be delivered for therapeutic effect due to target mediated drug disposition. Dianthus evaluated the potency of DNTH103 in vitro in a direct lysis assay using human red blood cells ("RBCs") which was compared to recombinantly-generated forms (in-vitro synthesized molecules whose molecular structure is predicted to be identical based on amino acid sequences from patent filings) of marketed antibody therapeutics, sutimlimab and ravulizumab. These latter antibodies target C1s (both proC1s and active C1s) and C5, respectively. In one representative experiment, the IC50, a widely used and informative measure of the amount of antibody required to inhibit 50% of baseline classical pathway activity, for DNTH103 was 5.8nM compared to 29.5nM for sutimlimab and 28.4nM for ravulizumab. While it is possible that findings in clinical trials will differ and the recombinantly-generated comparators may have subtle differences to the marketed products, this experiment demonstrates that a significantly lower dose of DNTH103 is required to achieve IC50 compared to sutimlimab and ravulizumab.
- ***Extended half-life.*** Dianthus engineered the Fc portion of DNTH103 to include YTE half-life extension technology to increase availability of DNTH103 in circulation thereby enabling extended complement inhibition, which may enable patients to dose less frequently. In Dianthus' preclinical studies, serum levels from non-human primates ("NHPs") indicated an elimination half-life of up to 21.7 days following I.V. and S.C. administration of DNTH103 and was comparable between both routes of administration. According to published scientific literature, Dianthus anticipated a significantly longer half-life in humans based on published PK findings from Phase 1 trials of other monoclonal antibodies that utilized YTE half-life extension technologies, such as MEDI-524-YTE (motavizumab-YTE) and STAR-0215. Based on data from the Phase 1 clinical trial, DNTH103 has a half-life of approximately 60 days.
- ***Lower risk of infection.*** Currently approved complement therapies for gMG (the C5 inhibitors) inhibit the terminal portion of all three complement pathways and have FDA Boxed Warnings for serious meningococcal infections and REMS. Through inhibition of active C1s, DNTH103 is designed to selectively target the classical pathway while leaving the lectin and alternative pathways intact with the aim of reducing the risk of infection from encapsulated bacteria. Notably, ENJAYMO®, a C1s classical pathway inhibitor, received FDA approval in 2022 for the treatment of hemolysis in adults with CAD without an FDA Boxed Warning or REMS. Dianthus believes that the FDA's approval of a C1s classical pathway inhibitor therapy with no FDA Boxed Warning or REMS evidences the potential for DNTH103 to achieve its target product profile of no FDA Boxed Warning or REMS.

- ***Clear biological rationale.*** The C1s protein has been well studied and extensively described in scientific literature. The classical complement pathway plays a clear role in antibody-mediated autoimmune and inflammatory diseases, such as gMG and others, given that the C1 complex, through C1q, directly binds to IgG and IgM antibody-antigen complexes that are generated during disease pathogenesis. This binding triggers activation of proteases, such as active C1s, which leads to cleavage of complement proteins, convertase generation and ultimately formation of the MAC on cell surfaces leading to cell death and tissue damage. In addition, ENJAYMO®, marketed by Sanofi S.A., is a C1s inhibitor that binds to both proC1s and active C1s and is an approved and effective treatment for hemolysis in adults with CAD. However, given it is not selective for the active form of the protein, the recommended dose by weight is 6,500 – 7,500mg administered Q2W through intravenous infusion during the maintenance period. Therefore, Dianthus believes there is an opportunity for an active C1s inhibitor that is designed to support lower dose, more convenient S.C. dosing (i.e., DNTH103's target product profile).
- ***Broad therapeutic potential in classical complement pathway-implicated diseases.*** The classical pathway is activated through interaction of the C1 complex with antibody-antigen complexes. Dianthus believes it is therefore rational to propose that compounds specifically targeting the classical pathway and specifically active C1s, such as DNTH103, would be well-suited for the potential treatment of autoimmune or inflammatory disease conditions where autoantibodies are implicated. Beyond gMG, Dianthus is also evaluating diseases in which the classical pathway plays a significant role in the disease pathology, such as MMN and CIDP. Dianthus expects to progress DNTH103 into Phase 2 clinical trials in these indications in 2024, beginning with MMN in the first half of 2024 and CIDP in the second half of 2024, subject to IND clearances or other regulatory authorizations.

DNTH103 for the Treatment of Generalized Myasthenia Gravis

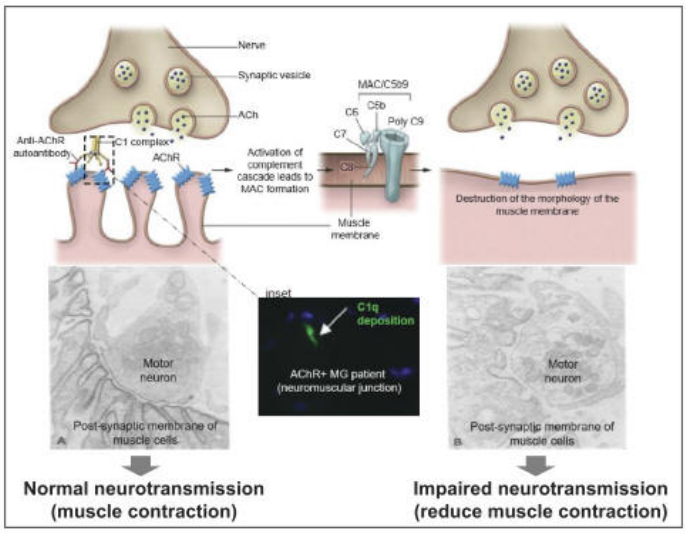
Overview of Myasthenia Gravis

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 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 patents). 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 and I.V. immunoglobulin therapy are therapeutic options, although these are more invasive treatments often reserved for MG crisis. 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, Dianthus believes 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 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.

Phase 1 Healthy Volunteer Study

DNTH103 is currently being evaluated in a first-in-human Phase 1 single and multiple ascending dose trial in healthy adult volunteers between the ages of 18 and 65 in New Zealand. Dianthus initiated this trial in November 2022 following approvals from the Health and Disability Ethics Committee ("HDEC") and the New Zealand Medicines and Medical Devices Safety Authority. The primary objective of the trial is to evaluate the safety and tolerability of DNTH103 and secondary objectives include evaluating pharmacokinetics, pharmacodynamics and immunogenicity—this study is not powered for statistical significance.

The trial is structured to include both a single-ascending dose and multiple ascending dose cohorts. The SAD part of this trial involves up to seven cohorts of up to 56 participants assigned to receive a single dose of DNTH103 or placebo in a 6:2 ratio. Doses in the SAD part of this trial may range from 1mg/kg to 50mg/kg I.V. infusion across four cohorts and 300mg to 600mg S.C. injection across three cohorts. The MAD part of this trial involves two cohorts of up to 16 participants assigned to receive three doses, two weeks apart, of DNTH103 or placebo in a 6:2 ratio administered S.C. Doses in the MAD part of the trial may range from 300mg to 600mg S.C. injections across two cohorts. Participants are followed for eight weeks after the first dose in a blinded placebo- controlled core phase before entering an unblinded extension to continue PK and PD monitoring.

DNTH103 has completed the dose cohorts that are required to progress into Phase 2 clinical trials, pending regulatory authorizations. In August of 2023, Dianthus reported data from 52 healthy volunteers that have been dosed across seven cohorts, including five SAD cohorts: 1mg/kg I.V., 10mg/kg I.V., 30mg/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, with no SAEs or complement-related infections, and demonstrated potent inhibition of the classical pathway and half-life of approximately 60 days. This favorable PK and PD profile allows DNTH103 to surpass the IC90 with Q2W dosing of a single 300mg/2mL S.C. injection. Dianthus conducted a PK simulation, utilizing the data from the 52 healthy volunteers, following an initial loading dose, that demonstrates 300mg S.C. DNTH103 serum concentration at steady state, when dosed Q2W, exceeds the DNTH103 serum concentration of 83ug/mL required to surpass IC90. Dianthus believes, based on published scientific literature related to other complement therapies, that the IC90 will be sufficient to achieve clinical activity in patients with neuromuscular autoimmune diseases such as gMG.

Data from the Phase 1 clinical trial of DNTH103 is expected to inform the design, parameters and objectives of a subsequent Phase 2 trial in gMG patients, as well as support the initiation of additional Phase 2 clinical trials in other indications.

Dianthus intends to submit an IND in the United States in the fourth quarter of 2023 and subsequently a CTA in the European Union to support the initiation of a global Phase 2 clinical trial in gMG in the first quarter of 2024.

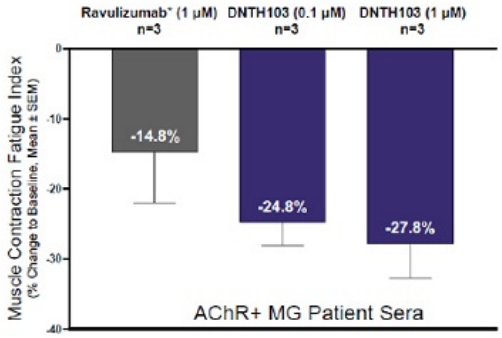
Planned Phase 2 Generalized Myasthenia Gravis Trial

The Phase 2 clinical trial is designed to be a global, multi-center, randomized, double-blind, placebo-controlled study in up to 60 patients on stable background therapy. The primary objective of this trial is expected to be to evaluate the safety and tolerability of DNTH103 in patients with gMG. The secondary objective of this trial is expected to be to evaluate the clinical efficacy as well as PK and PD to support dose selection of DNTH103 in future trials of DNTH103 in patients with gMG. Following an initial loading dose, DNTH103 is planned to be administered Q2W to these patients through S.C. injection. The S.C. treatment duration is expected to initially be 12 weeks with a 52-week open label extension. Dianthus intends to initiate a Phase 2 gMG trial in the first quarter of 2024 and report top-line results in the second half of 2025.

In Vitro Myasthenia Gravis Proof of Concept Study

DNTH103 was studied in a validated functional in vitro experiment simulating the neuromuscular junction in patients with AChR antibody positive MG with the objective of evaluating the impact of DNTH103 on muscle fatigue, a composite measure of neurotransmission and muscle contraction. In AChR antibody positive MG, IgG1 or IgG3 autoantibodies to the acetylcholine receptor induce local classical pathway activation and MAC formation, resulting in neuromuscular junction damage and subsequent disruption of neurotransmission and muscle contraction. Similar functional in vitro studies from Hesperos, Inc., have been published in peer-reviewed journals and used to support IND submissions for other neuromuscular conditions such as MMN and CIDP.

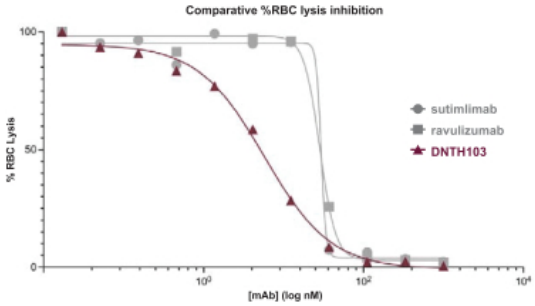
In this experiment, the nerve cells are continuously stimulated for two minutes and measurements of the muscle contractions are collected. The impact of the addition of serum from three different AChR antibody positive MG patients to the simulated neuromuscular junction was then assessed, causing muscle contraction to become weaker and fatigue due to neurotransmission impairment. The percent change in muscle fatigue index to baseline was then examined following the introduction of 1.0 µM of a tested recombinantly-generated form (in-vitro synthesized molecules whose molecular structure is predicted to be identical based on amino acid sequences from patent filings) of ravulizumab, and two concentrations of DNTH103, 1.0 µM and 0.1 µM. The results (as shown below) demonstrate that ravulizumab reduced muscle fatigue in AChR antibody positive MG patient samples, as expected. DNTH103 also reduced muscle fatigue in AChR antibody positive MG patient samples, indicating an improvement in neurotransmission and muscle contraction. The results provide further scientific rationale for DNTH103 in gMG.



* Engineered using patent sequence

Preclinical Data

Dianthus evaluated the potency of DNTH103 *in vitro* in a direct lysis assay using human RBCs, and for comparison also tested recombinantly-generated forms (in-vitro synthesized molecules whose molecular structure is predicted to be identical based on amino acid sequences from patent filings) of marketed antibody therapeutics, sutimlimab and ravulizumab. These latter antibodies target C1s (both active and inactive C1s) and C5, respectively. In one representative direct lysis experiment, the IC50, a widely used and informative measure of a drug's efficacy, for DNTH103 was 5.8nM compared to 29.5nM for sutimlimab and 28.4nM for ravulizumab as shown in the figure below. While it is possible that findings in clinical trials will differ and the recombinantly-generated comparators may have subtle differences to the marketed products, this experiment demonstrates that a significantly lower dose of DNTH103 is required to achieve IC50 compared to sutimlimab and ravulizumab.



	IC50* (nM)
sutimlimab**	29.5
ravulizumab**	28.4
DNTH103	**5.8**

* Representative run. Average IC50s are comparable, but run to run variability observed for all mAbs.
** Competitor products generated in the lab using amino acid sequences from patent filings.

Preclinical Safety Pharmacology and Toxicology

DNTH103 has been evaluated in several *in vitro* and *in vivo* preclinical studies. Dianthus believes the results from completed preclinical PK, PD, and toxicology studies supported further evaluation of DNTH103 in clinical trials. The following represents Dianthus' summary observations from its preclinical studies:

- ***Long-half life.*** PK analysis following 3-100 mg/kg I.V. or S.C. administration of DNTH103 showed an elimination half-life of up to 21.7 days after a single dose and 29.3 days after Q2W dosing for six months in NHPs. This is in contrast to the approximately 8-12 days half-life for a non-Fc-engineered IgG in NHPs;
- ***Linear PK.*** *In vivo* PK studies in NHPs showed that DNTH103 exhibited dose proportional exposure when administered I.V. or S.C., with no dose-dependent changes in PK properties as evidenced by the consistent half-life across doses; and

- ***Favorable Preclinical Safety Data.*** Based on NHP GLP and non-GLP toxicology studies completed to date, DNTH103 was generally well tolerated at 200 mg/kg I.V. in the 29-day study with three repeat doses administered Q2W, and at 20 mg/kg S.C. in the 26-week study with 13 repeat doses administered Q2W. As further described below, Dianthus considers the human-relevant no observed adverse effect level ("NOAEL") in the 26-week study to be 200 mg/kg S.C., the highest dose of DNTH103 evaluated in the study.

Pharmacokinetics / Toxicokinetics in Non-Human Primates

Two stand-alone single-dose PK studies were conducted in NHPs, with the overall range of doses explored between 3-100 mg/kg I.V. and 3-100 mg/kg S.C. Following S.C. administration of 3 mg/kg or 100 mg/kg DNTH103, slow absorption was evident with median time to peak concentration ("Tmax") ranging from three to seven days, as anticipated for S.C. administration. The Tmax after I.V. administration was at the end of the approximately one hour infusion. Serum levels of DNTH103 indicated an elimination half-life of up to 21.7 days following I.V. and S.C. administration, and reasonable dose proportionality was seen with both routes of administration.

Toxicokinetic data was also collected as part of the 29-day and 26-week good laboratory practice ("GLP") repeat dose toxicology studies in NHPs. Exposure to DNTH103, as assessed by mean maximum observed concentration measured after dosing ("C_{max}") and area under the concentration-time curve ("AUC_{tau}"), increased in a dose proportional manner.

- For the 29-day study, minor accumulation was observed after repeat I.V. and S.C. administration. At the I.V. NOAEL of 200 mg/kg, serum DNTH103 C_{max} and AUC_{tau} values after the final doses (on Day 29) were 7860 µg/mL and 28000 day*µg/mL, respectively. At the S.C. NOAEL of 70 mg/kg, serum DNTH103 C_{max} and AUC_{tau} values after the final doses (on Day 29) were 937 µg/mL and 12200 day*µg/mL, respectively.
- For the 26-week study, a minor but inconsistent trend was observed toward higher peak and total exposure in male animals compared to female animals. However, intergroup differences for C_{max} and AUCs suggest there was no meaningful exposure differences in the sexes. At the S.C. NOAEL of 20 mg/kg, serum DNTH103 C_{max} and $AUC_{0\text{-}336}$ values after the final dose (on Day 169) were 590 µg/mL and 7180 day*µg/mL, respectively, and mean half-life was 29.3 days. Across the dose range of 70 to 200 mg/kg DNTH103, mean C_{max} increased approximately 2-fold (1970 to 3850 µg/mL) and after the final dose (on Day 183) of 200 mg/kg DNTH103, the mean half-life was 24.6 days and accumulation of C_{max} and $AUC_{0\text{-}168}$ relative to Day 1 was approximately 2.5-fold and 2.7-fold, respectively.

In an 8-day single-dose GLP study in NHPs a single S.C. injection of 70 mg/kg DNTH103 was evaluated using two different formulations of DNTH103, which were 100 mg/mL and 150 mg/mL. The toxicokinetic properties of the two formulations were similar, including peak concentration time and total exposure.

Toxicology

Single Dose: 8-day GLP study and non-GLP PK study

The injection site tolerability of DNTH103 was evaluated in a single-dose GLP study in NHPs following a single S.C. injection of 70 mg/kg DNTH103, formulated at concentrations of 100 mg/mL and 150 mg/mL. Administration of DNTH103 by a single S.C. injection on Day 1 using two different formulations, 100 mg/mL and 150 mg/mL, was well tolerated. DNTH103-related microscopic findings at the injection site were only observed on Day 2, following administration of the 150 mg/mL formulation. Findings included minimal to mild mixed cell inflammation, minimal mononuclear cell infiltration, hemorrhage, edema and/or erythrophagocytosis within the S.C. injection site. These findings were not observed on Day 8, suggesting resolution of the findings observed on Day 2, nor were these findings observed following administration of the 100 mg/mL formulation.

In addition, a limited set of safety assessments were included as part of a non-GLP single dose PK study in NHPs, which aided dose selection for the subsequent pivotal 29-day NHP GLP repeat-dose toxicology study. These included clinical observations, injection site observations, body weight and limited clinical pathology. In this non-GLP PK study, transient loose stools and dehydration were observed in two out of three NHPs administered 3 mg/kg S.C. and three out of three NHPs administered 100 mg/kg S.C.; however, no notable observations were recorded for NHPs administered 100 mg/kg I.V. and no clear dose response was established. Therefore, these changes were not regarded as test-article related. Overall, no DNTH103-related adverse clinical observations were noted, and there were no DNTH103-related effects on body weight, clinical chemistry, or hematology parameters at I.V. and S.C. dose levels up to 100 mg/kg.

Multiple Dose Studies: 29-Day and 26-Week Studies

The potential toxicological effects of DNTH103 were evaluated in two NHP studies: a GLP, 29-day repeat-dose toxicity study and a GLP 26-week repeat dose toxicity study.

- In the 29-day repeat dose toxicity study, repeat I.V. and S.C. dosing of DNTH103 Q2W, all dose levels of 3, 70 or 200 mg/kg I.V. and 70 mg/kg S.C. were well tolerated in NHPs, resulting in no adverse findings. Specifically, there were no DNTH103-related clinical observations, neurological/musculoskeletal observations, changes in body weight, blood pressure, respiratory rate, body temperature, ophthalmology, electrocardiography, immunophenotyping by flow cytometry or urinalysis parameters and there were no DNTH103-related changes in organ weights, gross or microscopic pathology findings. Some mild to minimal reversible changes were observed in clinical pathology, complement levels and at the injection site, but only the elevation in complement C3a was conclusively attributed to DNTH103 administration and was considered non-adverse and toxicologically irrelevant. Given the absence of any DNTH103-related adverse effects, the NOAELs were 200 mg/kg I.V. and 70 mg/kg S.C., the highest doses evaluated for each route of administration in the study.
- In the 26-week repeat dose toxicity study, sexually mature NHPs received DNTH103 Q2W at dose levels of 20, 70 and 200 mg/kg S.C. The only adverse findings associated with the administration of DNTH103 indicate immune complex disease associated with ≥ 70 mg/kg DNTH103 in NHPs. These findings are consistent with previous preclinical reports of immune complex formation in NHPs administered human antibodies and are not predictive of immune complex formation in humans. Due to the adverse nature of immune complex disease in NHPs following administration of ≥ 70 mg/kg DNTH103, a human monoclonal antibody foreign to NHPs, the NOAEL for the 26-week repeat dose toxicity study was 20 mg/kg DNTH103 for NHPs. Because this immunogenicity finding is not predictive to humans, Dianthus considers the human-relevant NOAEL as 200 mg/kg S.C., the highest dose of DNTH103 evaluated in the study.

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. Dianthus believes 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 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 immunoglobin 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 (“SCIG”), plasmapheresis (“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.

Expanding Dianthus' Pipeline of Additional Next-Generation Complement Therapeutics

Dianthus has a dedicated team of scientists with extensive complement and antibody experience focused on expanding its pipeline of next-generation complement therapeutics targeting the active form of complement proteins. Dianthus expects its ongoing discovery efforts to nominate a new development candidate for an additional complement target in the second half of 2024.

Intellectual Property

Dianthus wholly owns the patent portfolio covering its C1s selective antibodies, including two pending U.S. provisional applications, one pending PCT application, and one pending non-provisional application in the United States. 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. Patents that could issue in the future that could cover DNTH103 would be expected to expire no earlier than 2043, subject to any disclaimers or extensions. Dianthus is developing potential pharmaceutical formulations for DNTH103 and will file patent applications to protect the same as appropriate.

Commercial

Should any of Dianthus' product candidates be approved for commercialization, it intends 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 Dianthus to realize the full commercial value of its programs. Given the company's stage of development, Dianthus has not yet established a commercial organization or distribution capabilities. In June 2022, Dianthus 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, Dianthus currently holds worldwide development and commercialization rights, including through exclusive licenses, to all of its product candidates.

Manufacturing

Dianthus does not currently own or operate facilities for product manufacturing, testing, storage, and distribution. Dianthus contracts with third parties for the manufacture and distribution of its product candidates. Because it relies on contract manufacturers, Dianthus employs personnel with extensive technical, manufacturing, analytical and quality experience. Dianthus' 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 its regulatory filings.

Competition

Dianthus expects 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, are approved by the FDA for the treatment of gMG in patients who are AChR positive. An additional development candidate from UCB S.A., Zilucoplan, a daily S.C. C5 inhibitor, is currently under regulatory review 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 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.

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 is conducting a Phase 2 clinical trial of efgartigimod, an I.V. FcRn inhibitor. Sanofi is conducting a Phase 2 proof-of-concept clinical trial of 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. Dianthus' ability to compete will significantly depend upon its ability to complete necessary clinical trials and regulatory approval processes, and effectively market any drug that it may successfully develop. Dianthus' 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 Dianthus may receive marketing approval include efficacy, safety and tolerability profile, dosing convenience, price, coverage, reimbursement and public opinion. Many of Dianthus' existing or potential competitors have substantially greater financial, technical and human resources than it does 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. Dianthus' 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 Dianthus' competitors.

Accordingly, competitors may be more successful than Dianthus 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 Dianthus' targeted indications by a competitor could render its product candidate non-competitive or obsolete, or reduce the demand for its product candidate before it can recover its development and commercialization expenses.

Collaboration, License and Services Agreements

Zenas BioPharma

In September 2020, Dianthus entered into an option agreement with Zenas BioPharma Limited ("Zenas BioPharma"), under which it 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, Dianthus was issued Zenas BioPharma common stock equivalent to one percent of its shares outstanding prior to a Series A financing. On a Research Program-by-Research Program basis, Zenas BioPharma also agreed to pay Dianthus a one-time payment of $1 million upon exercising its 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 its option, Dianthus entered into a license agreement with Zenas BioPharma (the "Zenas License Agreement"), under which it 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, Dianthus is 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 it previously incurred; (iii) reimbursement of a portion of certain CMC-related costs and expenses; and (iv) reimbursement of a portion of certain non-CMC-related costs and expenses. Additionally, Dianthus is 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 Dianthus for the royalty term of the Zenas License Agreement.

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

On March 22, 2021, Dianthus 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, Dianthus is 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. Dianthus 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 Dianthus 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, Dianthus entered into a cell line license agreement (the "Cell Line License Agreement") with WuXi Biologics. Under the Cell Line License Agreement, Dianthus received a non-exclusive, worldwide, sublicensable license to certain of WuXi Biologics' know-how, cell line, biological materials (the "WuXi Biologics Licensed Technology") 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, Dianthus agreed to pay WuXi Biologics a non-refundable license fee of $150,000. Additionally, if Dianthus manufactures all of its commercial supplies of bulk drug product with a manufacturer other than WuXi Biologics or its affiliates, it is 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 Dianthus manufactures part of its 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 Dianthus upon six months' prior written notice and its payment of all undisputed amounts due to WuXi Biologics through the effective date of termination, (ii) by WuXi Biologics for a material breach by Dianthus that remains uncured for 60 days after written notice, (iii) by WuXi Biologics if Dianthus fails 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, 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 Dianthus is developing. Dianthus, 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 it wishes to conduct studies or seek approval or licensure of its 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 it.

U.S. Biologics Regulation

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Public Health Service Act ("PHSA") and their implementing regulations, as well as other federal, state, local, and foreign statutes and regulations. 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 applicable regulations, including the FDA's current Good Laboratory Practices ("cGLP");
- submission to the FDA of an investigational new drug application, or 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 institutional review board ("IRB"), or ethics committee at each clinical site before the trial may be commenced;
- manufacture of the proposed biologic candidate in accordance with current Good Manufacturing Practices ("cGMPs");
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, current Good Clinical Practice ("cGCP") requirements and other clinical-trial related regulations 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 biologics license application ("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 potential audit of selected clinical investigation sites to assess compliance with GCPs;

- payment of user fees for FDA review of the BLA, unless a waiver is applicable; 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 the first clinical trial with a product candidate, Dianthus must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product 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.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with cGCPs, 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 guidance for whether or not a study may move forward at designated check points based on access to certain data from the study and may recommend halting 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. Sponsors of clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information, which is publicly available at ***www.clinicaltrials.gov***.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA. The FDA will accept a well- designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with cGCP requirements and the FDA is able to validate the data through an onsite inspection if deemed necessary.

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.

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.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical study investigators. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected suspected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical 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. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States. 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 ("PSP") within sixty days after an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs. 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 the BLA 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 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 cGCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it typically 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. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing. 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 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.

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 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 with due diligence 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 ("FDORA"), 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. Under the FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a product or indication approved under accelerated approval 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 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 Dianthus 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. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. After a BLA is approved for a biological product, the product also may be subject to official lot release. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biologics. 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 Dianthus and its 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 Dianthus and any third-party manufacturers that it 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;
- 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 Dianthus 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. FDA-approved interchangeable biosimilars may be substituted for the reference product without the intervention of the prescribing health care provider, subject to state laws, which differ by state.

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, lease, order, arrangement, 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. Dianthus' 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. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil monetary penalties.

Civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which impose criminal and civil penalties and 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; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. 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. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery.

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 knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements or representations relating to healthcare matters.

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, certain other licensed health care practitioners, 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.

Dianthus is also subject to federal price reporting laws and federal consumer protection and unfair competition laws. Federal price reporting laws require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/ or discounts on approved products. Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.

Further, Dianthus is 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 Dianthus' operations are found to be in violation of any of such laws or any other governmental regulations that apply, it 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 its 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 Dianthus' operations or the operations of its partners. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health ("HITECH"), and their respective implementing regulations imposes 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 health information for or on behalf of such covered entities. 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. Further, entities that knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to criminal penalties.

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, state laws govern the privacy and security of personal information, including health-related information, in certain circumstances. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, the California Consumer Privacy Act, which went into effect on January 1, 2020, creates new data privacy obligations for covered companies and provides new privacy rights to California residents.

Coverage and Reimbursement

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Dianthus' ability to successfully commercialize its product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow it to establish or maintain pricing sufficient to realize a sufficient return on its investment. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which Dianthus obtains 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 its 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 it to provide scientific and clinical support for the use of its product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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, net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Dianthus cannot be sure that reimbursement will be available for any product candidate that it commercializes and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

Finally, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union ("EU") provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of its product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

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 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. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and Dianthus expects there will be additional challenges and amendments to the ACA in the future.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011 and subsequent legislation, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through 2032. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. The U.S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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 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.

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 includes several provisions that may impact Dianthus' business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high- cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The effects of the IRA on its business and the healthcare industry in general is not yet known.

President Biden has also issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

Notwithstanding the IRA and President Biden's executive orders, continued legislative and enforcement interest exists in the United States with respect to specialty drug pricing practices. Specifically, Dianthus expects 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.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm its business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for its drugs or put pressure on its drug pricing, which could negatively affect Dianthus' business, financial condition, results of operations and prospects.

Other Government Regulation Outside of the United States

In addition to regulations in the United States, Dianthus is 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 its products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not Dianthus obtains FDA approval for a product, it 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 an 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 Protection Laws

The collection and use of personal health data and other personal data regarding individuals in the European Economic Area ("EEA") is governed by the provisions of the European General Data Protection Regulation (EU) 2016/679 ("EU GDPR") and related data protection laws in individual EEA member states, including additional requirements relating to health, genetic and biometric data implemented through national legislation. Similar processing of personal health data and other personal data regarding individuals in the United Kingdom ("UK") is governed by the UK General Data Protection Regulation ("UK GDPR") and the UK Data Protection Act 2018. In this document, "GDPR" refers to both the EU GDPR and the UK GDPR, unless specified otherwise. 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.

In addition, the GDPR imposes specific restrictions on the transfer of personal data to countries outside of the EEA/UK that are not considered by the Europe Commission ("EC") and the UK government as providing an adequate level of data protection (third countries), including the United States. 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") and the UK International Data Transfer Agreement/Addendum ("UK IDTA"). Where relying on the SCCs or UK IDTA for data transfers, Dianthus may also be required to carry out transfer impact assessments to assess whether the recipient is subject to local laws which allow public authority access to personal data.

The international transfer obligations under the EEA/UK data protection regimes will require effort and cost and may result in it needing to make strategic considerations around where EEA/UK personal data is located and which service providers Dianthus can utilize for the processing of EEA/UK personal data. Although the UK is regarded as a third country under the EU GDPR, the EC has issued a decision recognizing the UK as providing adequate protection under the EU GDPR ("Adequacy Decision") and, therefore, transfers of personal data originating in the EEA to the UK remain unrestricted. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. The UK government has also now introduced a Data Protection and Digital Information Bill ("UK Data Protection Bill") into the UK legislative process with the intention for this bill to reform the UK's data protection regime following Brexit. If passed, the final version of the UK Data Protection Bill may have the effect of further altering the similarities between the UK and EU data protection regime. This may lead to additional compliance costs and could increase its overall risk. The respective provisions and enforcement of the EU GDPR and UK GDPR may further diverge in the future and create additional regulatory challenges and uncertainties.

On March 25, 2022, the EC and the United States announced that they have agreed in principle on a new Trans-Atlantic Data Privacy Framework. Following this statement, on October 7, 2022, President Biden signed an Executive Order on 'Enhancing Safeguards for United States Signals Intelligence Activities', which implemented the agreement in principle. On that basis, the EC prepared a draft Adequacy Decision and launched its adoption procedure. While this new EU-U.S. privacy framework is expected to enter into force in 2023, there is still some uncertainty around the new framework.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA member states/UK may result in significant monetary fines for noncompliance of up to €20 million (£17.5 million for the UK) 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 EEA member states/UK 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 to the EEA/UK 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.

Compliance with the GDPR is a rigorous and time-intensive process that may increase Dianthus' cost of doing business or require it to change its business practices, and despite those efforts, there is a risk that Dianthus may be subject to fines, penalties and litigation in connection with European activities, which could in turn have a negative effect on its reputation and materially harm its business.

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 (EU) 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 it, harm to its reputation, and adversely impact its 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 Dianthus faces with regard to data protection regulation.

Drug and Biologic Development Process

Regardless of where they are conducted, all clinical trials included in applications for marketing authorization for human medicines in the EU must have been carried out in accordance with EU regulations.

This means that clinical trials conducted in the EU have to comply with EU clinical trial legislation but also that clinical trials conducted outside the EU have to comply with ethical principles equivalent to those set out in the EU, 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 one or 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 in the applicable EU member state(s) and one or more Ethics Committees. The national competent authority of all 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 national competent authorities 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 national competent authority and to the ethics committees of the EU member state where they occur.

A more unified procedure applies under the CTR. A sponsor can submit a single application for approval of a clinical trial through a centralized EU clinical trials portal (the "Clinical Trials Information System" or "CTIS"). One national competent authority (the reporting EU member state proposed by the applicant) will take the lead in validating and evaluating the application, and will 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. On January 31, 2023, submission of initial clinical trial applications via CTIS became 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.

Under both the former regime and the 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 European Medical Agency ("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") for the product concerned.

Drug Marketing Authorization

In the EU, medicinal products are subject to extensive pre- and post-market regulation by regulatory authorities at both the EU and national levels. To obtain regulatory approval of a product under the EU regulatory systems, Dianthus must submit an MAA under either the EU centralized procedure, or one of the national procedures in the EU.

Centralized Authorization Procedure

The centralized procedure provides for the grant of a single marketing authorization ("MA") that is issued by the EC following the scientific assessment of the application by the EMA and that is valid for all EU member states as well as in the three additional EEA member states (Norway, Iceland and Liechtenstein). The centralized procedure is compulsory for certain types of medicinal products, including for medicines developed by means of certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (gene therapy, somatic cell therapy or tissue-engineered medicines) and medicinal products with a new active substance indicated for the treatment of certain diseases (HIV/AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases). The centralized procedures is an option for medicinal products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or for which the grant of an MA through the centralized procedure would be in the interest of public health at the EU level.

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 marketing authorization. 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 and Mutual Recognition Procedures

Medicines that fall outside the mandatory scope of the centralized procedure can be authorized under a decentralized procedure where an applicant applies for simultaneous authorization in more than one EU member state, or 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 marketing authorization (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. 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 states, the concerned member states, are subsequently required to grant a marketing authorization 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. RMPs and Periodic Safety Update Reports ("PSURs") are routinely available to third parties requesting access, subject to limited redactions.

MA Validity Period

In the EU, an MA has 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.

Exceptional Circumstances/Conditional Approval

Similar to accelerated approval regulations in the United States, conditional MAs can be granted in the EU for medicines intended for treating, preventing or diagnosing seriously debilitating or life-threatening diseases, or in a public health emergency. 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, the following 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 post-authorization, (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. Once a conditional MA has been granted, the MA holder must fulfil specific obligations within defined timelines. A conditional MA must be renewed annually, but can be converted into a standard MA once the MA holder fulfils the obligations imposed and the complete data confirm that the medicine's benefits continue to outweigh its risks.

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. Innovative medicinal products (sometimes referred to as new chemical entities) approved in the EU generally qualify for eight years of data exclusivity and 10 years of marketing exclusivity.

If granted, the data exclusivity period begins on the date of the product's first MA in the EU and prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization 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). An additional 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. Additionally, a standalone one-year period of data exclusivity can be granted 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. 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 an MA 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 new Chemical Entities, or 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.

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. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as an orphan product if its sponsor can establish that (1) it is intended for the diagnosis, prevention or treatment of a life- threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000 Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to 10 years of market exclusivity for the approved therapeutic indication. An application for orphan drug designation (which is not a marketing authorization, as not all orphan-designated medicines reach the authorization application stage) must be submitted first before an MAA 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 ("COMP") reassesses the orphan drug designation of a product in parallel with the review for a marketing authorization; for a product to benefit from market exclusivity it must maintain its orphan drug designation at the time of marketing authorization review by the EMA and approval by the EC. Additionally, any marketing authorization granted for an orphan medicinal product must only cover the therapeutic indication(s) that are covered by the orphan drug designation.

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 marketing authorization, accept an application to extend an existing marketing authorization or grant marketing authorization 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.

During the period of market exclusivity, an MA may only be granted to a "similar medicinal product" for the same therapeutic indication if: (i) a second applicant can establish that its product, although similar to the authorized product, is safer, more effective or otherwise clinically superior; (ii) the MA holder for the authorized product consents to a second orphan medicinal product application; or (iii) the MA holder for the authorized product cannot supply enough orphan medicinal product.

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, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. 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 such a waiver or a deferral has been granted. Medicinal products that are granted an 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 ("SPC"), provided an application for such extension is made at the same time as filing the SPC application for the product, or at any point up to two years before the SPC expires, 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 an 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.

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 marketing authorization application 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 the Committee for Advanced Therapies, or 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 marketing authorizations. 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 Dianthus or by any of its 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.

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 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 EMA 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 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 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 Dianthus' 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 national competent 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 marketing authorization granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion, which is prohibited in the EU. 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.

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.

Other Markets

The UK formally left the EU on January 31, 2020 and the transition period, during which EU laws continued to apply to the UK, expired on December 31, 2020. This means EU laws now only apply to the UK in respect of Northern Ireland as laid out in the Northern Ireland Protocol. Following the end of the transition period, the EU and the UK concluded a trade and cooperation agreement ("TCA"), which applied provisionally from January 1, 2021 and entered into force on May 1, 2021.

The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended). Except in respect of the new CTR, the regulatory regime in Great Britain therefore largely aligns with current EU medicines regulations, however it is possible that these regimes will diverge more significantly in future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation. However, notwithstanding that there is no wholesale recognition of EU pharmaceutical legislation under the TCA, under a new framework which will be put in place by the Medicines and Healthcare products Regulatory Agency ("MHRA"), from January 1, 2024, the MHRA has stated that it will take into account decisions on the approval of marketing authorizations from the EMA (and certain other regulators) when considering an application for a Great Britain marketing authorization.

On February 27, 2023, the UK government and the EC announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA will be responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single UK-wide marketing authorization will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, so the UK government and the EU will enact legislative measures to bring it into law.

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 Dianthus fails 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 September 15, 2023, Dianthus had 43 employees, all of whom were employed full time and 29 of whom were engaged in research and development activities. Eleven of the company's employees hold Ph.D. or M.D. degrees. None of its employees are represented by a labor union or covered under a collective bargaining agreement. Dianthus considers its relationship with its employees to be good.

Facilities

Dianthus is currently a remote-based company and a majority of its employees work remotely. The company currently leases office space in Waltham, Massachusetts and in New York, New York. Its office in Waltham is approximately 2,750 square feet under a lease that expires in January 2025 and its office in New York is approximately 3,367 square feet under a lease that expires in August 2025. Dianthus' New York office is its corporate headquarters. As the company expands, Dianthus believes suitable additional or substitute space will be available as and when needed.

Legal Proceedings

From time to time, Dianthus may be subject to legal proceedings. It is not currently a party to or aware of any proceedings that it believes will have, individually or in the aggregate, a material adverse effect on its business, financial condition or results of operations. Regardless of outcome, litigation can have an adverse impact on Dianthus because of defense and settlement costs, diversion of management resources and other factors.

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

On September 11, 2023, Dianthus Therapeutics, Inc. (formerly Magenta Therapeutics, Inc.) (the "Company") completed its business combination with Dianthus Therapeutics OpCo, Inc. (formerly Dianthus Therapeutics, Inc.) ("Dianthus") in accordance with the terms of the Agreement and Plan of Merger, dated as of May 2, 2023 (the "Merger Agreement"), pursuant to which, among other matters, Dio Merger Sub, Inc., a wholly owned subsidiary of the Company ("Merger Sub"), merged with and into Dianthus, with Dianthus surviving as a wholly owned subsidiary of the Company (the "Merger"). Following the completion of the Merger, the business conducted by the Company became primarily the business conducted by Dianthus, which is a clinical-stage biotechnology company focused on developing next-generation complement therapeutics for patients living with severe autoimmune and inflammatory diseases.

The following discussion and analysis of Dianthus' financial condition and results of operations should be read together with Dianthus' financial statements and the related notes included as Exhibits 99.4 and 99.5 of the Company's Current Report on Form 8-K/A filed with the U.S. Securities and Exchange Commission (the "SEC") on September 21, 2023 (the "Current Report on Form 8-K/A") of which this Exhibit 99.3 is a part. This discussion contains forward-looking statements that involve risks and uncertainties, such as statements regarding Dianthus' plans, objectives, expectations, intentions and projections. Dianthus' actual results could differ materially from those described in or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Forward-Looking Statements" of the Company's Current Report on Form 8-K filed with the SEC on September 12, 2023 (the "Current Report on Form 8-K") and the Risk Factors included as Exhibit 99.1 of the Current Report on Form 8-K/A of which this Exhibit 99.3 is a part. Terms not defined herein shall have the meanings ascribed to them in the Company's definitive proxy statement/prospectus filed with the SEC on August 1, 2023.

Overview

Dianthus is a clinical-stage biotechnology company focused on developing next-generation complement therapeutics for patients living with severe autoimmune and inflammatory diseases. Dianthus believes its 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. Dianthus has 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, Dianthus aims to reduce the amount of drug required for a therapeutic effect. Dianthus intends to deliver its product candidate through a lower dose, less frequent, self-administered, convenient subcutaneous ("S.C.") injection suitable for a pre-filled pen.

Dianthus' 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 ("C1s"). The active form of C1s is generated during complement activation by cleavage of the inactive proC1s. 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 in August of 2023 from DNTH103's ongoing Phase 1 clinical trial in 52 healthy volunteers across seven dose cohorts validates the extended half-life and potent classical pathway inhibition and supports a potentially differentiated safety profile of DNTH103. The top-line 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 of 83ug/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 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 Risk Evaluation and Mitigation Strategy. Dianthus believes 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.

Background

Since its inception in 2019, Dianthus has devoted substantially all of its 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 its clinical trials and preclinical studies, business planning, developing and maintaining its intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these activities.

Dianthus does not own or operate, and currently has no plans to establish, any laboratory or manufacturing facilities. It relies, and expects to continue to rely, on third parties for the testing and manufacture of its product candidates, as well as for commercial manufacturing should any of its product candidates obtain marketing approval. Dianthus believes that this strategy allows it to maintain a more efficient infrastructure by eliminating the need to invest in its own laboratory and manufacturing facilities, equipment, and personnel while also enabling it to focus expertise and resources on the development of its product candidates.

Since its inception, Dianthus has funded its operations primarily with outside capital (e.g., proceeds from the sale of preferred stock) and has raised aggregate gross proceeds of $121.5 million from these private placements. However, Dianthus has incurred significant recurring losses, including net losses of $18.2 million and $10.6 million for the six months ended June 30, 2023 and 2022, respectively, and $28.5 million and $13.1 million for the years ended December 31, 2022 and 2021, respectively. In addition, Dianthus had an accumulated deficit of $64.1 million as of June 30, 2023. As of June 30, 2023, Dianthus had cash, cash equivalents and short-term investments of $61.1 million.

As of the completion of the Merger and the Dianthus pre-closing financing (as defined below), Dianthus believes that its existing cash, cash equivalents and short-term investments on hand of $184.0 million will be sufficient to fund its operations into the second quarter of 2026. Until Dianthus achieves profitability, management plans to fund its operations and capital expenditures with cash on hand and the issuance of capital stock. There can be no assurance that Dianthus will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to Dianthus. If Dianthus is unable to raise sufficient additional capital, it may be compelled to consider actions such as reducing the scope of its operations and planned capital expenditures or sell certain assets, including intellectual property assets.

Dianthus' 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 its research and development activities. Management expects that Dianthus' expenses and capital requirements will increase substantially in connection with its ongoing activities as they:

- advance 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 its intellectual property portfolio, including patents, trade secrets and know-how;
- implement operational, financial and management systems; and
- operate as a public company.

Dianthus does not have any products approved for commercial sale and has not generated any commercial revenue from product sales. Its 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 Dianthus expects, if it ever occurs, will take many years. Dianthus expects to spend a significant amount on development and marketing costs prior to such time. Dianthus will therefore require substantial additional capital to develop DNTH103 and any future product candidates and support its continuing operations. Dianthus may never succeed in achieving regulatory and marketing approval for DNTH103 or any future product candidates. Dianthus may obtain unexpected results from its preclinical and clinical trials. Dianthus 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 Dianthus can generate a sufficient amount of revenue from product sales or other sources, if ever, management expects to finance Dianthus' 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, Dianthus may be unable to raise additional capital from these sources on favorable terms, or at all. Its failure to obtain sufficient capital on acceptable terms when needed could have a material adverse effect on Dianthus' business, results of operations or financial condition, including requiring Dianthus to delay, reduce or curtail its research, product development or future commercialization efforts. Dianthus may also be required to license rights to product candidates at an earlier stage of development or on less favorable terms than it would otherwise choose. Dianthus' management cannot provide assurance that Dianthus will ever generate positive cash flow from operating activities. See "*—Liquidity and Capital Resources.*"

Option and License Agreements with Zenas

Dianthus is a party to an option agreement and license agreement with Zenas BioPharma Limited ("Zenas BioPharma"), a related party. In September 2020, Dianthus entered into an option agreement with Zenas BioPharma ("Zenas Option"), through which Dianthus provided Zenas BioPharma 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 June 2022, Dianthus 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. For the six months ended June 30, 2023 and 2022, Dianthus recognized related party license revenue totaling $1.4 million and $4.1 million, respectively, associated with the Zenas Agreements. For the years ended December 31, 2022 and 2021, Dianthus recognized related party license revenue totaling $6.4 million and $1.5 million, respectively, associated with the Zenas Agreements. For additional information on the Zenas Agreements, see Note 12 to the unaudited condensed financial statements for the six months ended June 30, 2023 and 2022 included as Exhibit 99.4 of the Current Report on Form 8-K/A of which this Exhibit 99.3 is a part.

Recent Developments

The Merger

On May 2, 2023, Dianthus entered into the Merger Agreement with the Company and Merger Sub. On September 11, 2023, Dianthus completed its business combination with the Company in accordance with the terms of the Merger Agreement, pursuant to which, among other matters, Merger Sub merged with and into Dianthus, with Dianthus surviving as a wholly owned subsidiary of the Company. Following the completion of the Merger, the business conducted by the Company became primarily the business conducted by Dianthus, 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 is intended to qualify for U.S. federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Code.

At the closing of the Merger, (a) each outstanding share of Dianthus common stock (including shares of Dianthus common stock issued upon conversion of Dianthus preferred stock and shares of Dianthus common stock issued in the Dianthus pre-closing financing) was converted into the right to receive a number of shares of Company common stock (after giving effect to the Reverse Stock Split (as defined in the Current Report on Form 8-K)) equal to the exchange ratio of approximately 0.2181 shares of Company common stock for each share of Dianthus common stock; (b) each then outstanding Dianthus' stock option and warrant that was not previously exercised immediately prior to the effective time of the Merger was assumed by the Company; and (c) each then outstanding Dianthus restricted stock unit immediately prior to the effective time of the Merger was assumed by the Company.

Pre-Closing Financing

Immediately prior to the completion of the Merger, and in order to provide Dianthus with additional capital for its development programs, Dianthus issued and sold, and certain new and current investors purchased, 2,873,988 shares of common stock of Dianthus and 210,320 Dianthus pre-funded warrants, exercisable for 210,320 shares of Dianthus common stock, at a purchase price of approximately $23.34 per share or $23.34 per warrant, for the aggregate amount of $72.0 million (the "Dianthus pre-closing financing").

Impact of COVID-19 Pandemic and Other Global Economic Events

In December 2019, a novel strain of coronavirus called COVID-19 emerged and has now spread globally. Dianthus continues to actively monitor the impact of the COVID-19 pandemic on its financial condition, liquidity, operations, suppliers, industry and workforce.

Although Dianthus has not experienced any significant adverse impact from the COVID-19 pandemic to date, Dianthus' financial condition, results of operations and liquidity could be negatively impacted by the COVID-19 pandemic in future periods. The extent to which the COVID-19 pandemic could impact its business will depend on future developments, which remain uncertain and cannot be predicted, including new information that may emerge concerning the continued severity of COVID-19 and variants of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. As the impact of the COVID-19 pandemic continues, it may have an adverse effect on Dianthus' results of future operations, financial position and liquidity, and on its ability to access capital. Even after the impact of the COVID-19 pandemic has subsided, Dianthus may continue to experience adverse impacts to its business as a result of an economic recession or depression that may occur in the future.

Additionally, uncertainty in the global economy presents significant risks to Dianthus' business. Dianthus is subject to continuing risks and uncertainties in connection with the current macroeconomic environment, including increases in inflation, rising interest rates, changes in foreign currency exchange rates, recent bank failures, geopolitical factors, including the ongoing conflict between Russia and Ukraine and the responses thereto, and supply chain disruptions. While management is closely monitoring the impact of the current macroeconomic conditions on all aspects of Dianthus' business, including the impacts on its participants in its Phase 1 clinical trial, employees, suppliers, vendors and business partners, the ultimate extent of the impact on Dianthus' 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 Dianthus' control and could exist for an extended period of time. Management 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 Risk Factors included as Exhibit 99.1 of the Current Report on Form 8-K/A of which this Exhibit 99.3 is a part.

Components of Results of Operations

Revenue

Since its inception, Dianthus has not generated any revenue from product sales, and management does not expect Dianthus to generate any revenue from the sale of products in the foreseeable future.

Under the Zenas Agreements, the consideration payable by Zenas Biopharma to Dianthus 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 Dianthus; (iii) reimbursement of a portion of costs related to chemistry, manufacturing and control ("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"), Dianthus 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, Dianthus will recognize the transaction price from the license agreement over Dianthus' estimated period to complete its activities. Dianthus 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. Dianthus believes this is the best measure of progress because other measures do not reflect how it transfers its performance obligation to Zenas Biopharma. In applying the cost-based input method of revenue recognition, Dianthus 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 performance obligations. A cost-based input method of revenue recognition requires management to make estimates of costs to complete 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, Dianthus 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 June 30, 2023 and December 31, 2022, no royalty revenue has been recognized.

Dianthus 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 Dianthus' control, Dianthus 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 Dianthus recognizes revenue. As of June 30, 2023 and December 31, 2022, no milestones had been achieved.

For the six months ended June 30, 2023 and 2022, Dianthus recognized related party license revenue totaling $1.4 million and $4.1 million, respectively, associated with the Zenas Agreements. For the years ended December 31, 2022 and 2021, Dianthus recognized related party license revenue totaling $6.4 million and $1.5 million, respectively, associated with the Zenas Agreements.

If Dianthus' development efforts for DNTH103 or any future product candidates are successful and result in regulatory approval, Dianthus may generate revenue from future product sales. If Dianthus enters 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. Dianthus cannot predict if, when, or to what extent Dianthus will generate revenue from the commercialization and sale of DNTH103 or any future product candidates or from license or collaboration agreements. Dianthus 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 Dianthus' operating expenses and consist primarily of external and internal expenses incurred in connection with the discovery and development of DNTH103 and other potential product candidates.

External expenses include:

- payments to third parties in connection with the research and development of DNTH103 and other potential product candidates, including agreements with third parties such as clinical research organizations ("CROs"), clinical trial sites and consultants;
- the cost of manufacturing products for use in Dianthus' clinical 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 DNTH103 and other potential 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.

Dianthus recognizes research and development expenses in the periods in which they are incurred. Its 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 Dianthus by its service providers or its estimate of the level of service that has been performed at each reporting date. Dianthus utilizes CROs for research and development activities and CDMOs for manufacturing activities and it does not have its own laboratory or manufacturing facilities. Therefore, Dianthus has 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, management expects that Dianthus' research and development expenses will increase substantially over the next several years as Dianthus advances DNTH103 into larger and later-stage clinical trials, works to discover and develop additional product candidates, seeks to expand, maintain, protect and enforce its intellectual property portfolio, and hires additional research and development personnel.

The successful development of DNTH103 or any future product candidates is highly uncertain, and management does 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, its 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 preclinical and clinical development activities;

- the number and scope of preclinical and clinical programs Dianthus pursues;
- Dianthus' 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 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 Dianthus encounters any serious adverse events in its 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 Dianthus establishes 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;
- Dianthus' arrangements with its CDMOs and CROs;
- development and timely delivery of commercial-grade drug formulations that can be used in Dianthus' planned clinical trials and for commercial launch;
- the impact of any business interruptions to Dianthus' operations or to those of the third parties with whom Dianthus works, particularly in light of the COVID-19 pandemic environment; 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 rent, utilities, depreciation, and maintenance, not otherwise included in research and development expenses. Dianthus recognizes general and administrative expenses in the periods in which they are incurred.

Dianthus expects that its general and administrative expenses will increase in the future to support its 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, Dianthus anticipates that it 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, Dianthus has not recorded any U.S. federal or state income tax benefits for the net losses it has incurred in each year or for its earned research tax credits due to uncertainty of realizing a benefit from those items. Dianthus maintains a full valuation allowance on its federal and state deferred tax assets as Dianthus' management has concluded that it is more likely than not that the deferred assets will not be utilized.

Results of Operations

Comparison of the Six Months Ended June 30, 2023 and 2022

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

	Six Months Ended June 30,	
	2023	2022
	(in thousands)	
Revenues:		
License revenue - related party	$ 1,445	$ 4,069
Operating expenses:		
Research and development	16,100	12,330
General and administrative	4,804	2,497
Total operating expenses	20,904	14,827
Loss from operations	(19,459)	(10,758)
Other income/(expense):		
Interest income	1,293	89
(Loss)/gain on currency exchange, net	(37)	100
Other expense	(26)	(7)
Total other income	1,230	182
Net loss	$ (18,229)	$ (10,576)
Comprehensive loss:		
Net loss	$ (18,229)	$ (10,576)
Other comprehensive income:		
Change in unrealized losses related to available-for-sale debt securities	142	—
Total other comprehensive income	142	—
Total comprehensive loss	$ (18,087)	$ (10,576)

License Revenue—Related Party

Under the terms of the Zenas Agreements, Dianthus recognized related party license revenue of $1.4 million and $4.1 million during the six months ended June 30, 2023 and 2022, respectively. The decrease was due to a decreased amount of CMC reimbursement due from Zenas Biopharma in the first six months of 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

The following table summarizes Dianthus' research and development expenses for the periods indicated:

	Six Months Ended June 30,	
	2023	2022
	(in thousands)	
External research and development expenses:		
DNTH103 program-related expenses:		
Preclinical study costs	$ 5,156	$ 1,769
CMC activities	2,774	6,909
Clinical operation activities	1,404	72
Third-party consulting services	956	1,241
License and milestone payments	50	200
Total DNTH103 program-related expenses	10,340	10,191
Discovery expenses	916	600
Total external research and development expenses	11,256	10,791
Internal research and development expenses:		
Personnel and related costs	4,277	1,325
Share-based compensation	332	113
Other costs	235	101
Total internal research and development expenses	4,844	1,539
Total research and development expenses	$ 16,100	$ 12,330

Research and development expenses were $16.1 million for the six months ended June 30, 2023, as compared to $12.3 million for the six months ended June 30, 2022, an increase of $3.8 million. This increase was due to (1) a $3.3 million increase in internal research and development costs, consisting of personnel and related costs, share-based compensation, and other costs and (2) a $0.5 million increase 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 $3.3 million increase in internal research and development costs was due to a $3.0 million increase in personnel and related costs, a $0.2 million increase in share-based compensation, and a $0.1 million increase in other costs. The increases were primarily due to the expansion of the research and development function with additional headcount commencing after the Dianthus Series A convertible preferred stock closing in April 2022.

The $0.5 million increase in external research and development costs was due to a $0.3 million increase in discovery activities and a $0.2 million increase in expenses related to its lead product candidate, DNTH103. For the first six months of 2023, as compared to the same period in 2022, there were increases of $3.4 million in preclinical study costs and $1.3 million in clinical activity costs, offset by decreases of $4.1 million in CMC activities, $0.3 million in third-party consulting services and $0.1 million in license and milestone payments. The increased amount of preclinical study costs resulted from increased toxicology activities, including a chronic toxicology study, in the first six months of 2023. The increased amount of clinical activity costs resulted from the commencement of the Phase 1 clinical trial in November 2022. 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 third-party consulting services resulted from the transition of research and development activities being conducted by full-time employees starting in April 2022. The decreased amount of license and milestone payments resulted from a one-time license payment in 2022.

General and Administrative Expenses

General and administrative expenses were $4.8 million for the six months ended June 30, 2023, as compared to $2.5 million for the six months ended June 30, 2022, an increase of $2.3 million. The increase was primarily due to increases of $1.1 million in personnel-related costs, $0.5 million in share-based compensation, $0.4 million in professional services costs, and $0.3 million increase in consulting costs. The increases were primarily due to building out the general and administrative function with additional headcount commencing after the Dianthus Series A convertible preferred stock closing in April 2022.

Income Tax

The provision for income taxes consists primarily of income taxes related to federal and state jurisdictions in which Dianthus conducts business. Dianthus maintains a full valuation allowance on its federal and state deferred tax assets as management has concluded that it is more likely than not that the deferred assets will not be utilized.

Comparison of the Years Ended December 31, 2022 and 2021

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

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Revenues:		
License revenue - related party	$ 6,417	$ 1,476
Operating expenses:		
Research and development	29,379	12,606
General and administrative	6,743	1,956
Total operating expenses	36,122	14,562
Loss from operations	(29,705)	(13,086)
Other income/(expense):		
Interest income	1,145	3
Gain/(loss) on currency exchange, net	136	(26)
Other expense	(52)	—
Total other income/(expense)	1,229	(23)
Net loss	$ (28,476)	$ (13,109)
Other comprehensive loss:		
Net loss	$ (28,476)	$ (13,109)
Change in unrealized losses related to available-for-sale debt securities	(161)	—
Comprehensive loss	$ (28,637)	$ (13,109)

License Revenue—Related Party

Under the terms of the Zenas Agreements, Dianthus recognized related party license revenue of $6.4 million and $1.5 million during the years ended December 31, 2022 and 2021, respectively. The increase was due to an increased amount of research and development reimbursement from Zenas Biopharma as a result of the increased activities for the DNTH103 program during the year ended December 31, 2022.

Research and Development Expenses

The following table summarizes Dianthus' research and development expenses for the periods indicated:

	Years Ended December 31,	
	2022	2021
	(in thousands)	
External research and development expenses:		
DNTH103 program-related expenses:		
Preclinical/IND-enabling studies	$ 8,345	$ 4,465
CMC activities	10,206	3,402
Clinical operation activities	538	—
Third-party consulting services	2,066	1,508
License and milestone payments	1,265	100
Total DNTH103 program-related expenses	22,420	9,475
Discovery expenses	1,167	2,464
Total external research and development expenses	23,587	11,939
Internal research and development expenses:		
Personnel and related costs	4,964	631
Share-based compensation	416	19
Other costs	412	17
Total internal research and development expenses	5,792	667
Total research and development expenses	$ 29,379	$ 12,606

Research and development expenses were $29.4 million for the year ended December 31, 2022, as compared to $12.6 million for the year ended December 31, 2021, an increase of $16.8 million. This increase was due to (1) a $11.7 million increase 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 and (2) a $5.1 million increase in internal research and development costs, consisting of personnel and related costs, share-based compensation, and other costs.

The $11.7 million increase in external research and development costs was primarily due to the activities related to its lead product candidate, DNTH103, including a $3.9 million increase in preclinical study costs, a $6.8 million increase in CMC activities, a $0.5 million increase in clinical activities, a $0.6 million increase in third-party consulting services and a $1.2 million increase in license and milestone payments, partially offset by a $1.3 million decrease in discovery activities, as DNTH103 moved from the discovery stage to the preclinical and clinical stage in mid-2021. Dianthus commenced a Phase 1 clinical trial of DNTH103 in November 2022 and in August of 2023 reported preliminarily topline results.

The $5.1 million increase in internal research and development costs was primarily due to a $4.3 million increase in personnel-related costs, a $0.4 million increase in share-based compensation, and a $0.4 million increase in other costs. The increases were primarily due to building out the research and development function with additional headcount.

General and Administrative Expenses

General and administrative expenses were $6.7 million for the year ended December 31, 2022, as compared to $2.0 million for the year ended December 31, 2021, an increase of $4.7 million. The increase was primarily due to an increase of $2.8 million in personnel and related costs, $1.1 million increase in share-based compensation, $0.3 million increase in professional services costs, $0.4 million in office and related expenses and $0.1 million in other costs. The increases were primarily due to building out the general and administrative function with additional headcount.

Income Tax

The provision for income taxes consists primarily of income taxes related to federal and state jurisdictions in which Dianthus conducts business. Dianthus maintains a full valuation allowance on its federal and state deferred tax assets as management has 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, Dianthus has not generated any revenue from product sales and has incurred significant operating losses and negative cash flows from its operations. Dianthus expects to continue to incur significant expenses and operating losses for the foreseeable future as Dianthus advances the clinical development of its product candidates. Dianthus 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 product candidates to support commercialization and providing general and administrative support for its operations, including the costs associated with operating as a public company. As a result, Dianthus will need additional capital to fund its operations, which Dianthus may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources. See the Risk Factors included as Exhibit 99.1 of the Current Report on Form 8-K/A of which this Exhibit 99.3 is a part for additional risks associated with Dianthus' substantial capital requirements.

Since its inception, Dianthus has funded its operations primarily through private placements of convertible preferred stock for gross proceeds of $121.5 million.

Going Concern

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)*, Dianthus 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 unaudited interim condensed financial statements were issued (the "issuance date"):

- Since its inception, Dianthus has funded its operations primarily with outside capital (e.g., proceeds from the sale of preferred stock) and has incurred significant recurring losses, including net losses of $18.2 million and $10.6 million for the six months ended June 30, 2023 and 2022, respectively, and $28.5 million and $13.1 million for the years ended December 31, 2022 and 2021, respectively. In addition, Dianthus had an accumulated deficit of $64.1 million as of June 30, 2023;
- Dianthus 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, Dianthus 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 one year beyond the issuance date. Dianthus 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 Dianthus 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 Dianthus' operations, a sale of assets, or other alternatives with strategic or financial partners.

Future Capital Requirements

Since inception, Dianthus has not generated any revenue from product sales. Management does not expect to generate any meaningful product revenue unless and until Dianthus obtains regulatory approval of and commercializes DNTH103 or any future product candidates, and management does not know when, or if, that will occur. Until Dianthus can generate significant revenue from product sales, if ever, it will continue to require substantial additional capital to develop DNTH103 or any future product candidates and fund operations for the foreseeable future.

Management expects Dianthus' expenses to increase in connection with its ongoing activities as described in greater detail below. Dianthus is subject to all the risks incident in the development of new biopharmaceutical products, and it may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may harm Dianthus' business.

In order to complete the development of DNTH103 or any future product candidates and to build the sales, marketing and distribution infrastructure that management believes will be necessary to commercialize product candidates, if approved, Dianthus will require substantial additional capital. Accordingly, until such time that Dianthus can generate a sufficient amount of revenue from product sales or other sources, if ever, management expects 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 Dianthus raises additional capital through equity financings or convertible debt securities, the ownership interest of its 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 its common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting Dianthus' ability to take specific actions, including restricting its operations and limiting its ability to incur liens, issue additional debt, pay dividends, repurchase its own common stock, make certain investments or engage in merger, consolidation, licensing, or asset sale transactions. If Dianthus raises capital through collaborations, partnerships, and other similar arrangements with third parties, it may be required to grant rights to develop and market product candidates that Dianthus would otherwise prefer to develop and market themselves. Dianthus may be unable to raise additional capital from these sources on favorable terms, or at all. Dianthus' 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 (including the ongoing COVID-19 pandemic) and otherwise. The failure to obtain sufficient capital on acceptable terms when needed could have a material adverse effect on Dianthus' business, results of operations or financial condition, including requiring Dianthus to delay, reduce or curtail its research, product development or future commercialization efforts. Dianthus may also be required to license rights to product candidates at an earlier stage of development or on less favorable terms than Dianthus would otherwise choose. Management cannot provide assurance that Dianthus will ever generate positive cash flow from operating activities.

Since its inception, Dianthus has funded its operations primarily with outside capital (e.g., proceeds from the sale of preferred stock) and has raised aggregate gross proceeds of $121.5 million from these private placements. However, Dianthus has incurred significant recurring losses. Dianthus had an accumulated deficit of $64.1 million as of June 30, 2023. As of June 30, 2023, Dianthus had cash, cash equivalents and short-term investments of $61.1 million. As of the completion of the Merger and Dianthus pre-closing financing, Dianthus believes that its existing cash, cash equivalents and short-term investments on hand of $184.0 million will be sufficient to fund its operations into the second quarter of 2026. Until Dianthus achieves profitability, management plans to fund its operations and capital expenditures with cash on hand and issuance of capital stock. There can be no assurance that Dianthus will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to Dianthus. If Dianthus is unable to raise sufficient additional capital, it may be compelled to consider actions such as reducing the scope of its operations and planned capital expenditures or sell certain assets, including intellectual property assets.

Management based projections of operating capital requirements on Dianthus' current operating plan, which includes several assumptions that may prove to be incorrect, and Dianthus may use all of its available capital resources sooner than management expects.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, Dianthus is unable to estimate the exact amount and timing of its capital requirements. Dianthus' 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 product candidates that Dianthus may pursue;
- the costs, timing, and outcome of regulatory review of Dianthus' product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing, and distribution, for any of Dianthus' product candidates for which it receives 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 Dianthus' products, should any of product candidates receive marketing approval;
- the cost and timing of attracting, hiring, and retaining skilled personnel to support Dianthus' operations and continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing Dianthus' intellectual property rights and defending intellectual property-related claims;
- Dianthus' 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 Dianthus acquires or in-licenses 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 Dianthus' product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, Dianthus' operating plans may change in the future, and Dianthus may need additional capital to meet the capital requirements associated with such operating plans.

Cash Flows

The following table summarizes Dianthus' cash flows for the periods indicated:

	Six Months June 30,		Year Ended December 31,	
	2023	2022	2022	2021
	(in thousands)			
Cash flows used in operating activities	$(15,015)	$(12,462)	$ (29,070)	$ (9,904)
Net cash provided by/(used in) investing activities	39,995	(69)	(59,819)	(33)
Cash flows provided by financing activities	—	96,676	96,676	14,912
Increase in cash, cash equivalents and restricted cash	$ 24,980	$ 84,145	$ 7,787	$ 4,975

Cash Flows from Operating Activities

For the six months ended June 30, 2023, net cash used in operating activities consisted of a net loss of $18.2 million, partially offset by a decrease in net operating assets and liabilities of $2.6 million and net non-cash operating expenses of $0.6 million. The decrease in net operating assets and liabilities was primary attributable to decreases in receivable from related party of $4.3 million, unbilled receivable from related party of $0.5 million and prepaid expenses and other current assets of $0.7 million, partially offset by an increase in deferred transaction costs of $1.2 million and a decrease in accounts payable, accrued expenses and lease liabilities of $1.7 million. The non-cash operating expenses consisted mainly of stock-based compensation expense of $1.0 million and amortization of right-of-use lease assets of $0.1 million, partially offset by accretion on short-term investments of $0.5 million.

For the six months ended June 30, 2022, net cash used in operating activities consisted of a net loss of $10.6 million and an increase in net operating assets and liabilities of $2.3 million, partially offset by net non-cash operating expenses of $0.4 million. The increase in net operating assets and liabilities was primarily due to increases in receivable from related party of $0.8 million, unbilled receivable from related party of $3.6 million and prepaid expenses and other current assets of $1.9 million, partially offset by increases in accounts payable, accrued expenses and lease liabilities of $3.1 million and deferred revenue – related party of $0.9 million. The non-cash operating expenses consisted mainly of stock-based compensation expense of $0.3 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.

For the year ended December 31, 2021, cash used in operating activities consisted of a net loss of $13.1 million, partially offset by a decrease in net operating assets and liabilities of $3.1 million. The decrease in net operating assets and liabilities was primarily due to an increase in accounts payable and accrued expenses of $4.9 million, partially offset by increases in receivable from related party of $0.5 million, unbilled receivable from related party of $1.0 million and prepaid expenses and other current assets of $0.3 million.

Cash Flows from Investing Activities

For the six months ended June 30, 2023, net cash provided by investing activities consisted of $43.9 million of proceeds from maturities of short-term investments, partially offset by $3.9 million of purchases of short-term investments and $35,000 of capital expenditures.

For the six months ended June 30, 2022, net cash used in investing activities consisted of $69,000 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.

For the year ended December 31, 2021, net cash used in investing activities consisted of $33,000 of capital expenditures.

Cash Flows from Financing Activities

For the six months ended June 30, 2023, net cash provided by financing activities consisted of $0.4 million of proceeds from promissory notes payable to related party, offset by a $0.4 million repayment of promissory notes payable to related party.

For the six months ended June 30, 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.

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.

For the year ended December 31, 2021, net cash provided by financing activities consisted of $14.9 million of net proceeds from the issuance of the Dianthus Series Seed 2 convertible preferred stock.

Contractual Obligations and Commitments

Lease Obligations

Dianthus leases space under operating leases agreements for administrative offices in New York, New York, and Waltham, Massachusetts, which expire in August 2025 and January 2025, respectively.

The following table summarizes Dianthus' contractual obligations and commitments as of June 30, 2023 (in millions):

	Payments Due by Period			
	2023	2024	2025	Total
Operating lease obligation	$0.2	$0.4	$0.2	$0.7

Research and Development and Manufacturing Agreements

Dianthus enters 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.

License and Collaboration Agreements

In August 2019, 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 Dianthus 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 license agreement was amended in October 2022. In addition to annual license fees, Dianthus is obligated to pay development and commercial milestone payments up to $12.8 million for the first selected antibody and up to $18.1 million for the second selected antibody.

In September 2022, Dianthus entered into a commercial platform license agreement and services agreement with Crystal Bioscience, Inc. ("Crystal") and OmniAb, Inc. ("OmniAb"), for (i) a worldwide, non-exclusive, non-sublicensable license under the Crystal 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, Dianthus is obligated to pay development milestones payments up to $12.2 million and to pay royalties in the low to mid-single digits.

In July 2020, Dianthus entered into a collaborative research agreement with IONTAS Limited ("IONTAS") to perform certain milestone-based research and development activities under its first development program. The agreement was amended in January 2023 to extend services to additional development programs. Dianthus is obligated to pay development and commercial milestone payments up to £5.4 million (approximately $6.8 million) with the first development program and up to £2.5 million (approximately $3.1 million) with the second development program.

Off-Balance Sheet Arrangements

Dianthus currently does not have, and did not have during the periods presented, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Significant Judgments and Estimates

Dianthus' financial statements are prepared in accordance with U.S. GAAP. 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 Dianthus' financial statements. Dianthus bases its estimates on historical experience, known trends and events and various other factors that management believes 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. Management evaluates estimates and assumptions on a periodic basis. Dianthus' actual results may differ from these estimates.

While Dianthus' significant accounting policies are described in more detail in Note 2 to the audited financial statements for the years ended December 31, 2022 and 2021 included as Exhibit 99.5 of the Company's Current Report on Form 8-K of which this Exhibit 99.3 is a part, management believes that the following accounting policies are critical to understanding Dianthus' historical and future performance, as the policies relate to the more significant areas involving management's judgments and estimates used in the preparation of the 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 the development activities of Dianthus; (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 and clinical activities and regulatory operations.

Dianthus enters consulting, research, and other agreements with commercial firms, researchers, and others for the provision of goods and services. Under such agreements, Dianthus 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 to Dianthus by its service providers or its 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, Dianthus 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 Dianthus' behalf.

Management makes estimates of Dianthus' accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to management at that time. There may also be instances in which payments made to Dianthus' vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing expenses, management estimates 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, management adjusts the accrual or the amount of prepaid expenses accordingly. Although Dianthus does not expect its estimates to be materially different from amounts actually incurred, management's 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 Dianthus' prior estimates of accrued research and development expenses.

Stock-Based Compensation

Dianthus 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 statements of operations and comprehensive loss based on their fair values. All of Dianthus' stock option awards are subject only to service-based vesting conditions. Management estimates the fair value of Dianthus' 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. Management estimates the fair value of the restricted stock awards using the fair value of Dianthus' common stock. Forfeitures are recognized as they are incurred.

Management utilizes estimates and assumptions in determining the fair value of Dianthus' common stock, including stock-based awards. Dianthus granted stock options at exercise prices that represented the fair value of its common stock on the specific grant dates. Dianthus 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 its common stock. Each valuation methodology includes estimates and assumptions that require management's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which Dianthus sold shares of convertible preferred stock, the superior rights and preferences of the convertible preferred stock senior to its common stock at the time, and a probability analysis of various liquidity events, such as a public offering or a sale of Dianthus, under differing scenarios. Changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

Due to the lack of a historical public market for the trading of Dianthus' common stock and a lack of company-specific historical and implied volatility data, management based its estimate of expected volatility on the historical volatility of a representative group of companies with similar characteristics to Dianthus, including stage of product development and life science industry focus. Dianthus believes the group selected has sufficiently similar economic and industry characteristics and includes companies that are most representative of Dianthus.

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.

Revenue Recognition—Zenas Agreements

Management analyzed 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 Dianthus 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, Dianthus considers relevant assumptions to estimate the standalone selling price, including, as applicable, market conditions, development timelines, probabilities of technical and regulatory success and forecasted revenues.

Management evaluates the performance obligations promised in the 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. Goods or services that meet these criteria are considered distinct performance obligations. Management 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, management evaluates the amount of potential transaction price and the likelihood that the transaction price will be received. Dianthus utilizes 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.

Dianthus applies 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. Dianthus evaluates 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, Dianthus evaluates 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.

Because the Zenas Agreements were negotiated with a single commercial objective, they are treated as a combined contract for accounting purposes. Dianthus 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. Dianthus 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. Dianthus determined that Zenas BioPharma’s right to exercise an option with respect to a second antibody sequence does not represent a material right.

Dianthus determined that the combined performance obligation is satisfied over time; therefore, Dianthus will recognize the transaction price from the license agreement over Dianthus’ estimated period to complete its activities. Dianthus 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. Dianthus believes this is the best measure of progress because other measures do not reflect how Dianthus transfers its performance obligation to Zenas Biopharma. In applying the cost-based input method of revenue recognition, Dianthus 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 performance obligations. A cost-based input method of revenue recognition requires management to make estimates of costs to complete Dianthus’ performance obligation. In making such estimates, judgment is required to evaluate assumptions related to cost estimates. Dianthus 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 Dianthus performs its obligations under these arrangements. Where applicable, amounts are recorded as unbilled revenue when Dianthus’ right to consideration is unconditional. Dianthus does 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.

Dianthus Therapeutics, Inc.

Unaudited Interim
Condensed Financial Statements

INDEX TO UNAUDITED INTERIM CONDENSED FINANCIAL STATEMENTS

DIANTHUS THERAPEUTICS, INC.

Condensed Balance Sheets
(in thousands, except share and per share data)
(unaudited)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 40,280	$ 15,365
Short-term investments	20,803	60,125
Receivable from related party	362	4,700
Unbilled receivable from related party	418	938
Prepaid expenses and other current assets	249	905
Deferred transaction costs	1,163	—
Total current assets	63,275	82,033
Property and equipment, net	149	142
Right-of-use lease assets	677	814
Other assets and restricted cash	174	121
Total assets	$ 64,275	$ 83,110
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 2,320	$ 1,167
Accrued expenses	3,874	6,608
Current portion of deferred revenue - related party	100	100
Current portion of lease liabilities	358	350
Total current liabilities	6,652	8,225
Deferred revenue - related party	763	791
Long-term lease liabilities	296	438
Total liabilities	7,711	9,454
Commitments and contingencies (Note 15)		
Preferred stock, $0.0001 par value per share; 33,336,283 shares authorized at June 30, 2023 and December 31, 2022		
Convertible preferred stock:		
Series Seed 1 convertible preferred stock, 6,500,000 shares designated, issued, and outstanding, liquidation preference of $6,500 at June 30, 2023 and December 31, 2022	6,436	6,436
Series Seed 2 convertible preferred stock, 3,829,265 shares designated, issued, and outstanding, liquidation preference of $15,000 at June 30, 2023 and December 31, 2022	14,912	14,912
Series A convertible preferred stock, 23,007,017 shares designated, issued, and outstanding, liquidation preference of $100,000 at June 30, 2023 and December 31, 2022	96,676	96,676
Total convertible preferred stock	118,024	118,024
Stockholders' deficit:		
Common stock, $0.0001 par value per share; 45,113,542 and 40,000,000 shares authorized at June 30, 2023 and December 31, 2022, respectively; 4,014,000 shares issued and outstanding at June 30, 2023 and December 31, 2022	—	—
Additional paid-in capital	2,656	1,661
Accumulated deficit	(64,097)	(45,868)
Accumulated other comprehensive loss	(19)	(161)
Total stockholders' deficit	(61,460)	(44,368)
Total liabilities and stockholders' deficit	$ 64,275	$ 83,110

The accompanying notes are an integral part of these unaudited interim condensed financial statements.

DIANTHUS THERAPEUTICS, INC.

Condensed Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Six Months Ended June 30,	
	2023	2022
Revenues:		
License revenue - related party	$ 1,445	$ 4,069
Operating expenses:		
Research and development	16,100	12,330
General and administrative	4,804	2,497
Total operating expenses	20,904	14,827
Loss from operations	(19,459)	(10,758)
Other income/(expense):		
Interest income	1,293	89
(Loss)/gain on currency exchange, net	(37)	100
Other expense	(26)	(7)
Total other income	1,230	182
Net loss	$ (18,229)	$ (10,576)
Net loss per share attributable to common stockholders, basic and diluted	$ (4.54)	$ (2.64)
Weighted-average number of common shares outstanding, used in computing net loss per common share, basic and diluted	4,011,824	4,008,324
Comprehensive loss:		
Net loss	$ (18,229)	$ (10,576)
Other comprehensive income:		
Change in unrealized losses related to available-for-sale debt securities	142	—
Total other comprehensive income	142	—
Total comprehensive loss	$ (18,087)	$ (10,576)

The accompanying notes are an integral part of these unaudited interim condensed financial statements.

DIANTHUS THERAPEUTICS, INC.

Condensed Statements of Changes in Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share data)
(unaudited)

	Convertible Preferred Stock							Stockholders' Deficit				
	Series Seed 1 Convertible Preferred Stock		Series Seed 2 Convertible Preferred Stock		Series A Convertible Preferred Stock		Total Convertible Preferred Stock	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumu Oth Compreh Los
	Shares	Amount	Shares	Amount	Shares	Amount		Shares	Amount			
Balance, December 31, 2021	6,500,000	$ 6,436	3,829,265	$ 14,912	—	$ —	$ 21,348	4,014,000	$ —	$ 143	$ (17,392)	$
Issuance of convertible preferred stock, net of issuance costs of $3,324	—	—	—	—	23,007,017	96,676	96,676	—	—	—	—	
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	344	—	
Net loss	—	—	—	—	—	—	—	—	—	—	(10,576)	
Balance, June 30, 2022	6,500,000	$ 6,436	3,829,265	$ 14,912	23,007,017	$ 96,676	$ 118,024	4,014,000	$ —	$ 487	$ (27,968)	$
Balance, December 31, 2022	6,500,000	$ 6,436	3,829,265	$ 14,912	23,007,017	$ 96,676	$ 118,024	4,014,000	$ —	$ 1,661	$ (45,868)	$
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	995	—	
Net loss	—	—	—	—	—	—	—	—	—	—	(18,229)	
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	—	
Balance, June 30, 2023	6,500,000	$ 6,436	3,829,265	$ 14,912	23,007,017	$ 96,676	$ 118,024	4,014,000	$ —	$ 2,656	$ (64,097)	$

The accompanying notes are an integral part of these unaudited interim condensed financial statements.

DIANTHUS THERAPEUTICS, INC.

Condensed Statements of Cash Flows
(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (18,229)	$ (10,576)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	28	9
Stock-based compensation expense	995	344
Accretion of discount on short-term investments	(566)	—
Amortization of right-of-use lease assets	137	29
Changes in operating assets and liabilities:		
Receivable from related party	4,338	(757)
Unbilled receivable from related party	520	(3,626)
Prepaid expenses and other current assets	656	(1,916)
Deferred transaction costs	(1,163)	—
Other assets	12	(32)
Accounts payable, accrued expenses and lease liabilities	(1,715)	3,126
Deferred revenue - related party	(28)	937
Net cash used in operating activities	(15,015)	(12,462)
Cash flows from investing activities:		
Capital expenditures	(35)	(69)
Purchases of short-term investments	(3,855)	—
Proceeds from maturities of short-term investments	43,885	—
Net cash provided by/(used in) investing activities	39,995	(69)
Cash flows from financing activities:		
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	—	96,676
Increase in cash, cash equivalents and restricted cash	24,980	84,145
Cash, cash equivalents and restricted cash, beginning of period	15,425	7,638
Cash, cash equivalents and restricted cash, end of period	$ 40,405	$ 91,783
Supplemental Disclosure		
Cash and cash equivalents	$ 40,280	$ 91,723
Restricted cash	125	60
Total cash, cash equivalents and restricted cash	$ 40,405	$ 91,783
Cash paid for interest	$ —	$ —
Cash paid for taxes	$ —	$ —
Additions to right-of-use lease assets from new operating lease liabilities	$ —	$ 285

The accompanying notes are an integral part of these unaudited interim condensed financial statements.

1. Nature of Organization and Operations

Dianthus Therapeutics, Inc. ("Dianthus" or the "Company") is a clinical-stage biotechnology company focused on developing next-generation complement therapeutics for patients with severe autoimmune and inflammatory diseases. Dianthus was incorporated in the State of Delaware on May 1, 2019 and its corporate headquarters is located in New York, New York.

Currently, the Company is devoting substantially all efforts and resources toward product research and development. 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.

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.

The Company's potential product candidates that are in development 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 and Going Concern

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 unaudited interim condensed financial statements were issued (the "issuance date"):

- Since its inception, the Company has funded its operations primarily with outside capital (e.g., proceeds from the sale of preferred stock) and has incurred significant recurring losses, including net losses of $18.2 million and $10.6 million for the six months ended June 30, 2023 and 2022, respectively. In addition, the Company had an accumulated deficit of $64.1 million as of June 30, 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 one year 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 unaudited interim condensed financial statements do not include any adjustments that might result from the outcome of these uncertainties. Accordingly, the unaudited interim condensed 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.

Proposed Merger

On May 2, 2023, the Company entered into the Agreement and Plan of Merger, dated as of May 2, 2023 (the "Merger Agreement"), with Magenta Therapeutics, Inc. ("Magenta") and Dio Merger Sub, Inc. ("Merger Sub"). Pursuant to the Merger Agreement, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into the Company, with the Company surviving as a wholly owned subsidiary of Magenta(the "Merger"). Concurrently with the execution of the Merger Agreement, and in order to provide the Company with additional capital for its development programs, the Company entered into a subscription agreement (the "Subscription Agreement") with certain new and current investors (the "Investors"), pursuant to which, subject to the terms and conditions of the Subscription Agreement, the Company agreed to issue and sell, and the Investors agreed to purchase, immediately prior to the completion of the Merger, an aggregate of approximately $70.0 million of common stock and pre-funded warrants of the Company in a pre-closing financing (the "pre-closing financing"). The board of directors of both Magenta and Dianthus have approved the Merger Agreement and the Merger. Completion of the Merger, which is expected in the second half of 2023, is subject to approval by Magenta's and Dianthus' shareholders and the satisfaction or waiver of certain other customary closing conditions. If the Merger is completed, the business of the Company will continue as the business of the combined company.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim condensed financial statements as of June 30, 2023 and for the six months ended June 30, 2023 and 2022 have been prepared in conformity with generally accepted accounting principles in the United States of America ("U.S. GAAP"), for interim financial information and pursuant to Article 10 of Regulation S-X of the Securities Act of 1933, as amended (the "Securities Act"). Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. These unaudited interim condensed financial statements have been prepared on the same basis as the Company's audited financial statements and include only normal and recurring adjustments that the Company believes are necessary to fairly state the Company's financial position and the results of its operations and cash flows. The results for the six months ended June 30, 2023 are not necessarily indicative of the results expected for the full fiscal year or any subsequent interim period. The unaudited interim condensed balance sheet as of December 31, 2022 has been derived from the audited financial statements at that date but does not include all disclosures required by U.S. GAAP for complete financial statements. Because all of the disclosures required by U.S. GAAP for complete financial statements are not included herein, these unaudited interim condensed financial statements and the notes accompanying them should be read in conjunction with the Company's audited financial statements as of and for the years ended December 31, 2022 and 2021, included as Exhibit 99.5 of the Company's Current Report on Form 8-K/A filed with the SEC on September 21, 2023 (the "Current Report on Form 8-K/A") of which this Exhibit 99.4 is a part. Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

The Company's significant accounting policies are disclosed in the audited financial statements for the years ended December 31, 2022 and 2021, included as Exhibit 99.5 of the Current Report on Form 8-K/A of which this Exhibit 99.4 is a part. Since the date of those financial statements, there have been no changes to its significant accounting policies except as noted below.

Deferred Transaction Costs

The Company capitalized certain legal, professional accounting and other third-party fees that were directly associated with the Merger and pre-closing financing, as described further in Note 17, as deferred transaction costs. Upon consummation of the Merger, these costs will be recorded as a reduction of additional paid-in capital. Should the Merger be abandoned, the deferred transaction costs would be expensed immediately as a charge to operating expenses in the condensed consolidated statements of operations and comprehensive loss. As of June 30, 2023, the Company had capitalized deferred transaction costs of $1.2 million.

Recently Adopted Accounting Pronouncements

On January 1, 2023, the Company adopted ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* for the fiscal year beginning January 1, 2023 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 unaudited interim condensed financial statements and related disclosures.

3. Short-Term Investments

The table below provides a summary of short-term investments (in thousands).

	June 30, 2023			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Available-for-sale, short-term investments:				
U.S. treasury securities	$ 12,970	$ —	$ (11)	$ 12,959
U.S. government agency securities	7,851	2	(9)	7,844
Total available-for-sale, short-term investments	$ 20,821	$ 2	$ (20)	$ 20,803

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Available-for-sale, short-term investments:				
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	$ 60,286	$ 3	$ (164)	$ 60,125

As of June 30, 2023 and December 31, 2022, the available-for-sale securities classified as short-term investments mature in one year or less. Unrealized gains and losses on available-for-sale securities as of June 30, 2023 and December 31, 2022 were not significant and were primarily due to changes in interest rates. There were no significant realized gains or losses recognized on the sale or maturity of available-for-sale investments during the six months ended June 30, 2023 or the year ended December 31, 2022.

The Company's available-for-sale securities consist of U.S. treasury and government agency securities. There were no impairments of the Company's assets measured and carried at fair value during the six months ended June 30, 2023 or the year ended December 31, 2022.

4. Prepaid Expenses and Other Current Assets

The following table provides a summary of prepaid expenses and other current assets (in thousands):

	June 30, 2023	December 31, 2022
Prepaid materials, supplies and services	$ 158	$ 820
Prepaid insurance	18	32
Other	73	53
Prepaid expenses and other current assets	$ 249	$ 905

5. Property and Equipment

The following table provides a summary of property and equipment (in thousands):

	June 30, 2023	December 31, 2022
Computer equipment	$ 167	$ 131
Furniture and fixtures	40	41
Subtotal	207	172
Less: accumulated depreciation	(58)	(30)
Property and equipment, net	$ 149	$ 142

Depreciation expense was $28,000 and $9,000 in the six months ended June 30, 2023 and 2022, respectively.

6. Fair Value of Financial Instruments

Management calculates the fair value of assets and liabilities that qualify as financial instruments and includes additional information in the notes to the unaudited interim condensed financial statements when the fair value is different than the carrying value of these financial instruments. 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.

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 (at least annually) 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.

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

Description	Fair Value at June 30, 2023	Level 1	Level 2	Level 3
Recurring Assets:				
Cash equivalents:				
Money market fund	$ 36,982	$36,982	$ —	$ —
Short-term investments:				
U.S. treasury securities	12,959	12,959	—	—
U.S. government agency securities	7,844	—	7,844	—
Total assets measured at fair value	$ 57,785	$49,941	$7,844	$ —

Description	Fair Value at December 31, 2022	Level 1	Level 2	Level 3
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	$ 73,970	$59,357	$14,613	$ —

There have been no transfers between levels for the six months ended June 30, 2023 or the year ended December 31, 2022.

7. Accrued Expenses

The following table provides a summary of accrued expenses (in thousands):

	June 30, 2023	December 31, 2022
Accrued external research and development	$1,760	$ 4,329
Accrued compensation	1,853	2,084
Accrued professional fees and other	261	195
Accrued expenses	$3,874	$ 6,608

8. Leases

The Company leases space under operating leases for administrative offices in New York, New York, and Waltham, 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 (in thousands):

	Six Months Ended June 30,	
	2023	2022
Operating lease cost	$ 175	$ 44
Variable lease cost	13	3
Short-term lease cost	—	28
Total operating lease costs	$ 188	$ 75

The Company recorded the operating lease costs within the general and administrative expenses line item in the condensed statements of operations and comprehensive loss for the six months ended June 30, 2023 and 2022.

Maturities of operating lease liabilities, which do not include short-term leases, as of June 30, 2023, are as follows (in thousands):

2023 (remaining 6 months)	$178
2024	365
2025	188
Total undiscounted operating lease payments	731
Less: imputed interest	(77)
Present value of operating lease liabilities	$654
Balance sheet classification:	
Current portion of lease liabilities	$358
Long-term lease liabilities	296
Total operating lease liabilities	$654

The weighted-average remaining term of operating leases was 24 months and the weighted-average discount rate used to measure the present value of operating lease liabilities was 10.4% as of June 30, 2023.

9. Convertible Preferred Stock

As of June 30, 2023 and December 31, 2022, the Company was authorized to issue 33,336,283 shares of preferred stock, par value $0.0001 per share.

Series Seed 1: On July 19, 2019, the Company executed a Series Seed 1 Convertible Preferred Stock Purchase Agreement ("Series Seed 1"). In connection with this agreement, the Company issued 1,642,500 shares of Series Seed Convertible Preferred Stock, at a price of $1.00 per share. Gross proceeds from the issuance were approximately $1.6 million. The Series Seed 1 provided for an additional closing to the same investors upon the approval of the Company's Board of Directors. On April 22, 2020, the Company completed an additional closing and issued an additional 1,857,500 shares of Series Seed 1 Convertible Preferred Stock, at a price of $1.00 per share. Gross proceeds from this issuance were approximately $1.9 million.

On December 1, 2020, the Company executed an amendment to the Series Seed 1 providing for a third closing, which was completed on the same date. In connection with this amendment, the Company issued 3,000,000 shares of Series Seed 1 Convertible Preferred Stock, at a price of $1.00 per share. Gross proceeds from the third closing issuance were $3.0 million. This amendment provided for a potential fourth closing, which did not occur.

Series Seed 2: In May 2021, the Company executed a Series Seed 2 Convertible Preferred Stock Purchase Agreement ("Series Seed 2"). In connection with this agreement, the Company issued 3,829,265 shares of Series Seed 2 Convertible Preferred Stock, at a price of $3.9172 per share. Gross proceeds from the issuance were $15.0 million.

Series A: In April 2022, the Company executed a Series A Convertible Preferred Stock Purchase Agreement ("Series A"). In connection with this agreement, the Company issued 23,007,017 shares of Series A Convertible Preferred Stock, at a price of $4.3465 per share. Gross proceeds from the issuance were $100.0 million.

The Series Seed 1, Series Seed 2 and Series A preferred stock are collectively referred to as "Preferred Stock" and have the following characteristics:

Voting

Each holder of outstanding shares of Preferred Stock shall be entitled to cast the number of votes equal to the number of whole shares of Common Stock into which the shares of Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter.

Dividends

The holders of Preferred Stock are entitled to receive dividends, as specified in the Company's Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation"), if and when declared by the Company's Board of Directors. The Series Seed preferred stockholders are entitled to receive dividends at a rate of $0.06 per annum per share. The Series Seed 2 preferred stockholders are entitled to receive dividends at a rate of $0.235 per annum per share. The Series A preferred stockholders are entitled to receive dividends at a rate of $0.2608 per annum per share. Such dividends are not cumulative. Since the Company's inception, no dividends have been declared or paid to the holders of Preferred Stock.

Liquidation, dissolution or winding up

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or deemed liquidation event (as defined in the Certificate of Incorporation), the holders of the Preferred Stock have first priority to be paid an amount equal to the greater of (i) the respective Preferred Stock issuance price plus dividends declared but unpaid or (ii) such amounts that would have been owed to the holders of Preferred Stock if the Preferred Stock shares had been converted to common stock prior to the liquidation event. Following payment to the holders of Preferred Stock, all remaining assets of the Company will be distributed to the common stock shareholders on a pro rata basis.

Conversion

Each share of Preferred Stock is convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of common stock on the terms set forth in the Certificate of Incorporation.

Mandatory conversion shall occur upon either (a) the closing of the sale of shares of common stock to the public at a price of at least $8.6930 per share (subject to appropriate adjustment as defined in the Certificate of Incorporation), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act, resulting in at least $40.0 million of gross proceeds to the Company and in connection with such offering the common stock is listed for trading on the Nasdaq Stock Market's National Market, the New York Stock Exchange or another exchange or marketplace approved the Company's Board of Directors, or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the Requisite Holders (as defined in the Certificate of Incorporation).

The Company must reserve and keep available out of its authorized but unused capital stock such number of authorized shares of common stock to sufficiently effect the conversion of all outstanding Preferred Stock.

Redemption

Shares of Preferred Stock are not redeemable at the election of the holder thereof. Any shares of Preferred Stock that are redeemed or otherwise acquired by the Company shall be automatically and immediately cancelled and retired (as defined in the Certificate of Incorporation).

Adjustment of conversion price upon issuance of additional shares of common stock

In the event the Company issues additional shares of common stock without consideration or consideration less than the Preferred Stock conversion price in effect immediately prior to such issuance, then the Preferred Stock conversion price shall be adjusted in accordance with the adjustment formula (as set forth in the Certificate of Incorporation).

10. Stockholders' Deficit

Common Stock

As of June 30, 2023 and December 31, 2022, the Company was authorized to issue 45,113,542 and 40,000,000 shares of common stock, respectively, with a par value of $0.0001 per share.

The Common Stock has the following characteristics:

Voting

The holders of common stock are entitled to one vote for each share of common stock held at all meetings of stockholders (and written actions in lieu of meetings); provided, however, that, except as otherwise required by law, holders of common stock, as such, shall not be entitled to vote on any amendment to the Certificate of Incorporation that relates solely to the terms of one or more outstanding series of preferred stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to the Certificate of Incorporation or pursuant to the Delaware General Corporation Law.

Dividends

The holders of common stock are entitled to receive dividends, if and when declared by the Company's Board of Directors. Since the Company's inception, no dividends have been declared or paid to the holders of common stock.

Liquidation, dissolution or winding up

In the event of any voluntary or involuntary liquidation, dissolution, or winding-up of the Company, the holders of common stock are entitled to share ratably in the Company's remaining assets, following priority payments to the Company's preferred stockholders.

11. Stock-Based Compensation

In July 2019, the Company's Board of Directors adopted, and the stockholders approved, the Dianthus Therapeutics, Inc. 2019 Stock Plan (the "2019 Plan"). As of June 30, 2023, there were 7,755,810 shares of common stock reserved under the 2019 Plan for issuance to officers, employees, consultants, and directors of the Company. The 2019 Plan, which is administered by the Compensation Committee of the Company's Board of Directors, expires in July 2029.

As of June 30, 2023, the Company had issued 6,865,655 awards from the 2019 Plan and had 890,155 shares available for future grant. Shares that are expired, terminated, surrendered, or canceled under the 2019 Plan without having been fully exercised will be available for future awards.

Stock Options

The exercise price for stock options is determined at the discretion of the Compensation Committee of the Company's Board of Directors. All stock options granted to any person possessing less than 10% of the total combined consolidated voting power of all classes of stock may not have an exercise price of less than 100% of the fair market value of the common stock on the grant date. All stock options granted to any person possessing more than 10% of the total combined consolidated voting power of all classes of stock may not have an exercise price of less than 110% of the fair market value of the common stock on the grant date. The option term may not be greater than ten years from the date of the grant. Stock options granted to persons possessing more than 10% of the total combined consolidated voting power of all classes of stock may not have an option term of greater than five years from the date of the grant.

The vesting period for equity-based awards is determined at the discretion of the Compensation Committee of the Company's Board of Directors, which is generally four years. For awards granted to employees and non-employees with four-year vesting terms, vesting is generally either:

- 25% of the option vests on the first anniversary of the grant date and the remaining stock vest equally each month for three years thereafter, or
- Equal vesting on a monthly basis, on the last day of the month following the vesting commencement date.

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 six months ended June 30, 2023 and 2022.

	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Risk-free interest rate	3.81%	3.00%
Expected term (in years)	6.1	5.9
Expected volatility	85.04%	87.16%
Expected dividend yield	0%	0%

The following table summarizes stock option activity under the 2019 Plan for the six months ended June 30, 2023:

	Number of stock options outstanding	Weighted average exercise price per share	Weighted average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Balance at December 31, 2022	5,840,110	$ 1.73	9.3	$ 621
Granted, fair value of $2.02 per share	1,611,145	2.70		
Forfeited	(599,600)	1.84		
Balance at June 30, 2023	6,851,655	$ 1.95	9.0	$ 6,014
Exercisable options at June 30, 2023	1,911,894	$ 1.68	8.7	$ 1,970
Unvested options at June 30, 2023	4,939,761	$ 2.06	9.1	$ 4,044

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 six months ended June 30, 2023 was $2.02 per share.

Restricted Stock

In April 2020, the Company executed a restricted stock award agreement with a consultant to purchase 14,000 shares of common stock at an exercise price of $0.03 per share. The restricted stock award vests 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 contains restrictions on the ability to sell, assign or pledge the shares awarded. The restricted stock agreement contains 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 Company's common stock on the date of the award was $0.03 per share.

The Company has not issued any restricted stock since April 2020. As of June 30, 2023, a total of approximately 12,833 shares of restricted common stock were vested and approximately 1,167 shares remained unvested. As of June 30, 2023, the unrecognized stock-based compensation expense for the restricted award was immaterial.

Stock Warrants

In April 2021, the Company issued 21,450 warrants for the purchase of common stock at an exercise price of $0.36 per share. The warrants vest over a four-year period on a straight-line basis and have a grant date fair value of $0.25 per warrant. The Company has not issued any warrants since April 2021. As of June 30, 2023, the warrants have a weighted average remaining contractual term of 7.8 years and a remaining weighted average vesting period of 1 month.

Stock-based compensation expense

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

	Six Months Ended June 30,	
	2023	2022
Research and development	$ 332	$ 112
General and administrative	663	232
Total stock-based compensation expense	$ 995	$ 344

As of June 30, 2023, there was $7.0 million of total unrecognized compensation cost related to stock options granted under the 2019 Plan. The Company expects to recognize that cost over a remaining weighted-average period of 2.9 years.

12. License Revenue – Related Party

In September 2020, the Company entered into an Option Agreement with Zenas ("Zenas Option"), a related party (See Note 16). 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.

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, *Revenue from Contracts with Customers* ("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 $1.0 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, up to a pre-defined annual limit; (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, up to a pre-defined annual limit; (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 June 30, 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). As of June 30, 2023, no royalty revenue has been recognized.

For the six months ended June 30, 2023 and 2022, the Company recognized related party license revenue totaling $1.4 million and $4.1 million, respectively, associated with the Zenas Agreements. As of June 30, 2023, the Company recorded a related party receivable of $0.4 million, unbilled related party receivable of $0.4 million, current deferred related party revenue of $0.1 million and noncurrent deferred related party revenue of $0.8 million on its condensed balance sheet.

13. Income Taxes

For the six months ended June 30, 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.

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.

The Company has not recorded any liabilities for unrecognized tax benefits as of June 30, 2023 and 2022. The Company will recognize interest and penalties related to uncertain tax positions, if any, in income tax expense. As of June 30, 2023 and 2022, the Company had no accrued interest or penalties related to uncertain tax positions.

14. Net Loss Per Share

Basic and diluted net loss per common share were calculated as follows (in thousands, except share and per share data):

	Six Months Ended June 30,	
	2023	2022
Numerator:		
Net loss	$ (18,229)	$ (10,576)
Denominator:		
Weighted-average common shares outstanding	4,014,000	4,014,000
Less: weighted-average unvested restricted shares of common stock	(2,176)	(5,676)
Weighted-average shares used to compute net loss per common share, basic and diluted	4,011,824	4,008,324
Net loss per share attributable to common stockholders, basic and diluted	$ (4.54)	$ (2.64)

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 common shares 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:

	Six Months Ended June 30,	
	2023	2022
Convertible preferred stock (as converted)	33,336,282	33,336,282
Stock options outstanding	6,851,655	5,379,110
Unvested restricted shares of common stock	1,167	4,667
Warrants for the purchase of common stock	21,450	21,450
Total	40,210,554	38,741,509

15. 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 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 for amounts owed under the Alloy license agreement within the research and development expenses line item in the condensed statement of operations and comprehensive loss during each of the six months ended June 30, 2023 and 2022, respectively.

Crystal Bioscience, Inc. and OmniAb, Inc.:

In September 2022, the Company entered into a commercial platform license agreement and services agreement with Crystal Bioscience, Inc. ("Crystal") and OmniAb, Inc. ("OmniAb"), both subsidiaries of Ligand Pharmaceuticals Incorporated (collectively, "Ligand").

- Crystal granted the Company a worldwide, non-exclusive, non-sublicensable license under the Crystal technology to use chicken animals (solely at Crystal's facilities and through Crystal personnel) for generation of OmniAb Antibodies for research purposes.
- OmniAb granted the Company a worldwide, non-exclusive license under the OmniAb technology to use rodent animals (solely at approved CRO facilities and through approved CRO personnel) for generation of OmniAb Antibodies for research purposes. Such license is non-sublicensable except to an approved contract research organization.

Upon the achievement of certain development milestones, the Company is obligated to make additional payments to Ligand 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 $0.2 million for amounts owed under the Ligand license agreement within the research and development expenses line item in the condensed statement of operations and comprehensive loss during the six months ended June 30, 2023.

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 (approximately $3.9 million) and £2.3 million (approximately $2.9 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 (approximately $3.1 million). The Company has recorded $1.4 million and $0.6 million for amounts owed under the IONTAS collaborative research license agreement within the research and development expenses line item in the condensed statements of operations and comprehensive loss during each of the six months ended June 30, 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 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 unaudited interim condensed financial statements as of June 30, 2023 and 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 June 30, 2023 and 2022, the Company had standing agreements with consultants, contractors or service providers whose terms do not yield material long-term commitments.

16. Related Party Transactions

Viridian, LLC:

In June 2019, the Company entered into a Technology Assignment Agreement (the "TAA") with Viridian, LLC ("Viridian"), a related party. The Company considers Viridian to be a related party because two of its members have a seat on the Board of Directors of the Company. The TAA assigns to the Company exclusively throughout the world all rights, title, and interest to all technology and know-how applicable to the research, development, commercialization, and manufacturing of human therapeutic products that target a specific protein. In exchange for the TAA, the Company issued to Viridian 4,000,000 shares of the Company's common stock with a fair value of $0.02 per share. There are no future obligations to Viridian in connection with the TAA. As of June 30, 2023 and December 31, 2022, Viridian owned approximately 13% of the Company's outstanding shares (assuming the conversion of all preferred stock into common stock).

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 June 30, 2023 and December 31, 2022, Tellus and affiliated entities owned approximately 17%, and the Fairmount Funds and affiliated entities owned approximately 14% of the Company's outstanding shares (assuming the conversion of all preferred stock into common stock). See Note 12 for more information. In connection with these agreements, the Company recognized $1.4 million and $4.1 million within the license revenue – related party line item in the condensed statements of operations and comprehensive loss for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, the Company recorded a related party receivable of $0.4 million, unbilled related party receivable of $0.4 million, current deferred related party revenue of $0.1 million and noncurrent deferred related party revenue of $0.8 million on its 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 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 June 30, 2023 and December 31, 2022, respectively, was not material to its unaudited interim condensed 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 $376,770 to the Company at an interest rate of 4.5% per annum. On March 15, 2023, the Company repaid principal and interest in the amount of $376,862 to the Fairmount Funds in satisfaction of its obligations under the promissory notes.

17. Subsequent Events

Management has evaluated subsequent events through September 20, 2023, the date which the financial statements were available to be issued and determined that there were no additional subsequent events requiring recording or disclosure in the Company's financial statements except as noted below.

On September 11, 2023, the Company completed its business combination with Magenta in accordance with the terms of the Merger Agreement, pursuant to which, among other matters, Merger Sub merged with and into the Company, with the Company surviving as a wholly owned subsidiary of Magenta, or the Merger. The Merger is 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"). References to share and per share amounts in the following paragraphs 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 the Company's preferred stock was converted into a share of common stock. At the effective time of the Merger, Magenta issued an aggregate of approximately 11,021,248 shares of common stock to the Company's stockholders, based on an exchange ratio of approximately 0.2181 shares of common stock for each share of the Company's capital stock, including those shares of the Company's common stock issued upon the conversion of the preferred stock and those shares of the Company's common stock issued in the pre-closing financing (as described below), resulting in approximately 14,813,295 shares of common stock of the combined company being issued and outstanding immediately following the effective time of the Merger.

Immediately prior to the completion of the Merger, pursuant to the Subscription Agreement, as amended, the Company issued and sold, and the Investors purchased, 2,873,988 shares of the Company's common stock and 210,320 of pre-funded warrants, exercisable for 210,320 shares of the Company's 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 million.

In connection with the completion of the Merger, the Company changed its name to Dianthus Therapeutics OpCo, Inc., Magenta changed its name from "Magenta Therapeutics, Inc." to "Dianthus Therapeutics, Inc." and the business conducted by the combined company became primarily the business conducted by the Company.

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 balance sheets of Dianthus Therapeutics, Inc. (the "Company") as of December 31, 2022 and 2021, the related 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, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred significant losses and negative cash flows from operations and has limited capital resources to fund ongoing operations, which raises substantial doubt about its ability to continue as a going concern. Management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

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 and in accordance with auditing standards generally accepted in the United States of America. 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.

/s/ Deloitte & Touche LLP

Morristown, New Jersey
May 15, 2023

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

DIANTHUS THERAPEUTICS, INC.

Balance Sheets

(in thousands, except share and per share data)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 15,365	$ 7,638
Short-term investments	60,125	—
Receivable from related party	4,700	469
Unbilled receivable from related party	938	1,007
Prepaid expenses and other current assets	905	274
Total current assets	82,033	9,388
Property and equipment, net	142	33
Right-of-use operating lease assets	814	—
Other assets and restricted cash	121	30
Total assets	$ 83,110	$ 9,451
Liabilities, Convertible Preferred Stock and Stockholders' Equity/(Deficit)		
Current liabilities:		
Accounts payable	$ 1,167	$ 1,359
Accrued expenses	6,608	3,993
Current portion of deferred revenue—related party	100	—
Current portion of operating lease liabilities	350	—
Total current liabilities	8,225	5,352
Deferred revenue—related party	791	—
Long-term operating lease liabilities	438	—
Total liabilities	9,454	5,352
Commitments and contingencies (Note 15)		
Preferred stock, $0.0001 par value per share; 33,336,283 and 10,329,266 shares authorized at December 31, 2022 and 2021, respectively		
Convertible preferred stock:		
Series Seed 1 convertible preferred stock, 6,500,000 shares designated, issued, and outstanding, liquidation preference of $6,500 at December 31, 2022 and 2021	6,436	6,436
Series Seed 2 convertible preferred stock, 3,829,265 shares designated, issued, and outstanding, liquidation preference of $15,000 at December 31, 2022 and 2021	14,912	14,912
Series A convertible preferred stock, 23,007,017 shares designated, issued, and outstanding, liquidation preference of $100,000 at December 31, 2022	96,676	—
Total convertible preferred stock	118,024	21,348
Stockholders' equity/(deficit):		
Common stock, $0.0001 par value per share; 40,000,000 shares authorized, 4,014,000 shares issued and outstanding at December 31, 2022 and 2021	—	—
Additional paid-in capital	1,661	143
Accumulated deficit	(45,868)	(17,392)
Accumulated other comprehensive loss	(161)	—
Total stockholders' equity/(deficit)	(44,368)	(17,249)
Total liabilities, convertible preferred stock and stockholders' equity/(deficit)	$ 83,110	$ 9,451

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

DIANTHUS THERAPEUTICS, INC.

Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

	Years Ended December 31,	
	2022	2021
Revenues:		
License revenue—related party	$ 6,417	$ 1,476
Operating expenses:		
Research and development	29,379	12,606
General and administrative	6,743	1,956
Total operating expenses	36,122	14,562
Loss from operations	(29,705)	(13,086)
Other income/(expense):		
Interest income	1,145	3
Gain/(loss) on currency exchange, net	136	(26)
Other expense	(52)	—
Total other income/(expense)	1,229	(23)
Net loss	$ (28,476)	$ (13,109)
Net loss per share attributable to common stockholders, basic and diluted	$ (7.10)	$ (3.27)
Weighted-average number of common shares outstanding, used in computing net loss per common share, basic and diluted	4,009,204	4,005,704
Other comprehensive loss:		
Net loss	$ (28,476)	$ (13,109)
Other comprehensive loss:		
Change in unrealized losses related to available-for-sale debt securities	(161)	—
Total other comprehensive loss	(161)	—
Total comprehensive loss	$ (28,637)	$ (13,109)

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

DIANTHUS THERAPEUTICS, INC.

Statements of Changes in Convertible Preferred Stock and Stockholders' Equity/(Deficit)

(in thousands, except share data)

	Convertible Preferred Stock							Stockholders' Equity/(Deficit)					
	Series Seed 1 Convertible Preferred Stock		Series Seed 2 Convertible Preferred Stock		Series A Convertible Preferred Stock		Total Convertible Preferred Stock	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity/ (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount		Shares	Amount				
Balance, January 1, 2021	6,500,000	$ 6,436	—	$ —	—	$ —	$ 6,436	4,014,000	$ —	$ 80	$ (4,283)	$ —	$ (4,203)
Issuance of convertible preferred stock, net of issuance costs of $88	—	—	3,829,265	14,912	—	—	14,912	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	63	—	—	63
Net loss	—	—	—	—	—	—	—	—	—	—	(13,109)	—	(13,109)
Balance, December 31, 2021	6,500,000	$ 6,436	3,829,265	$ 14,912	—	$ —	$ 21,348	4,014,000	$ —	$ 143	$ (17,392)	$ —	$ (17,249)
Issuance of convertible preferred stock, net of issuance costs of $3,324	—	—	—	—	23,007,017	96,676	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	6,500,000	$ 6,436	3,829,265	$ 14,912	23,007,017	$ 96,676	$ 118,024	4,014,000	$ —	$ 1,661	$ (45,868)	$ (161)	$ (44,368)

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

DIANTHUS THERAPEUTICS, INC.

Statements of Cash Flows

(in thousands)

	Years Ended December 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (28,476)	$ (13,109)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	30	—
Stock-based compensation expense	1,518	63
Accretion on short-term investments	(606)	—
Amortization of right-of-use operating lease assets	117	—
Changes in operating assets and liabilities:		
Receivable from related party	(4,231)	(469)
Unbilled receivable from related party	69	(1,007)
Prepaid expenses and other current assets	(631)	(271)
Other assets	(31)	(30)
Accounts payable, accrued expenses and operating lease liabilities	2,280	4,919
Deferred revenue—related party	891	—
Net cash used in operating activities	(29,070)	(9,904)
Cash flows from investing activities:		
Capital expenditures	(139)	(33)
Purchases of short-term investments	(61,680)	—
Proceeds from maturities of short-term investments	2,000	—
Net cash used in investing activities	(59,819)	(33)
Cash flows from financing activities:		
Proceeds from issuance of Series A convertible preferred stock	100,000	—
Payment of issuance costs for Series A convertible preferred stock	(3,324)	—
Proceeds from issuance of Series Seed 2 convertible preferred stock	—	15,000
Payment of issuance costs for Series Seed 2 convertible preferred stock	—	(88)
Net cash provided by financing activities	96,676	14,912
Increase in cash, cash equivalents and restricted cash	7,787	4,975
Cash, cash equivalents and restricted cash, beginning of period	7,638	2,663
Cash, cash equivalents and restricted cash, end of period	$ 15,425	$ 7,638
Supplemental Disclosure		
Cash and cash equivalents	$ 15,365	$ 7,638
Restricted cash	60	—
Total cash, cash equivalents and restricted cash	$ 15,425	$ 7,638
Cash paid for interest	$ —	$ —
Cash paid for taxes	$ —	$ —
Additions to right-of-use lease assets from new operating lease liabilities	$ 931	$ —

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

1. Nature of Organization and Operations

Dianthus Therapeutics, Inc. ("Dianthus" or the "Company") is a clinical-stage biotechnology company focused on developing next-generation complement therapeutics for patients with severe autoimmune and inflammatory diseases. Dianthus was incorporated in the State of Delaware on May 1, 2019 and its corporate headquarters is located in New York, New York.

Currently, the Company is devoting substantially all efforts and resources toward product research and development. 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 will obtain necessary regulatory approval, or that any approved product 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.

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.

The Company's potential product candidates that are in development 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 and Going Concern

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 evaluated the following adverse conditions and events that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the accompanying financial statements were issued (the "issuance date"):

- Since its inception, the Company has funded its operations primarily with outside capital (i.e., proceeds from the sale of preferred stock) and has incurred significant recurring losses, including net losses of $28.5 million and $13.1 million for the years ended December 31, 2022 and 2021, respectively. In addition, the Company had an accumulated deficit of $45.9 million as of December 31, 2022;
- The Company expects to continue to incur significant recurring losses and rely on outside capital to fund its operations for the foreseeable future; and
- The Company expects its available cash, cash equivalents and short-term investments on hand as of the issuance date will not be sufficient to fund its obligations as they become due for at least one year beyond the issuance date.

While the Company is seeking to secure additional outside capital as of the issuance date, management can provide no assurance such capital will be secured or on terms that are acceptable to the Company.

Similarly, as disclosed in Note 17, while the Company plans to consummate a reverse merger and concurrent private financing during the second half of fiscal year 2023, management can provide no assurance the reverse merger and concurrent private financing will be consummated on terms that are acceptable to the Company, if at all.

In the event the Company is unable to secure additional outside capital and/or consummate the reverse merger and concurrent private financing, 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. These uncertainties raise substantial doubt about the Company's ability to continue as a going concern.

The accompanying financial statements do not include any adjustments that might result from the outcome of these uncertainties. Accordingly, the 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. generally accepted accounting principles ("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 Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

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 ("CEO"). The Company operates as a single operating segment and has one reportable segment.

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.

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 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, 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 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.

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 12 and 16 for more information. The receivable represents amounts earned and billed to Zenas but not yet collected while unbilled receivable represents amounts estimated to be earned but not yet billed to Zenas. The receivable and unbilled receivable are reported at net realizable value. Management of the Company regularly evaluates the creditworthiness of Zenas and their financial condition and does not require collateral from Zenas. As of December 31, 2022 and 2021, 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 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 8.

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 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 balance sheet.

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 adopted 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 balance sheets.

Effective January 1, 2021, the Company early adopted ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20)* which reduces complexity in applying U.S. GAAP to certain financial instruments with characteristics of liability and equity. The ASU removes the guidance that requires entities to account for beneficial conversion features and cash conversion features in equity, separately from the host convertible debt or preferred stock. The adoption did not have any impact on the Company's financial statement presentation or disclosures.

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 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 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 12.

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, 2022 and 2021, 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 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.

Management utilizes estimates and assumptions in determining the fair value of the Company's common stock. Stock options were granted at exercise prices that represented the fair value of the Company's common stock on the specific grant dates. 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 the Company's common stock. Each valuation methodology includes estimates and assumptions that require management's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of convertible preferred stock, the superior rights and preferences of the convertible preferred stock senior to the Company's common stock at the time, and a probability analysis of various liquidity events, such as a public offering or sale of the Company, under differing scenarios. Changes to the key assumptions used in the valuations could result in materially different fair values of common stock at each valuation date.

Due to the lack of a historical public market for the trading of the Company's common stock and a lack of company-specific historical and implied volatility data, management based 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 sufficient similar economic and industry characteristics and includes companies that are most representative of the Company.

Management used 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.

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 net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per share attributable to common stockholders is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period, including potential dilutive common shares. For periods in which the Company has reported net losses, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their impact is anti-dilutive. Additional information is included in Note 14.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326)*. The new standard adjusts the accounting for assets held at amortized costs basis, including marketable securities accounted for as available for sale. 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. For public entities, the guidance was effective for annual reporting periods beginning after December 15, 2019 and for interim periods within those fiscal years. For nonpublic entities and emerging growth companies that choose to take advantage of the extended transition period, the guidance was effective for annual reporting periods beginning after December 15, 2020. Early adoption is permitted for all entities. In November 2019, the FASB issued ASU No. 2019-10, which deferred the effective date for nonpublic entities and emerging growth companies to annual reporting periods beginning after December 15, 2022, including interim periods within those fiscal years. The Company does not believe the guidance will have a material impact on its financial statements.

3. Short-Term Investments

The table below provides a summary of short-term investments (in thousands) as of December 31, 2022. There were no short-term investments as of December 31, 2021.

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Available-for-sale, short-term investments:				
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	$ 60,286	$ 3	$ (164)	$60,125

As of December 31, 2022, the available-for-sale securities classified as short-term investments mature in one year or less. Unrealized gains and losses on available-for-sale securities as of December 31, 2022 were not significant and were primarily due to changes in interest rates. There were no significant realized gains or losses recognized on the sale or maturity of available-for-sale investments for the years ended December 31, 2022 and 2021.

4. Prepaid Expenses and Other Current Assets

The following table provides a summary of prepaid expenses and other current assets (in thousands):

	December 31,	
	2022	2021
Prepaid materials, supplies and services	$820	$243
Prepaid insurance	32	21
Other	53	10
Prepaid expenses and other current assets	$905	$274

5. Property and Equipment

The following table provides a summary of property and equipment (in thousands):

	December 31,	
	2022	2021
Computer equipment	$131	$—
Furniture and fixtures	41	—
Construction-in-process	—	33
Subtotal	172	33
Less: accumulated depreciation	(30)	—
Property and equipment, net	$142	$ 33

Depreciation expense was $30 thousand for the year ended December 31, 2022. No depreciation expense was recognized during the year ended December 31, 2021 as the assets had not yet been placed in service as of that date.

6. Fair Value of Financial Instruments

Management calculates the fair value of assets and liabilities that qualify as financial instruments and includes additional information in the notes to the financial statements when the fair value is different than the carrying value of these financial instruments. The estimated fair value of accounts receivable, accounts payable and accrued expenses approximate their carrying amounts due to the relatively short maturity of these 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.

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

Description	Fair Value at December 31, 2022	Level 1	Level 2	Level 3
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	$ 73,970	$59,357	$14,613	$ —

Description	Fair Value at December 31, 2021	Level 1	Level 2	Level 3
Recurring Assets:				
Cash equivalents:				
Money market fund	$ 7,675	$ 7,675	$ —	$ —
Total assets measured at fair value	$ 7,675	$ 7,675	$ —	$ —

7. Accrued Expenses

The following table provides a summary of accrued expenses (in thousands):

	December 31,	
	2022	2021
Accrued external research and development	$4,329	$3,560
Accrued compensation	2,084	207
Accrued professional fees and other	195	226
Accrued expenses	$6,608	$3,993

8. Leases

The Company leases space under operating leases for administrative offices in New York, New York and Waltham, 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 (in thousands):

	Years Ended December 31,	
	2022	2021
Operating lease cost	$198	$—
Variable lease cost	4	—
Short-term lease cost	34	17
Total operating lease costs	$236	$ 17

The Company records the operating lease costs within the general and administrative expenses line item in the statements of operations and comprehensive loss during the years ended December 31, 2022 and 2021.

Maturities of operating lease liabilities, which do not include short-term leases, as of December 31, 2022, are as follows (in thousands):

2023	$ 351
2024	365
2025	188
Total undiscounted operating lease payments	904
Less: imputed interest	(116)
Present value of operating lease liabilities	$ 788
Balance sheet classification:	
Current portion of lease liabilities	$ 350
Long-term lease liabilities	438
Total operating lease liabilities	$ 788

The weighted-average remaining term of operating leases was 30 months and the weighted-average discount rate used to measure the present value of operating lease liabilities was 10.3% as of December 31, 2022.

9. Convertible Preferred Stock

As of December 31, 2022 and 2021, the Company was authorized to issue 33,336,283 and 10,329,266 shares of preferred stock, respectively, par value $0.0001 per share.

Series Seed 1: On July 19, 2019, the Company executed a Series Seed 1 Convertible Preferred Stock Purchase Agreement ("Series Seed 1"). In connection with this agreement, the Company issued 1,642,500 shares of Series Seed Convertible Preferred Stock, at a price of $1.00 per share. Gross proceeds from the issuance were approximately $1.6 million. The Series Seed 1 provided for an additional closing to the same investors upon the approval of the Company's Board of Directors. On April 22, 2020, the Company completed an additional closing and issued an additional 1,857,500 shares of Series Seed 1 Convertible Preferred Stock, at a price of $1.00 per share. Gross proceeds from this issuance were approximately $1.9 million.

On December 1, 2020, the Company executed an amendment to the Series Seed 1 providing for a third closing which was completed on the same date. In connection with this amendment, the Company issued 3,000,000 shares of Series Seed 1 Convertible Preferred Stock, at a price of $1.00 per share. Gross proceeds from the third closing issuance were $3.0 million. This amendment provided for a potential fourth closing, which did not occur.

Series Seed 2: In May 2021, the Company executed a Series Seed 2 Convertible Preferred Stock Purchase Agreement ("Series Seed 2"). In connection with this agreement, the Company issued 3,829,265 shares of Series Seed 2 Convertible Preferred Stock, at a price of $3.9172 per share. Gross proceeds from the issuance were $15.0 million.

Series A: In April 2022, the Company executed a Series A Convertible Preferred Stock Purchase Agreement ("Series A"). In connection with this agreement, the Company issued 23,007,017 shares of Series A Convertible Preferred Stock, at a price of $4.3465 per share. Gross proceeds from the issuance were $100.0 million.

The Series Seed 1, Series Seed 2 and Series A preferred stock are collectively referred to as "Preferred Stock" and have the following characteristics:

Voting

Each holder of outstanding shares of Preferred Stock shall be entitled to cast the number of votes equal to the number of whole shares of Common Stock into which the shares of Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter.

Dividends

The holders of Preferred Stock are entitled to receive dividends, as specified in the Company's Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation"), if and when declared by the Company's Board of Directors. The Series Seed preferred stockholders are entitled to receive dividends at a rate of $0.06 per annum per share. The Series Seed 2 preferred stockholders are entitled to receive dividends at a rate of $0.235 per annum per share. The Series A preferred stockholders are entitled to receive dividends at a rate of $0.2608 per annum per share. Such dividends are not cumulative. Since the Company's inception, no dividends have been declared or paid to the holders of Preferred Stock.

Liquidation, dissolution or winding up

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or deemed liquidation event (as defined in the Certificate of Incorporation), the holders of the Preferred Stock have first priority to be paid an amount equal to the greater of (i) the respective Preferred Stock issuance price plus dividends declared but unpaid or (ii) such amounts that would have been owed to the holders of Preferred Stock if the Preferred Stock shares had been converted to common stock prior to the liquidation event.

Following payment to the holders of Preferred Stock, all remaining assets of the Company will be distributed to the common stock shareholders on a pro rata basis.

Conversion

Each share of Preferred Stock is convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of common stock on the terms set forth in the Certificate of Incorporation.

Mandatory conversion shall occur upon either (a) the closing of the sale of shares of common stock to the public at a price of at least $8.6930 per share (subject to appropriate adjustment as defined in the Certificate of Incorporation), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $40.0 million of gross proceeds to the Company and in connection with such offering the Common Stock is listed for trading on the Nasdaq Stock Market's National Market, the New York Stock Exchange or another exchange or marketplace approved the Company's Board of Directors, or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the Requisite Holders (as defined in the Certificate of Incorporation).

Redemption

Shares of Preferred Stock are not redeemable at the election of the holder thereof. Any shares of Preferred Stock that are redeemed or otherwise acquired by the Company shall be automatically and immediately cancelled and retired (as defined in the Certificate of Incorporation).

Adjustment of conversion price upon issuance of additional shares of common stock

In the event the Company issues additional shares of common stock without consideration or consideration less than the Preferred Stock conversion price in effect immediately prior to such issuance, then the Preferred Stock conversion price shall be adjusted in accordance with the adjustment formula (as set forth in the Certificate of Incorporation).

10. Stockholders' Equity/(Deficit)

Common Stock

As of December 31, 2022 and 2021, the Company was authorized to issue 40,000,000 and 17,000,000 shares of common stock, respectively, with a par value of $0.0001 per share. In January 2023, the Company amended its Certificate of Incorporation to increase the authorized common stock to 45,113,542 shares.

The Common Stock has the following characteristics:

Voting

The holders of common stock are entitled to one vote for each share of common stock held at all meetings of stockholders (and written actions in lieu of meetings); provided, however, that, except as otherwise required by law, holders of common stock, as such, shall not be entitled to vote on any amendment to the Certificate of Incorporation that relates solely to the terms of one or more outstanding series of preferred stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to the Certificate of Incorporation or pursuant to the Delaware General Corporation Law.

Dividends

The holders of common stock are entitled to receive dividends, if and when declared by the Company's Board of Directors. Since the Company's inception, no dividends have been declared or paid to the holders of common stock.

Liquidation, dissolution or winding up

In the event of any voluntary or involuntary liquidation, dissolution, or winding-up of the Company, the holders of common stock are entitled to share ratably in the Company's remaining assets, following priority payments to the Company's preferred stockholders.

11. Stock-Based Compensation

In July 2019, the Company's Board of Directors adopted, and the stockholders approved, the Dianthus Therapeutics, Inc. 2019 Stock Plan (the "2019 Plan"). As of December 31, 2022, there were 7,755,810 shares of common stock reserved under the 2019 Plan for issuance to officers, employees, consultants, and directors of the Company. The 2019 Plan is administered by the Compensation Committee of the Company's Board of Directors.

As of December 31, 2022, the Company had issued 5,854,110 awards from the 2019 Plan and had 1,901,700 shares available for future grant. Shares that are expired, terminated, surrendered, or canceled under the 2019 Plan without having been fully exercised will be available for future awards.

Stock Options

The exercise price for stock options is determined at the discretion of the Compensation Committee of the Company's Board of Directors. All stock options granted to any person possessing less than 10% of the total combined consolidated voting power of all classes of stock may not have an exercise price of less than 100% of the fair market value of the common stock on the grant date. All stock options granted to any person possessing more than 10% of the total combined consolidated voting power of all classes of stock may not have an exercise price of less than 110% of the fair market value of the common stock on the grant date. The option term may not be greater than ten years from the date of the grant. Stock options granted to persons possessing more than 10% of the total combined consolidated voting power of all classes of stock may not have an option term of greater than five years from the date of the grant.

The vesting period for equity-based awards is determined at the discretion of the Compensation Committee of the Company's Board of Directors, which is generally four years. For awards granted to employees and non-employees with four-year vesting terms, vesting is generally either:

- 25% of the option vests on the first anniversary of the grant date and the remaining stock vest equally each month for three years thereafter, or
- Equal vesting on a monthly basis, on the last day of the month following the vesting commencement date.

The following table summarizes the assumptions used to determine the grant-date fair value of stock options granted, presented on a weighted average basis:

	Years Ended December 31,	
	2022	2021
Risk-free interest rate	3.08%	1.20%
Expected term (in years)	5.9	6.1
Expected volatility	87.28%	87.67%
Expected dividend yield	0%	0%

The following table summarizes stock option activity:

	Number of stock options outstanding	Weighted average exercise price per share	Weighted average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Balance at January 1, 2021	—	$ —		$ —
Granted, fair value of $0.94 per share	1,140,113	1.29		
Balance at December 31, 2021	1,140,113	1.29	9.7	194
Granted, fair value of $1.36 per share	4,730,802	1.84		
Forfeited	(30,805)	1.65		
Balance at December 31, 2022	5,840,110	$ 1.73	9.3	$ 621
Exercisable options at December 31, 2022	830,786	$ 1.56	9.1	$ 229
Unvested options at December 31, 2022	5,009,324	$ 1.76	9.4	$ 392

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 years ended December 31, 2022 and 2021 was $1.36 and $0.94, respectively.

Restricted Stock

In April 2020, the Company executed a restricted stock award agreement with a consultant to purchase 14,000 shares of common stock at an exercise price of $0.03 per share. The restricted stock award vests 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 contains restrictions on the ability to sell, assign or pledge the shares awarded. The restricted stock agreement contains 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 Company's common stock on the date of the award was $0.03 per share.

The Company did not issue any restricted stock during the years ended December 31, 2022 and 2021. As of December 31, 2022, a total of approximately 11,083 shares of restricted common stock were vested and approximately 2,917 shares remained unvested. As of December 31, 2022, the unrecognized stock-based compensation expense for the restricted award was immaterial.

Stock Warrants

In April 2021, the Company issued 21,450 warrants for the purchase of common stock at an exercise price of $0.36 per share. The warrants vest over a four-year period on a straight-line basis and have a grant date fair value of $0.25 per warrant.

The weighted average assumptions used to determine the fair value of the warrants were as follows:

	Year Ended December 31, 2021
Risk-free interest rate	1.14%
Expected term (in years)	6.1
Expected volatility	82.80%
Expected dividend yield	0%

The Company did not issue any warrants during the year ended December 31, 2022. As of December 31, 2022, the warrants have a weighted average remaining contractual term of 8.3 years and a remaining weighted average vesting period of 7 months.

Stock-based compensation expense

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

	Years Ended December 31,	
	2022	2021
Research and development	$ 416	$ 19
General and administrative	1,102	44
Total stock-based compensation expense	$1,518	$ 63

As of December 31, 2022, there was $5.9 million of total unrecognized compensation cost related to stock options granted under the 2019 Plan. The Company expects to recognize that cost over a remaining weighted-average period of 3.2 years.

12. License Revenue—Related Party

In September 2020, the Company entered into an Option Agreement with Zenas (“Zenas Option”), a related party (See Note 16). 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.

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 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 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, 2022, 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). As of December 31, 2022, no royalty revenue has been recognized.

For the years ended December 31, 2022 and 2021, the Company recognized related party license revenue totaling $6.4 million and $1.5 million, respectively, associated with the Zenas Agreements. 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 balance sheet.

13. Income Taxes

For the years ended December 31, 2022 and 2021, 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:

	Years Ended December 31,	
	2022	2021
Federal statutory income tax rate	21.0%	21.0%
State taxes, net of federal benefit	2.2%	6.3%
Research tax credits	2.2%	2.5%
Other	-3.0%	-0.1%
Increase in deferred tax asset valuation allowance	-22.4%	-29.7%
Effective income tax rate	0.0%	0.0%

The following table provides a summary of net deferred tax assets (in thousands):

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 5,383	$ 4,651
Tax credit carryforwards	1,120	483
Capitalized research and development costs	4,315	—
Accrued expenses	484	57
Share-based compensation	273	4
Lease liabilities	183	—
Organizational costs	4	5
Gross deferred tax assets	11,762	5,200
Valuation allowance	(11,566)	(5,194)
Total deferred tax assets	196	6
Deferred tax liabilities:		
Right-of-use lease assets	(189)	—
Prepaid expenses	(7)	(6)
Net deferred tax assets	$ —	$ —

As of December 31, 2022, the Company had federal net operating loss carryforwards of approximately $24.5 million, all of which have no expiration date and can be carried forward indefinitely; however, they are limited to a deduction to 80% of annual taxable income. The Company had state tax net operating loss carryforwards of approximately $20.1 million, which begin to expire in 2038.

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, 2022 and 2021 related primarily to the increase in net operating loss carryforwards, capitalized research and development expenses and research tax credit carryforwards. During the year ended December 31, 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, 2022 and 2021 and were as follows (in thousands):

	Years Ended December 31,	
	2022	2021
Valuation allowance as of beginning of year	$ 5,194	$1,307
Net increases recorded to income tax provision	6,372	3,887
Valuation allowance as of end of year	$11,566	$5,194

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.

The Company has not recorded any liabilities for unrecognized tax benefits as of December 31, 2022 or 2021. The Company will recognize interest and penalties related to uncertain tax positions, if any, in income tax expense. As of December 31, 2022 and 2021, the Company had no accrued interest or penalties related to uncertain tax positions.

14. Net Loss Per Share

Basic and diluted net loss per common share were calculated as follows (in thousands, except share and per share data):

	Years Ended December 31,	
	2022	2021
Numerator:		
Net loss	$ (28,476)	$ (13,109)
Denominator:		
Weighted-average common shares outstanding	4,014,000	4,014,000
Less: weighted-average unvested restricted shares of common stock	(4,796)	(8,296)
Weighted-average shares used to compute net loss per common share, basic and diluted	4,009,204	4,005,704
Net loss per share attributable to common stockholders, basic and diluted	$ (7.10)	(3.27)

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 common shares 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:

	Years Ended December 31,	
	2022	2021
Convertible preferred stock (as converted)	33,336,282	10,329,265
Stock options outstanding	5,840,110	1,140,113
Unvested restricted shares of common stock	2,917	6,417
Warrants for the purchase of common stock	21,450	21,450
Total	39,200,759	11,497,245

15. 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 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 $0.5 million and $0.1 million for amounts owed under the Alloy license agreement within the research and development expenses line item in the statements of operations and comprehensive loss during the years ended December 31, 2022 and 2021, respectively.

Crystal Bioscience, Inc. and OmniAb, Inc.:

In September 2022, the Company entered into a commercial platform license agreement and services agreement with Crystal Bioscience, Inc. ("Crystal") and OmniAb, Inc. ("OmniAb"), both subsidiaries of Ligand Pharmaceuticals Incorporated (collectively, "Ligand").

- Crystal granted the Company a worldwide, non-exclusive, non-sublicensable license under the Crystal technology to use chicken animals (solely at Crystal's facilities and through Crystal personnel) for generation of OmniAb Antibodies for research purposes.
- OmniAb granted the Company a worldwide, non-exclusive license under the OmniAb technology to use rodent animals (solely at approved CRO facilities and through approved CRO personnel) for generation of OmniAb Antibodies for research purposes. Such license is non-sublicensable except to an approved contract research organization.

Upon the achievement of certain development milestones, the Company is obligated to make additional payments to Ligand 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 $0.1 million for amounts owed under the Ligand license agreement within research and development expenses line item in the statement of operations and comprehensive loss during the year ended December 31, 2022.

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 $1.7 million and $2.7 million for amounts owed under the IONTAS collaborative research license agreement within the research and development expenses line item in the statements of operations and comprehensive loss during the years ended December 31, 2022 and 2021, 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 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 financial statements as of December 31, 2022 or 2021.

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, 2022 and 2021, the Company had standing agreements with consultants, contractors or service providers whose terms do not yield material long-term commitments.

16. Related Party Transactions

Viridian, LLC:

In June 2019, the Company entered into a Technology Assignment Agreement (the "TAA") with Viridian, LLC ("Viridian"), a related party. The Company considers Viridian to be a related party because two of its members have a seat on the Board of Directors of the Company. The TAA assigns to the Company exclusively throughout the world all rights, title, and interest to all technology and know-how applicable to the research, development, commercialization, and manufacturing of human therapeutic products that target a specific protein.

In exchange for the TAA, the Company issued to Viridian 4,000,000 shares of the Company's common stock with a fair value of $0.02 per share. There are no future obligations to Viridian in connection with the TAA. As of December 31, 2022 and 2021, Viridian owned approximately 13% and 35%, respectively, of the Company's outstanding shares (assuming the conversion of all preferred stock into common stock).

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 Executive Chairman of the Board of Directors of Zenas and (ii) 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, 2022 and 2021, Tellus and affiliated entities owned approximately 17% and 42%, respectively, and Fairmount Funds and affiliated entities owned approximately 14% and 13%, respectively, of the Company's outstanding shares (assuming the conversion of all preferred stock into common stock). See Note 12 for more information. In connection with these agreements, the Company recognized $6.4 million and $1.5 million within the license revenue—related party line item in the statements of operations and comprehensive loss for the years ended December 31, 2022 and 2021, respectively. 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 balance sheet. As of December 31, 2021, the Company recorded a related party receivable of $0.5 million and unbilled related party receivable of $1.0 million on its 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, 2022 and 2021, respectively, was not material to its 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.

17. Subsequent Events

Management has evaluated subsequent events through May 15, 2023, the date which the financial statements were available to be issued and determined that there were no additional subsequent events requiring recording or disclosure in the Company's financial statements except as noted below.

The Company issued 958,677 stock option awards from the 2019 Plan during the period January 1, 2023 until May 15, 2023.

On May 2, 2023, the Company entered into a Merger Agreement with Magenta Therapeutics, Inc. ("Magenta") and Dio Merger Sub, Inc. ("Merger Sub"). Pursuant to the Merger Agreement, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into the Company with the Company continuing as a wholly owned subsidiary of Magenta and the surviving corporation of the merger ("Merger"). Concurrently with the execution of the Merger Agreement, and in order to provide the Company with additional capital for its development programs prior to the closing of this Merger, certain new and current investors have agreed to purchase an aggregate of approximately $70 million of common stock and pre-funded warrants of the Company in a pre-closing financing. The board of directors of both Magenta and Dianthus have approved the Merger Agreement and the Merger. Completion of the transaction, which is expected in the second half of 2023, is subject to approval by Magenta's and Dianthus' shareholders and the satisfaction or waiver of certain other customary closing conditions.

SELECTED HISTORICAL FINANCIAL DATA AND UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

Terms not defined herein shall have the meanings ascribed to them in the Company's definitive proxy statement/prospectus filed with the U.S. Securities and Exchange Commission (the "SEC") on August 1, 2023.

Selected Historical Consolidated Financial Data of Magenta

The following tables summarize the consolidated financial data of Dianthus Therapeutics, Inc. (formerly Magenta Therapeutics, Inc.), a Delaware corporation (the "Company" or "Magenta"). The consolidated statement of operations data for the six months ended June 30, 2023 and 2022 and the consolidated balance sheet data as of June 30, 2023 have been derived from the unaudited condensed consolidated financial statements included in Magenta's Quarterly Report on Form 10-Q filed with the SEC on August 3, 2023. The consolidated statement of operations data for the years ended December 31, 2022 and 2021 and the consolidated balance sheet data as of December 31, 2022, and 2021 have been derived from the audited consolidated financial statements included in Magenta's Annual Report on Form 10-K, filed with the SEC on March 23, 2023. You should read the following selected condensed consolidated financial data together with Magenta's "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" and Magenta's consolidated financial statements and the related notes included in Magenta's Quarterly Report on Form 10-Q filed with the SEC on August 3, 2023 and included in Magenta's Annual Report on Form 10-K, filed with the SEC on March 23, 2023. Magenta's historical results are not necessarily indicative of results that should be expected in any future period and Magenta's results for the interim period are not necessarily indicative of the results that should be expected for the full year ending December 31, 2023.

Selected Consolidated Statement of Operations Data:

	Six Months Ended June 30,		Year Ended December 31,	
	2023	2022	2022	2021
	(in thousands, except share and per share data)			
Operating expenses				
Research and development	$ 8,134	$ 28,150	$ 55,141	$ 46,766
General and administrative	11,450	13,767	25,761	27,926
Restructuring and other charges	19,921	—	—	—
Total operating expenses	39,505	41,917	80,902	74,692
Loss from operations	(39,505)	(41,917)	(80,902)	(74,692)
Interest and other income, net	7,051	1,696	4,440	3,556
Net loss	$ (32,454)	$ (40,221)	$ (76,462)	$ (71,136)
Net loss per share, basic and diluted	$ (8.56)	$ (10.94)	$ (20.61)	$ (20.71)
Weighted average common shares outstanding, basic and diluted	3,790,504	3,675,462	3,710,771	3,434,300

Selected Consolidated Balance Sheet Data:

	As of June 30, 2023	As of December 31, 2022	2021
		(in thousands)	
Cash and cash equivalents	$ 62,633	$ 57,626	$ 131,650
Marketable securities	14,960	54,415	45,276
Working capital[(1)]	74,604	101,053	169,830
Total assets	78,638	146,645	189,934
Total liabilities	4,034	40,687	17,262
Accumulated deficit	(434,483)	(402,029)	(325,567)
Total stockholders' equity	74,604	105,958	172,672

(1) Working capital is defined as current assets less current liabilities.

Selected Historical Condensed Financial Data of Dianthus

The following tables summarize the financial data of Dianthus Therapeutics OpCo, Inc. (formerly Dianthus Therapeutics, Inc.), a Delaware corporation ("Dianthus"). The statement of operations data for the six months ended June 30, 2023 and 2022, and the balance sheet data as of June 30, 2023, have been derived from Dianthus' unaudited condensed financial statements included as Exhibit 99.4 of the Company's Current Report on Form 8-K/A filed with the SEC on September 21, 2023 (the "Current Report on Form 8-K/A") of which this Exhibit 99.6 is a part. The statement of operations data for the years ended December 31, 2022, and 2021, and the balance sheet data as of December 31, 2022 and 2021, have been derived from Dianthus' audited financial statements included as Exhibit 99.5 of the Current Report on Form 8-K/A of which this Exhibit 99.6 is a part. You should read the following selected financial data together with Dianthus' "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" and Dianthus' financial statements and related notes included as Exhibits 99.3, 99.4 and 99.5, respectively, of the Current Report on Form 8-K/A of which this Exhibit 99.6 is a part. Dianthus' historical results are not necessarily indicative of results that should be expected in any future period and Dianthus' results for the interim period are not necessarily indicative of the results that should be expected for the full year ending December 31, 2023.

Selected Condensed Statement of Operations Data:

	Six Months Ended June 30, 2023	2022	Year Ended December 31, 2022	2021
		(in thousands, except share and per share data)		
Revenues				
License revenue—related party	$ 1,445	$ 4,069	$ 6,417	$ 1,476
Operating expenses				
Research and development	16,100	12,330	29,379	12,606
General and administrative	4,804	2,497	6,743	1,956
Total operating expenses	20,904	14,827	36,122	14,562
Loss from operations	(19,459)	(10,758)	(29,705)	(13,086)
Other income/(expense)				
Interest income	1,293	89	1,145	3
(Loss)/gain on currency exchange, net	(37)	100	136	(26)
Other expense	(26)	(7)	(52)	—
Total other income/(expense), net	1,230	182	1,229	(23)
Net loss	$ (18,229)	$ (10,576)	$ (28,476)	$ (13,109)
Net loss per common share, basic and diluted	$ (4.54)	$ (2.64)	$ (7.10)	$ (3.27)
Weighted average common shares outstanding, basic and diluted	4,011,824	4,008,324	4,009,204	4,005,704

Selected Condensed Balance Sheet Data:

	As of June 30, 2023	As of December 31, 2022	2021
		(in thousands)	
Cash and cash equivalents	$ 40,280	$ 15,365	$ 7,638
Short-term investments	20,803	60,125	—
Working capital[(1)]	56,623	73,808	4,036
Total assets	64,275	83,110	9,451
Total liabilities	7,711	9,454	5,352
Convertible preferred stock	118,024	118,024	21,348
Accumulated deficit	(64,097)	(45,868)	(17,392)
Total stockholders' deficit	(61,460)	(44,368)	(17,249)

(1) Working capital is defined as current assets less current liabilities.

Selected Unaudited Pro Forma Condensed Combined Financial Data of Magenta and Dianthus

The following unaudited pro forma condensed combined financial information reflects the merger (as defined below) as a reverse asset acquisition accounted for as a reverse recapitalization in accordance with GAAP. For accounting purposes, Dianthus was considered to be acquiring Magenta in the merger. This determination was primarily based on the expectation that, immediately following the merger: (i) Dianthus' equity holders owns a substantial majority of the voting rights in the combined company; (ii) Dianthus' largest stockholders retain the largest interest in the combined company; (iii) Dianthus designated a majority (six of eight) of the initial members of the board of directors of the combined company; and (iv) Dianthus' executive management team became the management of the combined company.

Accordingly, for accounting purposes: (i) the merger was treated as the equivalent of Dianthus issuing stock to acquire the net assets of Magenta, (ii) the net assets of Magenta are recorded based on their fair value in the financial statements at the time of closing, substantially all of which consisted of cash and cash equivalents, marketable securities, as well as other nominal non-operating assets, and therefore approximated the historical carrying value of the assets and (iii) the reported historical operating results of the combined company prior to the merger are those of Dianthus.

At the effective date of the merger, substantially all of Magenta's assets consisted of cash and cash equivalents, marketable securities, and nominal non-operating assets. Since Magenta's non-operating assets, other than cash and cash equivalents and marketable securities, had nominal value upon closing of the merger, Magenta accounted for the reverse asset acquisition as a reverse recapitalization. There were no intangible assets related to MGTA-145 or MGTA-45 program candidates, or the MGTA-117 antibodies as of the effective date of the merger since all such assets had been sold to third parties. In addition, sales of other assets completed prior to the closing of the merger were of only nominal value and resulted in nominal cash, given the early development stage of such assets.

The unaudited pro forma condensed combined balance sheet assumes that the Dianthus pre-closing financing (as defined below) and the merger were consummated as of June 30, 2023, and combines the historical balance sheets of Magenta and Dianthus as of such date. The unaudited pro forma condensed combined statement of operations for the six months ended June 30, 2023, and for the year ended December 31, 2022, assumes that the Dianthus pre-closing financing (as defined below) and the merger were consummated as of January 1, 2022, and combines the historical results of Magenta and Dianthus for the respective periods presented.

The selected unaudited pro forma condensed combined financial data are presented for illustrative purposes only and are not necessarily indicative of the combined financial position or results of operations of future periods or the results that actually would have been realized had the entities been a single entity during these periods. The selected unaudited pro forma condensed combined financial data as of and for the six months ended June 30, 2023, and as of December 31, 2022, are derived from the unaudited pro forma condensed combined financial information and should be read in conjunction with that information. For more information, please see the section titled "*Unaudited Pro Forma Condensed Combined Financial Information*" below.

Selected Unaudited Pro Forma Condensed Combined Statement of Operations:

	Six Months Ended June 30, 2023	Year Ended December 31, 2022
	(in thousands, except share and per share data)	
Revenues		
License revenue—related party	$ 1,445	$ 6,417
Operating expenses		
Research and development	24,234	84,669
General and administrative	16,254	38,596
Restructuring and other charges	19,921	—
Total operating expenses	60,409	123,265
Loss from operations	(58,964)	(116,848)
Other income/(expense)		
Interest and other income, net	5,093	5,585
(Loss)/gain on currency exchange, net	(37)	136
Other (expense)/income	(26)	3,279
Total other income/(expense), net	5,030	9,000
Net loss	$ (53,934)	$ (107,848)
Net loss per share, basic and diluted	$ (3.59)	$ (7.22)
Weighted average common shares outstanding, basic and diluted	15,025,437	14,946,706

Selected Unaudited Pro Forma Condensed Combined Balance Sheet Data:

	June 30, 2023
	(in thousands)
Cash and cash equivalents	$ 162,139
Short-term investments	35,763
Working capital[(1)]	183,886
Total assets	202,139
Total liabilities	18,312
Accumulated deficit	(76,142)
Total stockholders' equity	183,827

(1) Working capital is defined as current assets less current liabilities.

Unaudited Pro Forma Condensed Combined Financial Information

The following unaudited pro forma condensed combined financial information is based on Magenta's historical consolidated financial statements and Dianthus' historical financial statements as adjusted to give effect to the merger of the companies, accounted for as a reverse acquisition accounted for as a reverse recapitalization, and to the issuance of shares and Dianthus pre-funded warrants in the Dianthus pre-closing financing (as defined below) and to Magenta's 1:16 reverse stock split.

The Merger

On May 2, 2023, Magenta, Merger Sub, and Dianthus, entered into the Merger Agreement, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub merged with and into Dianthus, with Dianthus continuing as a wholly owned subsidiary of Magenta and the surviving corporation of the merger (the "merger"). The merger is 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. The merger was consummated on September 11, 2023 and the business of Dianthus will continue as the business of the combined company.

Subject to the terms and conditions of the Merger Agreement, at the effective time of the merger, each share of Dianthus common stock outstanding immediately prior to the effective time, including (i) those shares of Dianthus common stock issued upon conversion of the Dianthus preferred stock, which conversion occurred immediately prior to the effective time of the merger, and (ii) those shares of common stock and Dianthus pre-funded warrants issued in connection with Dianthus pre-closing financing (as defined below), were converted into the right to receive a number of shares of Magenta common stock or pre-funded warrants to acquire Magenta common stock based on the exchange ratio calculated in accordance with the Merger Agreement (the "Exchange Ratio").

In April 2023, Magenta sold certain assets, including intellectual property, related to the CD117 antibodies including the clinical antibody that was used with MGTA-117, MGTA-45 program and MGTA-145 program for upfront payments of $3.3 million and contingent payments of up to $20.0 million upon the achievement of certain milestones. The accompanying unaudited pro forma condensed combined financial information includes an adjustment to reflect the upfront payments of $3.3 million from the April 2023 asset sales.

The contingent cash flow streams resulting from the April 2023 sales of certain assets, including intellectual property, related to its MGTA-117 antibody, MGTA-45 program and MGTA-145 program, are considered to be variable consideration that is not probable to be received by Magenta as the achievement of the milestones is highly susceptible to factors outside of Magenta's influence that are not expected to be resolved for a long period of time, if at all. The value of such contingent cash flow streams is therefore not material to Magenta or the merger.

At the effective time of the merger, Magenta and a rights agent entered into a Contingent Value Rights Agreement, or the CVR Agreement, pursuant to which Magenta's stockholders of record as of immediately prior to the effective time of the merger received one non-transferable CVR for each outstanding share of Magenta common stock held by such stockholder on such date. Pursuant to the CVR Agreement, each CVR holder will be entitled to rights to receive a pro rata portion of certain proceeds, if any, received by Magenta after the effective time of the merger, which proceeds will include the contingent payments related to the April 2023 asset sales. As of the effective date of the merger, Magenta does not believe that it has a liability, as the contingent events obligating Magenta to pay Magenta's stockholders of record are not probable of occurring. If, following the merger, Magenta were to record a receivable once the variable consideration is not constrained, for the contingent payments resulting from the April 2023 asset sales, it would also record a corresponding liability.

Accordingly, the merger is treated as a reverse acquisition accounted for as a reverse recapitalization in accordance with GAAP because on the effective date of the merger, substantially all of Magenta's assets consist of cash and cash equivalents, marketable securities, as well as other nominal non-operating assets.

Under certain circumstances further described in the Merger Agreement, the ownership percentages of Dianthus securityholders and Magenta securityholders were subject to adjustment to the extent that Magenta's net cash as of the closing was less than $59.5 million or greater than $60.5 million and to the extent there were any changes to the amount of the Dianthus pre-closing financing (as defined below). Immediately after the consummation of the merger, based on the Exchange Ratio of approximately 0.2181 and Magenta's net cash at closing of approximately $68.6 million, Dianthus securityholders owned approximately 77.0% of Magenta capital stock, and Magenta securityholders owned approximately 23.0% of Magenta capital stock, after giving effect to the Dianthus pre-closing financing (as defined below).

The Dianthus Pre-Closing Financing

In connection with the Merger Agreement, certain third parties entered into a subscription agreement, as amended (the "subscription agreement"), with Dianthus to purchase shares of Dianthus common stock, par value $0.0001 per share and, if applicable, Dianthus pre-funded warrants, in the form agreed between Dianthus and the applicable purchasers to acquire that number of shares of common stock, at a per share purchase price defined in the subscription agreement, for an aggregate purchase price of approximately $72.0 million (the "Dianthus pre-closing"). The aggregate purchase price of $72.0 million was fixed, while the purchase price per share or warrant and the aggregate number of shares and warrants to be purchased was subject to change pursuant to the terms of the subscription agreement. The Dianthus pre-closing financing was contingent on and occurred immediately prior to the closing of the merger. Shares of the Dianthus common stock and Dianthus pre-funded warrants issued pursuant to the Dianthus pre-closing financing were converted into shares of Magenta common stock and Magenta pre-funded warrants, respectively, in accordance with the Exchange Ratio at the effective time.

The unaudited pro forma condensed combined balance sheet assumes that the Dianthus pre-closing financing, and the merger were consummated as of June 30, 2023, and combines the historical balance sheets of Magenta and Dianthus as of such date. The unaudited pro forma condensed combined statement of operations for the six months ended June 30, 2023, and year ended December 31, 2022, assumes that the Dianthus pre-closing financing and the merger were consummated as of January 1, 2022, and combines the historical results of Magenta and Dianthus for the periods presented.

The unaudited pro forma condensed combined financial information is presented for illustrative purposes only and is not necessarily indicative of the combined financial position or results of operations of future periods or the results that actually would have been realized had the entities been a single entity during these periods.

The unaudited pro forma condensed combined financial information is based on the assumptions and adjustments that are described in the accompanying notes. Accordingly, the pro forma adjustments are preliminary, subject to further revision as additional information becomes available and additional analyses are performed and have been made solely for the purpose of providing unaudited pro forma condensed combined financial information. Differences between these preliminary estimates and the final accounting, expected to be completed after the closing, will occur and these differences could have a material impact on the accompanying unaudited pro forma condensed combined financial information and the combined organization's future results of operations and financial position.

The unaudited pro forma condensed combined financial information does not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the integration of the two companies. The unaudited pro forma condensed combined financial information is not necessarily indicative of the financial position or results of operations in future periods or the results that actually would have been realized had Magenta and Dianthus been a combined organization during the specified periods. The actual results reported in periods following the merger may differ significantly from those reflected in the unaudited pro forma condensed combined financial information presented herein for a number of reasons, including, but not limited to, differences in the assumptions used to prepare this unaudited pro forma condensed combined financial information.

The unaudited pro forma condensed combined financial information, including the notes thereto, should be read in conjunction with the separate historical financial statements of Magenta and Dianthus, Magenta's *"Management's Discussion and Analysis of Financial Condition and Results of Operations"* included in its Quarterly Report on Form 10-Q filed with the SEC on August 3, 2023, and Dianthus' *"Management's Discussion and Analysis of Financial Condition and Results of Operations"* included in Exhibit 99.3 of this Current Report on Form 8-K/A of which this Exhibit 99.6 is a part.

Accounting rules require evaluation of certain assumptions, estimates, or determination of financial statement classifications. The accounting policies of Magenta may materially vary from those of Dianthus. During preparation of the unaudited pro forma condensed combined financial information, management has performed a preliminary analysis and is not aware of any material differences, and accordingly, this unaudited pro forma condensed combined financial information assumes no material differences in accounting policies. Following the merger, management will conduct a final review of Magenta accounting policies in order to determine if differences in accounting policies require adjustment or reclassification of Magenta results of operations or reclassification of assets or liabilities to conform to Dianthus' accounting policies and classifications. As a result of this review, management may identify differences that, when conformed, could have a material impact on this unaudited pro forma condensed combined financial information.

UNAUDITED PRO FORMA CONDENSED COMBINED BALANCE SHEET
AS OF JUNE 30, 2023
(in thousands)

	Historical		Transaction Accounting Adjustments		Pro Forma Combined Total
	Dianthus	Magenta			
Assets					
Current assets:					
Cash and cash equivalents	$ 40,280	$ 62,633	$ 59,226	(a)(b)(c)(j)(k)	$ 162,139
Short-term investments	20,803	14,960	—		35,763
Receivable from related party	362	—	—		362
Unbilled receivable from related party	418	—	—		418
Prepaid expense and other current assets	249	1,045	—		1,294
Deferred transaction costs	1,163	—	—		1,163
Total current assets	63,275	78,638	59,226		201,139
Property and equipment, net	149	—	—		149
Right-of-use lease assets	677	—	—		677
Other assets and restricted cash	174	—	—		174
Total assets	$ 64,275	$ 78,638	$ 59,226		$ 202,139
Liabilities, convertible preferred stock and stockholders' equity (deficit)					
Current liabilities:					
Accounts payable	$ 2,320	$ 813	$ —		$ 3,133
Accrued expense and other current liabilities	3,874	3,221	6,567	(b)(c)(i)	13,662
Current portion of deferred revenue—related party	100	—	—		100
Current portion of lease liabilities	358	—	—		358
Total current liabilities	6,652	4,034	6,567		17,253
Deferred revenue—related party	763	—	—		763
Long-term lease liabilities	296	—	—		296
Total liabilities	7,711	4,034	6,567		18,312
Convertible preferred stock	118,024	—	(118,024)	(d)	—
Stockholders' equity (deficit):					
Common stock	—	61	(46)	(a)(d)(f)(e)	15
Additional paid-in capital	2,656	509,029	(251,712)	(a)(c)(d)(e)(f)(h)	259,973
Accumulated other comprehensive loss	(19)	(3)	3	(e)	(19)
Accumulated deficit	(64,097)	(434,483)	422,438	(b)(e)(h)(i)(j)(k)	(76,142)
Total stockholders' equity (deficit)	(61,460)	74,604	170,683		183,827
Total liabilities, convertible preferred stock and stockholders' equity	$ 64,275	$ 78,638	$ 59,226		$ 202,139

The accompanying notes are an integral part of this unaudited pro forma condensed combined financial information.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS FOR THE SIX MONTHS ENDED JUNE 30, 2023
(in thousands, except share and per share data)

	Historical		Transaction Accounting Adjustments		Pro Forma Combined Total
	Dianthus	Magenta			
Revenues					
License revenue—related party	$ 1,445	$ —	$ —		$ 1,445
Operating expenses					
Research and development	16,100	8,134	—		24,234
General and administrative	4,804	11,450	—		16,254
Restructuring and other charges	—	19,921	—		19,921
Total operating expenses	20,904	39,505	—		60,409
Loss from operations	(19,459)	(39,505)	—		(58,964)
Interest and other income, net	1,293	7,051	(3,251)	(j)	5,093
Loss on currency exchange, net	(37)	—	—		(37)
Other expense	(26)	—	—		(26)
Total other income/(expense), net	1,230	7,051	(3,251)		5,030
Net loss	$ (18,229)	$ (32,454)	$ (3,251)		$ (53,934)
Net loss per share, basic and diluted	$ (4.54)	$ (8.56)			$ (3.59)
Weighted average common shares outstanding, basic and diluted	4,011,824	3,790,504		(g)	15,025,437

The accompanying notes are an integral part of this unaudited pro forma condensed combined financial information.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2022
(in thousands, except share and per share data)

	Historical		Transaction Accounting Adjustments		Pro Forma Combined Total
	Dianthus	Magenta			
Revenues					
License revenue —related party	$ 6,417	$ —	$ —		$ 6,417
Operating expenses					
Research and development	29,379	55,141	149	(h)	84,669
General and administrative	6,743	25,761	6,092	(b)(h)(i)	38,596
Total operating expenses	36,122	80,902	6,241		123,265
Loss from operations	(29,705)	(80,902)	(6,241)		(116,848)
Interest and other income, net	1,145	4,440	—		5,585
Loss on currency exchange, net	136	—	—		136
Other (expense)/income	(52)	—	3,331	(j)(k)	3,279
Total other income/(expense), net	1,229	4,440	3,331		9,000
Net loss	$ (28,476)	$ (76,462)	$ (2,910)		$ (107,848)
Net loss per share, basic and diluted	$ (7.10)	$ (20.61)			$ (7.22)
Weighted average common shares outstanding, basic and diluted	4,009,204	3,710,771		(g)	14,946,706

The accompanying notes are an integral part of this unaudited pro forma condensed combined financial information.

NOTES TO THE UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

1. Description of the Transaction

Description of the merger

On May 2, 2023, Magenta entered into the Merger Agreement with Dianthus and Merger Sub. On September 11, 2023, Magenta completed its business combination with Dianthus in accordance with the terms of the Merger Agreement, pursuant to which, among other matters, Merger Sub merged with and into Dianthus, with Dianthus surviving the merger as a wholly-owned subsidiary of Magenta, and Magenta being the surviving corporation of the merger. In connection with the closing of the merger, the combined company changed its name to Dianthus Therapeutics, Inc.

Subject to the terms and conditions set forth in the Merger Agreement, Dianthus stockholders received a number of shares of Magenta common stock determined at the closing of the merger based on the Exchange Ratio.

At the effective time of the merger, each share of Dianthus common stock outstanding immediately prior to the effective time, including (i) those shares of Dianthus common stock issued upon conversion of the Dianthus preferred stock, which conversion occurred immediately prior to the effective time of the merger, and (ii) those shares of Dianthus common stock and Dianthus pre-funded warrants issued in connection with Dianthus pre-closing financing, were converted into the right to receive a number of shares of Magenta common stock and Magenta pre-funded warrants, respectively, based on the Exchange Ratio. The Exchange Ratio is approximately 0.2181 shares of Magenta common stock for each share of Dianthus common stock. Under the Exchange Ratio formula in the Merger Agreement, immediately after the merger, Magenta securityholders owned approximately 23.0% of the outstanding shares of capital stock of the combined company, and former Dianthus securityholders, including former Dianthus securityholders that purchased shares of Dianthus common stock and Dianthus pre-funded warrants in the Dianthus pre-closing financing, owned approximately 77.0% of the outstanding shares of capital stock of the combined company.

The percentage ownership of the combined company was derived using a stipulated value of Dianthus of approximately $297.0 million, inclusive of the Dianthus pre-closing financing, and a stipulated value of Magenta of approximately $88.6 million. The valuation of Magenta was determined based on net cash as defined in the Merger Agreement, of approximately $68.6 million as of a determination date prior to the closing of the merger, plus an additional $20.0 million of enterprise value. The fair value of consideration transferred was not indicative of the combined entities' enterprise value upon consummation of the merger. As the merger is accounted for as a reverse acquisition accounted for as a reverse recapitalization, any difference between the consideration to be transferred in the merger and the fair value of the net assets acquired is recorded as an adjustment to additional paid-in capital.

Each stock option granted under Dianthus' 2019 Plan that was outstanding immediately prior to the effective time of the merger, was assumed by Magenta and became an option to acquire, on the same terms and conditions as were applicable to such Dianthus stock option immediately prior to the effective time of the merger, a number of shares of Magenta common stock equal to the number of shares of Dianthus' common stock subject to the unexercised portion of the Dianthus stock option immediately prior to the effective time of the merger, multiplied by the Exchange Ratio (rounded down to the nearest whole share number) with an exercise price per share for the options equal to the exercise price per share of such Dianthus stock option immediately prior to the effective time of the merger divided by the Exchange Ratio (rounded up to the nearest whole cent). Such assumed options continue to be governed by the terms and conditions of Dianthus' 2019 Plan. Under the terms of the Merger Agreement, prior to the closing of the merger, the board of directors of Magenta acted to (i) accelerate the vesting of equity certain awards of Magenta and (ii) extend the expiration time of Magenta options with an exercise price of $2.00 or less, in each case, in accordance with the terms of the Merger Agreement.

Each restricted stock unit granted by Dianthus, that was outstanding immediately prior to the effective time of the merger, was converted into a restricted stock unit of Magenta on the same terms and conditions as were applicable to such Dianthus restricted stock unit immediately prior to the effective time of the merger, a number of shares of Magenta common stock equal to the number of shares of Dianthus' common stock subject to the unvested portion of Dianthus restricted stock unit immediately prior to the effective time of the merger, multiplied by the Exchange Ratio (rounded down to the nearest whole share number).

Each warrant granted by Dianthus that was outstanding immediately prior to the effective time of the merger was converted into a warrant to purchase shares of Magenta common stock on the same terms and conditions as were applicable to such Dianthus warrant immediately prior to the effective time of the merger, a number of shares of Magenta common stock equal to the number of shares of Dianthus' common stock subject to the warrant immediately prior to the effective time of the merger, multiplied by the Exchange Ratio (rounded down to the nearest whole share number) with an exercise price per share for the warrant equal to the exercise price per share of such Dianthus warrant immediately prior to the effective time of the merger divided by the Exchange Ratio (rounded up to the nearest whole cent).

In April 2023, Magenta sold certain assets, including intellectual property, related to the CD117 antibodies including the clinical antibody that was used with MGTA-117, MGTA-45 program and MGTA-145 program for upfront payments of $3.3 million and contingent payments of up to $20.0 million upon the achievement of certain milestones. The accompanying unaudited pro forma condensed combined financial information includes an adjustment to reflect the upfront payments of $3.3 million from the April 2023 asset sales.

The contingent cash flow streams resulting from the April 2023 sales of certain assets, including intellectual property, related to its MGTA-117 antibody, MGTA-45 program and MGTA-145 program, are considered to be variable consideration that is not probable to be received by Magenta as the achievement of the milestones is highly susceptible to factors outside of Magenta's influence that are not expected to be resolved for a long period of time, if at all. The value of such contingent cash flow streams is therefore not material to Magenta or the merger.

At the effective time of the merger, Magenta and a rights agent entered into a Contingent Value Rights Agreement, or the CVR Agreement, pursuant to which Magenta's stockholders of record as of immediately prior to the effective time of the merger received one non-transferable CVR for each outstanding share of Magenta common stock held by such stockholder on such date. Pursuant to the CVR Agreement, each CVR holder will be entitled to rights to receive a pro rata portion of certain proceeds, if any, received by Magenta after the effective time of the merger, which proceeds will include the contingent payments related to the April 2023 asset sales. As of the effective date of the Merger, Magenta does not believe that it has a liability, as the contingent events obligating Magenta to pay Magenta's stockholders of record are not probable of occurring. If, following the merger, Magenta were to record a receivable once the variable consideration is not constrained, for the contingent payments resulting from the April 2023 asset sales, it would also record a corresponding liability.

Accordingly, the merger is treated as a reverse acquisition accounted for as a reverse recapitalization in accordance with GAAP because on the effective date of the merger, substantially all of Magenta's assets consisted of cash and cash equivalents, marketable securities, as well as other nominal non-operating assets.

Dianthus Pre-Closing Financing

Concurrently with the execution and delivery of the Merger Agreement, certain parties entered into the subscription agreement with Dianthus pursuant to which they agreed, subject to the terms and conditions of such agreement, to purchase, prior to the consummation of the merger, approximately 13.2 million shares of Dianthus common stock and approximately 1.0 million Dianthus pre-funded warrants to purchase approximately 1.0 million shares of Dianthus common stock for an aggregate gross purchase price of approximately $72.0 million. The aggregate purchase price of $72.0 million was fixed, while the purchase price per share or warrant and the aggregate number of shares and warrants to be purchased was subject to change pursuant to the terms of the subscription agreement. The consummation of the transactions contemplated by such agreements was conditioned on the satisfaction or waiver of the conditions set forth in the Merger Agreement. Shares of Dianthus common stock and Dianthus pre-funded warrants issued pursuant to the Dianthus pre-closing financing were converted into the right to receive shares of common stock and pre-funded warrants, respectively, of Magenta in the merger in accordance with the Exchange Ratio at the effective time.

2. Basis of Pro Forma Presentation

The unaudited pro forma condensed combined financial information gives effect to Magenta's 1:16 reverse stock split.

The unaudited pro forma condensed combined financial information was prepared in accordance with GAAP and pursuant to the rules and regulations of Article 11 of Regulation S-X. The unaudited pro forma condensed combined balance sheet as of June 30, 2023 was prepared using the historical balance sheets of Magenta and Dianthus as of June 30, 2023. The unaudited pro forma condensed combined statement of operations for the six months ended June 30, 2023, and for the year ended December 31, 2022, were prepared using the historical statements of operations and comprehensive loss of Magenta and Dianthus for the six months ended June 30, 2023, and for the year ended December 31, 2022, respectively, and gives effect to the merger as if it occurred on January 1, 2022.

For accounting purposes, Dianthus is considered the acquirer, and the merger is accounted for as a reverse acquisition accounted for as a reverse recapitalization of Magenta by Dianthus because upon the closing of the merger, substantially all of Magenta's assets consisted of cash and cash equivalents, marketable securities, as well as other nominal non-operating assets.

Under reverse recapitalization accounting, the subsequent financial statements of the combined company reflect the operations of the acquirer for accounting purposes together with a deemed issuance of shares, equivalent to the shares held by the former stockholders of the legal acquirer and a recapitalization of the equity of the accounting acquirer. The accompanying unaudited proforma condensed combined financial information was derived from the historical financial statements of Magenta and Dianthus and include adjustments to give pro forma effect to reflect the accounting for the transaction in accordance with GAAP. The historical financial statements of Dianthus will become the historical financial statements of the combined company.

Dianthus and Magenta may incur significant costs associated with integrating their operations after the merger is completed. The unaudited pro forma condensed combined financial information does not reflect the costs of any integration activities or benefits that may result from realization of future cost savings from operating efficiencies which may result from the merger.

To the extent that there are significant changes to the business following completion of the merger, the assumptions and estimates set forth in the unaudited pro forma condensed financial information could change significantly. Accordingly, the pro forma adjustments are subject to further adjustments as additional information becomes available and as additional analyses are conducted. There can be no assurances that these additional analyses will not result in material changes to the estimates of fair value.

3. Preliminary Estimated Purchase Price

For purposes of this unaudited pro forma condensed combined financial information, the total estimated purchase price is summarized as follows (in thousands, except share and per share amounts):

Estimated number of common shares of the combined company to be owned by Magenta stockholders[1]	3,792,047
Multiplied by the fair value per share of Magenta common stock[2]	$ 11.84
Estimated fair value of Magenta common stock issued	$ 44,898
Estimated fair value of stock options and restricted stock units attributable to precombination services[3]	$ 201
Estimated purchase price	$ 45,099

(1) The final purchase price will be determined based on the number of shares of Magenta common stock of the combined company that Magenta stockholders own as of the closing date of the merger. For purposes of this unaudited pro forma condensed combined financial information, the estimated number of shares is based on a total of 3,792,047 shares of Magenta common stock outstanding as of September 1, 2023, adjusted to reflect the impact of the Magenta 1:16 reverse stock split.

(2) The estimated purchase price was based on the closing price of Magenta common stock as reported on the Nasdaq Capital Market on September 1, 2023, adjusted to reflect the impact of the Magenta 1:16 reverse stock split.

(3) Based on the capitalization of Magenta as of June 30, 2023, 4,384 outstanding unvested Magenta restricted stock units and 69,300 stock options will be accelerated in connection with the merger, adjusted to reflect the impact of the Magenta 1:16 reverse stock split. The acquisition date fair value of these Magenta restricted stock units and Magenta stock options attributable to the pre-combination services is included in the estimated purchase price. The acquisition date fair value of these merger restricted stock units and stock options is calculated based on the number of such Magenta restricted stock units and Magenta stock options expected to vest assuming that the merger closed on June 30, 2023. The following table presents, on a weighted average basis, the assumptions used in the Black-Scholes option-pricing model to determine the estimated acquisition-date fair value of the assumed Magenta equity awards:

Risk-free interest rate	5.16%
Expected term (in years)	1.32
Expected volatility	60.11%
Expected dividend yield	0%

The actual purchase consideration for the net assets of Magenta will vary based on Magenta share price at closing; however, any difference between the consideration transferred and the fair value of the net assets of Magenta following determination of the actual purchase consideration for it will be reflected as an adjustment to additional paid-in capital. The estimated purchase consideration reflected in this unaudited pro forma condensed combined financial information does not purport to represent what the actual purchase consideration will be when the merger is completed.

Under reverse recapitalization accounting, the subsequent financial statements of the combined company will reflect the operations of Dianthus for accounting purposes together with a deemed issuance of shares, equivalent to the shares held by the former stockholders of Magenta and a recapitalization of the equity of Dianthus.

4. Shares of Magenta Common Stock Issued to Dianthus' Stockholders upon Closing of the Merger

Prior to the merger, all outstanding convertible preferred stock of Dianthus was converted into common stock of Dianthus. At the effective time of the merger, Magenta issued 12,725,235 shares of common stock (including the shares of the common stock issuable upon exercise of outstanding options, restricted stock units and warrants), adjusted to reflect the impact of the Magenta 1:16 reverse stock split, to the shareholders of Dianthus in the merger, determined as follows:

	Shares
Dianthus shares of common stock outstanding	4,026,833
Dianthus shares of common stock issuable upon exercise of outstanding warrants and options to purchase common stock	6,838,205
Shares of Dianthus common stock issued upon conversion of Dianthus convertible preferred stock	33,336,282
Estimated shares of Dianthus common stock upon consummation of the Dianthus pre-closing financing	14,144,555
Total Dianthus common equivalent shares	58,345,875
Exchange Ratio	0.2181
Shares of Magenta common stock issued to Dianthus shareholders upon closing of the merger	12,725,235

5. Transaction Accounting Adjustments

Adjustments included in the column under the heading "Transaction Accounting Adjustments" are primarily based on information contained within the Dianthus pre-closing financing and the Merger Agreement. Further analysis will be performed after the completion of the merger to confirm these estimates.

Based on Dianthus management's review of Magenta's summary of significant accounting policies, the nature and amount of any adjustments to the historical consolidated financial statements of Magenta to conform to the accounting policies of Dianthus are not expected to be significant.

Both Dianthus and Magenta have a history of generating net operating losses and maintain a full valuation allowance against their net deferred tax assets. As a result, both entities have not previously reflected an income tax benefit or expense within the financial statement period presented. Management has not identified any changes to the income tax positions due to the merger that would result in an incremental tax expense or benefit. Accordingly, no tax-related adjustments have been reflected for the pro forma adjustments.

The pro forma adjustments, based on preliminary estimates that may change significantly as additional information is obtained, are as follows:

(a) To reflect $72.0 million in proceeds, less estimated issuance costs of $4.3 million, in connection with the consummation of the Dianthus pre-closing financing, in which approximately 13.2 million shares of Dianthus common stock and approximately 1.0 million Dianthus pre-funded warrants to acquire approximately 1.0 million of Dianthus shares of common stock are to be issued. The merger was contingent upon the Dianthus pre-closing financing, which closed immediately prior to the closing of the merger. If the Dianthus pre-closing financing did not close, Dianthus and Magenta were not required to complete the merger. Based on an assessment of the Dianthus pre-funded warrants specific terms in the draft agreement and applicable authoritative guidance in ASC 480 and ASC 815, the combined company will account for the Dianthus pre-funded warrants as equity-classified instruments.

(b) To reflect preliminary estimated transaction costs of $4.8 million in connection with the merger, such as advisor fees, legal fees, printer fees, and accounting expenses that are expected to be incurred by Magenta, which were not accrued as of June 30, 2023, and the cost of the D&O tail policy of $2.6 million that is expected to be incurred by Magenta and Dianthus. As $4.1 million of these costs had been already paid by the date of this Current Report on Form 8-K/A, the adjustment was recorded as a decrease in cash of $4.1 million, an increase in accrued liabilities of $3.3 million, and an increase in accumulated deficit of $7.4 million.

(c) To reflect preliminary estimated transaction costs of $3.5 million in connection with the merger, such as advisor fees, legal fees, printer fees, and accounting expenses that are expected to be incurred by Dianthus. As $2.7 million of these costs had been already paid by the date of this Current Report on Form 8-K/A, the adjustment was recorded as a decrease to cash of $2.7 million, an increase in accrued liabilities of $0.8 million, and a reduction to additional paid-in capital of $3.5 million. As the merger is accounted for as a reverse recapitalization equivalent to the issuance of equity for the net assets of Magenta, these direct and incremental costs are treated as a reduction of the net proceeds received within additional paid-in capital.

(d) To reflect the conversion of 33.3 million shares of Dianthus convertible preferred stock into shares of Dianthus common stock on a 1-for-1 basis, which occurred immediately prior to the effective time of the merger.

(e) To reflect the elimination of Magenta historical equity.

(f) To reflect the effect of the reverse recapitalization of Magenta for a total of $74.6 million, which is the net assets of Magenta as of June 30, 2023.

(g) The pro forma combined basic and diluted earnings per share have been adjusted to reflect the pro forma net loss for the six months ended June 30, 2023, and the year ended December 31, 2022. In addition, the number of shares used in calculating the pro forma combined basic and diluted net loss per share has been adjusted to reflect the total number of shares of common stock of the combined company that would be outstanding as of the merger closing date after giving effect to the 1:16 reverse stock split, including the impact of the shares of Dianthus common stock issued in the Dianthus pre-closing financing. For the six months ended June 30, 2023, and the year ended December 31, 2022, the pro forma weighted average shares outstanding has been calculated as follows:

	June 30, 2023	December 31, 2022
Weighted-average Dianthus common shares outstanding—basic and diluted	4,011,824	4,009,204
Impact of Dianthus pre-closing financing assuming consummation as of January 1, 2022	14,144,555	14,144,555
Impact of Dianthus convertible preferred stock assuming conversion as of January 1, 2022	33,336,282	33,336,282
Total	51,492,661	51,490,041
Application of the Exchange Ratio to historical Dianthus weighted-average common shares outstanding	0.2181	0.2181
Adjusted Dianthus weighted-average common shares outstanding	11,230,549	11,229,978
Impact of Magenta common stock related to stock awards that accelerated vesting as of January 1, 2022	4,384	5,957
Weighted-average Magenta common shares outstanding—basic and diluted	3,790,504	3,710,771
Pro forma combined weighted average number of shares of common stock—basic and diluted	15,025,437	14,946,706

(h) To reflect $0.5 million of share-based compensation costs recognized as a result of the merger due to the following:

a. the fair value of the outstanding unvested awards that fully vested immediately prior to the completion of the merger of $0.2 million; and

b. the difference between the total value of the replacement awards and the portion attributable to pre-combination service of $0.3 million.

These share-based compensation costs are reflected as an increase in additional paid-in capital and an increase to accumulated deficit in the unaudited pro forma condensed combined balance sheet. Magenta share-based compensation costs of $0.5 million are reflected as research and development expense and general and administrative expense in the unaudited pro forma condensed combined statement of operations for the year ended December 31, 2022.

(i) To reflect Magenta's estimated compensation expense of $4.3 million related to change-in-control cash payments, retention and severance payments resulting from pre-existing employment agreements or from Magenta board of directors approval that will be payable in cash in connection with the merger but were not incurred as of June 30, 2023, an increase to accrued expenses and accumulated deficit in the unaudited pro forma condensed combined balance sheet. As $1.8 million of these costs had been already paid by the date of this Current Report on Form 8-K/A, and $1.6 million was accrued in the historical Magenta's consolidated balance sheet as of June 30, 2023, the adjustment was recorded as a decrease to cash of $1.8 million, an increase in accrued liabilities of $2.5 million, an increase in general and administrative expenses of $2.5 million and an increase in accumulated deficit of $4.3 million. Magenta's compensation costs of $2.5 million are reflected as general and administrative expense, respectively, in the unaudited pro forma condensed combined statement of operations for the year ended December 31, 2022.

(j) To reflect $3.3 million of upfront payments received in connection with the April 2023 asset sales as if the asset sales had occurred on January 1, 2022. In April 2023, the Company sold certain assets, including intellectual property, related to the CD117 antibodies including the clinical antibody that was used with MGTA-117, MGTA-45 program and MGTA-145 program and allocated $3.3 million to the transaction price of such sales.

(k) To reflect $0.1 million of upfront payment received in connection with the July 2023 E-478 asset sale as if the asset sales had occurred on January 1, 2022.

(l) The total impact to equity for the above adjustments as reflected in the table below:

(in thousands, except share data)		Common Stock – Dianthus Shares	Common Stock – Dianthus Amount	Common Stock – Magenta Shares	Common Stock – Magenta Amount	Additional Paid-in-Capital	Accumulated Deficit	AOCI	Stockholders' equity
Conversion of outstanding Dianthus' convertible preferred stock into common stock	(d)	33,336,282	$ 12	—	$ —	$ 118,012	$ —	$—	$ 118,024
Dianthus pre-closing financing	(a)	14,144,555	1	—	—	67,678	—	—	67,679
Pre-combination stock-based compensation	(h)	—	—	—	—	500	(500)	—	—
Elimination of Magenta's historical equity carrying value	(e)	—	—	(3,790,762)	(61)	(509,029)	434,483	3	(74,604)
Exchange of outstanding Dianthus common stock into Magenta common stock based on the Exchange Ratio		(51,507,670)	(13)	11,023,502	11	2	—	—	—
Reverse recapitalization of Magenta	(f)	—	—	3,794,227	4	74,600	—	—	74,604
Retention and severance payments to Magenta employees	(i)	—	—	—	—	—	(4,262)	—	(4,262)
Transaction costs associated with the merger	(b),(c)	—	—	—	—	(3,475)	(7,363)	—	(10,838)
July 2023 asset sale	(k)	—	—	—	—	—	80	—	80
Total adjustment		(4,026,833)	$ —	11,026,967	$ (46)	$ (251,712)	$ 422,438	$ 3	$ 170,683