

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2024

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-38541

**Dianthus Therapeutics, Inc.**  
(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

7 Times Square, 43rd Floor  
New York, New York

(Address of principal executive offices)

81-0724163

(I.R.S. Employer  
Identification No.)

10036

(Zip Code)

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

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 5, 2024, the registrant had 29,596,965 shares of common stock, \$0.001 par value per share, outstanding.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of the federal securities laws, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts included in this Quarterly Report on Form 10-Q are forward-looking statements, including, without limitation, statements concerning our plans, objectives, goals, expectations, hopes, beliefs, intentions, assumptions, projections, estimates or strategies and any underlying assumptions regarding the future, our future results of operations and financial position, including the sufficiency of our existing cash resources to fund our operations for as long as anticipated, our liquidity, capital resources, costs and expenses, capital requirements, commitments and contingencies, the development or commercial potential of DNTH103 or any other product candidate, our anticipated preclinical and clinical drug development activities, in particular with respect to DNTH103, and any timelines, developments or results in connection therewith, including the timing of data, the efficacy, safety profile, dosing amount or frequency, method of delivery or other potential therapeutic benefits of DNTH103, the receipt or timing of potential regulatory designations, approvals and commercialization of any product candidates and other statements, including those included under the sections titled “*Risk Factors*” and “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*” and elsewhere in this Quarterly Report on Form 10-Q. In some cases, you can identify forward-looking statements by terms such as “aim,” “may,” “might,” “will,” “would,” “shall,” “objective,” “intend,” “target,” “should,” “could,” “can,” “expect,” “anticipate,” “believe,” “design,” “estimate,” “forecast,” “predict,” “project,” “potential,” “possible,” “plan,” “seek,” “contemplate,” “goal,” “likely” or “continue” or the negative of these terms and similar expressions intended to identify forward-looking statements, but the absence of these terms does not mean that a statement is not forward-looking. Forward-looking statements are not historical facts and are based on our current expectations and beliefs with respect to future events and their potential effects and impacts. There can be no assurance that future events affecting us will be those that have been anticipated. Given the significant risks and uncertainties, you should not place undue reliance on these forward-looking statements.

There are a number of risks, uncertainties and other factors that could cause our actual results or outcomes, or the timing of our results or outcomes, to differ materially from the forward-looking statements expressed or implied in this Quarterly Report on Form 10-Q. Such risks, uncertainties and other factors include, among others, the following risks, uncertainties and factors:

- expectations regarding the strategies, prospects, plans, expectations and objectives of our management for future operations of the Company;
- risks associated with our ability to manage expenses and unanticipated spending and costs that could reduce our cash resources;
- risks related to our ability to correctly estimate our operating expenses and other events;
- changes in capital resource requirements;
- our ability to obtain, maintain and protect our intellectual property rights, in particular those related to our product candidates;
- our ability to advance the development of DNTH103 and our other potential product candidates or preclinical activities under the timelines we anticipate in planned and future clinical trials;
- our ability to replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of our product candidates;
- our ability to realize the anticipated benefits of our research and development programs, strategic partnerships, licensing programs or other collaborations;
- regulatory requirements or developments, and our ability to obtain necessary approvals from the U.S. Food and Drug Administration (the “FDA”) or other regulatory authorities;
- our ability to manufacture product candidates in conformity with the FDA or other regulatory authorities’ requirements and to scale up manufacturing of our product candidates to commercial scale, if approved;
- changes to clinical trial designs and regulatory pathways;
- developments and projections relating to our expected or existing competitors or industry;
- unexpected costs, charges or expenses resulting from the Reverse Merger;
- legislative, regulatory, political, geopolitical and macroeconomic developments beyond our control, including inflationary pressures, general economic slowdown or a recession, high interest rates, changes in monetary policy or foreign currency exchange rates, instability in financial institutions, the prospect of a shutdown of the U.S. federal government, the ongoing

conflict in Ukraine, conflict in the Middle East, rising tensions between China and Taiwan, the attacks on marine vessels traversing the Red Sea and the responses thereto, pandemics or other public health crises and supply chain disruptions;

- success in retaining, recruiting or changes required in, our officers, key employees or directors;
- the liquidity and trading of our securities;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- our ability to successfully develop and commercialize any technology that we may in-license or products we may acquire;
- our ability to successfully operate in non-U.S. jurisdictions in which we may choose to do business, including compliance with applicable regulatory requirements and laws;
- our reliance on third-party contract development and manufacturer organizations to manufacture and supply product candidates;
- our ability to establish satisfactory pricing and obtain adequate reimbursement from government and third-party payors of products and product candidates that receive regulatory approvals, if any;
- our ability to successfully commercialize product candidates, if approved, and the rate and degree of market acceptance of such product candidates;
- risks related to our ability to obtain additional financing and raise capital as necessary to fund operations or pursue business opportunities;
- the direct and indirect effects of widespread health emergencies on our workforce, operations, financial results and cash flows;
- severe weather and seasonal factors;
- our inability to continue to grow and manage our growth effectively;
- our inability to comply with, and the effect on our business of, evolving legal standards and regulations, including those concerning data protection, consumer privacy and sustainability and evolving labor standards; and
- our ability to remediate material weaknesses or other deficiencies in our internal control over financial reporting or to maintain effective disclosure controls and procedures and internal control over financial reporting.

There may be other factors that may cause our actual results or outcomes, or the timing of those results or outcomes, to differ materially from the forward-looking statements expressed or implied in this Quarterly Report on Form 10-Q, including factors disclosed in the sections titled "*Risk Factors*" and "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" and elsewhere in this Quarterly Report on Form 10-Q, in the section titled "*Risk Factors*" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and in our other filings with the Securities and Exchange Commission ("SEC"). You should evaluate all forward-looking statements made in this Quarterly Report on Form 10-Q in the context of these risks and uncertainties.

We caution you that the risks, uncertainties and other factors referred to above and elsewhere in this Quarterly Report on Form 10-Q may not contain all of the risks, uncertainties and other factors that may affect our future results, operations and outcomes. Moreover, new risks emerge from time to time. It is not possible for us to predict all risks. In addition, we cannot assure you that we will realize the results, benefits or developments that we expect or anticipate or, even if substantially realized, that they will result in the consequences or affect us or our business in the way expected. Past performance is not indicative of future performance.

Any forward-looking statements contained in this Quarterly Report on Form 10-Q apply only as of the date of this Quarterly Report on Form 10-Q and are expressly qualified in their entirety by the cautionary statements included in this Quarterly Report on Form 10-Q. Except as required by law, we disclaim any intent to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changes in assumptions or otherwise.

**Explanatory Note**

Unless context otherwise requires, references to “we,” “our,” “us,” “Dianthus,” the “Company,” or the “combined company” in this Quarterly Report on Form 10-Q refer to Dianthus Therapeutics, Inc. (formerly Magenta Therapeutics, Inc.) after the completion of the Reverse Merger (as defined elsewhere in this Quarterly Report on Form 10-Q), the term “Former Dianthus” refers to Dianthus Therapeutics OpCo, Inc. (formerly Dianthus Therapeutics, Inc.), and the term “Magenta” refers to the Company prior to completion of the Reverse Merger.

**PART I—FINANCIAL INFORMATION**

**Item 1. Condensed Consolidated Financial Statements (Unaudited)**

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

	September 30, 2024	December 31, 2023
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 33,671	\$ 132,325
Short-term investments	247,452	41,393
Receivable from related party	1,390	294
Unbilled receivable from related party	1,293	184
Prepaid expenses and other current assets	3,683	3,255
Total current assets	287,489	177,451
Long-term investments	61,482	—
Property and equipment, net	189	185
Right-of-use operating lease assets	352	615
Other assets and restricted cash	4,736	1,154
Total assets	<u>\$ 354,248</u>	<u>\$ 179,405</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 7,572	\$ 2,610
Accrued expenses	7,727	6,504
Current portion of deferred revenue - related party	100	100
Current portion of operating lease liabilities	311	417
Total current liabilities	15,710	9,631
Deferred revenue - related party	640	736
Long-term operating lease liabilities	—	168
Total liabilities	16,350	10,535
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Preferred stock; \$0.001 par value per share; authorized shares – 10,000,000 at September 30, 2024 and December 31, 2023; issued and outstanding – none at September 30, 2024 and December 31, 2023	—	—
Common stock; \$0.001 par value per share; authorized shares – 150,000,000 at September 30, 2024 and December 31, 2023; issued and outstanding shares – 29,366,352 and 14,817,696 at September 30, 2024 and December 31, 2023, respectively	29	15
Additional paid-in capital	483,140	258,231
Accumulated deficit	(145,952)	(89,423)
Accumulated other comprehensive income	681	47
Total stockholders' equity	337,898	168,870
Total liabilities and stockholders' equity	<u>\$ 354,248</u>	<u>\$ 179,405</u>

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

**DIANTHUS THERAPEUTICS, INC.**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
<b>Revenues:</b>				
License revenue - related party	\$ 2,172	\$ 924	\$ 4,909	\$ 2,369
<b>Operating expenses:</b>				
Research and development	25,544	7,960	56,692	24,060
General and administrative	6,528	8,723	18,165	13,527
Total operating expenses	32,072	16,683	74,857	37,587
Loss from operations	(29,900)	(15,759)	(69,948)	(35,218)
Other income/(expense):				
Interest income	4,445	1,027	13,375	2,320
Gain on investment in related party	307	—	307	—
Loss on currency exchange, net	(48)	(16)	(91)	(53)
Other income/(expense)	22	(15)	(172)	(41)
Total other income	4,726	996	13,419	2,226
Net loss	<u>\$ (25,174)</u>	<u>\$ (14,763)</u>	<u>\$ (56,529)</u>	<u>\$ (32,992)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.74)</u>	<u>\$ (3.78)</u>	<u>\$ (1.73)</u>	<u>\$ (17.40)</u>
Weighted-average number of shares of common stock outstanding including shares issuable under equity-classified pre-funded warrants, used in computing net loss per share of common stock, basic and diluted	<u>34,236,728</u>	<u>3,906,886</u>	<u>32,614,771</u>	<u>1,896,605</u>
<b>Comprehensive loss:</b>				
Net loss	\$ (25,174)	\$ (14,763)	\$ (56,529)	\$ (32,992)
Other comprehensive income:				
Change in unrealized gains related to available-for-sale debt securities	718	15	634	157
Total other comprehensive income	718	15	634	157
Total comprehensive loss	<u>\$ (24,456)</u>	<u>\$ (14,748)</u>	<u>\$ (55,895)</u>	<u>\$ (32,835)</u>

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

**DIANTHUS THERAPEUTICS, INC.**

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

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensi ve Income/(Loss )	Total Stockholders' Equity/(Deficit )
	Shares	Amount	Shares	Amount				
Balance, December 31, 2023	—	\$ —	14,817,696	\$ 15	\$ 258,231	\$ (89,423 )	\$ 47	\$ 168,870
Issuance of common stock and pre-funded warrants in connection with the private placement, net of issuance costs of \$14,665	—	—	14,500,500	14	215,319	—	—	215,333
Exercise of stock options	—	—	30,430	—	271	—	—	271
Stock-based compensation expense	—	—	—	—	2,035	—	—	2,035
Net loss	—	—	—	—	—	(13,748 )	—	(13,748 )
Other comprehensive loss	—	—	—	—	—	—	(74 )	(74 )
Balance, March 31, 2024	—	\$ —	29,348,626	\$ 29	\$ 475,856	\$ (103,171 )	\$ (27 )	\$ 372,687
Exercise of stock options	—	—	3,514	—	47	—	—	47
Stock-based compensation expense	—	—	—	—	3,101	—	—	3,101
Net loss	—	—	—	—	—	(17,607 )	—	(17,607 )
Other comprehensive loss	—	—	—	—	—	—	(10 )	(10 )
Balance, June 30, 2024	—	\$ —	29,352,140	\$ 29	\$ 479,004	\$ (120,778 )	\$ (37 )	\$ 358,218
Exercise of stock options	—	—	14,212	—	296	—	—	296
Stock-based compensation expense	—	—	—	—	3,840	—	—	3,840
Net loss	—	—	—	—	—	(25,174 )	—	(25,174 )
Other comprehensive gain	—	—	—	—	—	—	718	718
Balance, September 30, 2024	—	\$ —	29,366,352	\$ 29	\$ 483,140	\$ (145,952 )	\$ 681	\$ 337,898
Balance, December 31, 2022	33,336,282	\$ 118,024	875,279	\$ —	\$ 1,661	\$ (45,868 )	\$ (161 )	\$ (44,368 )
Stock-based compensation expense	—	—	—	—	533	—	—	533
Net loss	—	—	—	—	—	(7,089 )	—	(7,089 )
Other comprehensive income	—	—	—	—	—	—	104	104
Balance, March 31, 2023	33,336,282	\$ 118,024	875,279	\$ —	\$ 2,194	\$ (52,957 )	\$ (57 )	\$ (50,820 )
Stock-based compensation expense	—	—	—	—	462	—	—	462
Net loss	—	—	—	—	—	(11,140 )	—	(11,140 )
Other comprehensive income	—	—	—	—	—	—	38	38
Balance, June 30, 2023	33,336,282	\$ 118,024	875,279	\$ —	\$ 2,656	\$ (64,097 )	\$ (19 )	\$ (61,460 )
Exercise of common stock options	—	—	2,798	1	4	—	—	5
Conversion of convertible preferred stock to common stock in connection with the Reverse Merger	(33,336,282 )	(118,024 )	7,269,183	1	118,023	—	—	118,024
Issuance of common stock and pre-funded warrants in the pre-closing financing, net of issuance costs of \$4,250	—	—	2,873,988	—	67,750	—	—	67,750
Issuance of common stock to former stockholders of Magenta Therapeutics, Inc. in connection with the Reverse Merger	—	—	3,796,514	—	71,595	—	—	71,595
Adjustment for change in common stock par value in connection with the Reverse Merger	—	—	—	13	(13 )	—	—	—
Reverse recapitalization transaction costs	—	—	—	—	(3,964 )	—	—	(3,964 )
Stock-based compensation expense	—	—	—	—	1,179	—	—	1,179
Net loss	—	—	—	—	—	(14,763 )	—	(14,763 )
Other comprehensive income	—	—	—	—	—	—	15	15
Balance, September 30, 2023	—	\$ —	14,817,762	\$ 15	\$ 257,230	\$ (78,860 )	\$ (4 )	\$ 178,381

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



**DIANTHUS THERAPEUTICS, INC.**

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

	Nine Months Ended September 30,	
	2024	2023
<b>Cash flows from operating activities:</b>		
Net loss	\$ (56,529)	\$ (32,992)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	70	47
Stock-based compensation expense	8,976	2,174
Accretion of discount on investment securities	(3,281)	(896)
Amortization of right-of-use operating lease assets	264	205
Gain on investment in related party	(307)	—
Changes in operating assets and liabilities:		
Receivable from related party	(1,096)	4,468
Unbilled receivable from related party	(1,109)	419
Prepaid expenses and other current assets	(428)	2,546
Other assets	(3,111)	10
Accounts payable, accrued expenses and operating lease liabilities	5,911	(942)
Deferred revenue - related party	(96)	(46)
Net cash used in operating activities	(50,736)	(25,007)
<b>Cash flows from investing activities:</b>		
Capital expenditures	(74)	(100)
Purchases of investment securities	(305,628)	(31,195)
Proceeds from maturities of investment securities	42,000	59,785
Net cash (used in)/provided by investing activities	(263,702)	28,490
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of stock options	614	5
Proceeds from the private placement	229,998	—
Payment of issuance costs in connection with the private placement	(14,665)	—
Proceeds from the pre-closing financing	—	72,000
Payment of issuance costs in connection with pre-closing financing	—	(50)
Cash acquired in connection with the reverse recapitalization	—	69,738
Payment of reverse recapitalization transaction costs	—	(3,254)
Proceeds from issuance of promissory notes payable to related party	—	377
Repayment of promissory notes payable to related party	—	(377)
Net cash provided by financing activities	215,947	138,439
(Decrease)/increase in cash, cash equivalents and restricted cash	(98,491)	141,922
Cash, cash equivalents and restricted cash, beginning of period	132,391	15,425
Cash, cash equivalents and restricted cash, end of period	<u>\$ 33,900</u>	<u>\$ 157,347</u>
<b>Supplemental Disclosure</b>		
Cash and cash equivalents	\$ 33,671	\$ 157,282
Restricted cash	229	65
Total cash, cash equivalents and restricted cash	<u>\$ 33,900</u>	<u>\$ 157,347</u>
Issuance costs in connection with pre-closing financing included in accrued expenses	<u>\$ —</u>	<u>\$ 4,200</u>
Transaction costs related to reverse recapitalization included in accounts payable and accrued expenses	<u>\$ —</u>	<u>\$ 710</u>
Conversion of convertible preferred stock into common stock	<u>\$ —</u>	<u>\$ 118,024</u>
Additions to right-of-use lease assets from new operating lease liabilities	<u>\$ —</u>	<u>\$ 89</u>

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

**DIANTHUS THERAPEUTICS, INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
(in thousands, except share and per share data, unless otherwise stated)

**1. Organization, Description of Business and Liquidity**

***Business***

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

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

***Reverse Merger and Pre-Closing Financing***

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

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

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

At the effective time of the Reverse Merger, the 2019 Stock Plan (as discussed in Note 12) was assumed by the Company, and each outstanding and unexercised option to purchase shares of Former Dianthus common stock immediately prior to the effective time of the Reverse Merger was assumed by the Company and converted into an option to purchase shares of Company common stock, with necessary adjustments to the number of shares and exercise price to reflect the exchange ratio, and each outstanding and unexercised warrant to purchase shares of Former Dianthus common stock immediately prior to the effective time of the Reverse Merger (including the Former Dianthus pre-funded warrants sold in the pre-closing financing) was converted into a warrant to purchase shares of Company common stock, with necessary adjustments to the number of shares and exercise price to reflect the exchange ratio.

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

On September 11, 2023, prior to the effective time of the Reverse Merger, the Company entered into a contingent value rights agreement (the "CVR Agreement") with a rights agent, pursuant to which pre-Reverse Merger holders of Magenta common stock received one non-transferable contingent value right (each, a "CVR") for each outstanding share of Magenta common stock held by such stockholder immediately prior to the effective time of the Reverse Merger on September 11, 2023. Subject to, and in accordance with, the terms and conditions of the CVR Agreement, each CVR represents the contractual right to receive a pro rata portion of the proceeds, if any, received by the Company as a result of (i) contingent payments made to the Company, such as milestone, royalty or earnout, when received under any pre-Reverse Merger disposition agreements related to Magenta's pre-Reverse Merger assets and (ii) the Company's sale of assets after the effective date of the Reverse Merger and prior to December 31, 2023, in each case, received within a three-year period following the closing of the Reverse Merger. As of September 30, 2024, no payments have been received under the CVR Agreement.

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

#### **2024 Private Placement**

On January 22, 2024, the Company entered into a securities purchase agreement for a private placement with certain institutional and accredited investors. At the closing of the private placement on January 24, 2024, the Company sold and issued 14,500,500 shares of common stock at a price per share of \$12.00, and pre-funded warrants to purchase 4,666,332 shares of common stock at a purchase price of \$11.999 per pre-funded warrant, which represents the per share purchase price of the common stock less the \$0.001 per share exercise price for each pre-funded warrant, for an aggregate purchase price of approximately \$230 million. The pre-funded warrants are exercisable at any time after the date of issuance. A holder of pre-funded warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. A holder of pre-funded warrants may increase or decrease this percentage to a percentage not in excess of 19.99% by providing at least 61 days' prior notice to the Company.

#### **Risks and Uncertainties**

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

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

## **Liquidity**

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

- Since its inception, the Company has funded its operations primarily with outside capital and has incurred significant recurring losses, including net losses of \$56.5 million and \$33.0 million for the nine months ended September 30, 2024 and 2023, respectively. In addition, the Company had an accumulated deficit of \$146.0 million as of September 30, 2024;
- 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 investments on hand will be sufficient to fund its obligations as they become due for at least twelve months beyond the issuance date. The Company expects that its research and development and general and administrative costs will continue to increase significantly, including in connection with conducting clinical trials and manufacturing for its existing product candidate and any future product candidates to support commercialization and providing general and administrative support for its operations, including the costs associated with operating as a public company.

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

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

## **2. Summary of Significant Accounting Policies**

### ***Basis of Presentation***

The accompanying unaudited condensed consolidated financial statements as of September 30, 2024 and for the nine months ended September 30, 2024 and 2023 have been prepared in conformity with 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 condensed consolidated 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 three and nine months ended September 30, 2024 are not necessarily indicative of the results expected for the full fiscal year or any subsequent interim period. The unaudited condensed consolidated balance sheet as of December 31, 2023 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 condensed consolidated financial statements and the notes accompanying them should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2023, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission ("SEC") on March 21, 2024. 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").

### ***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 unaudited condensed consolidated balance sheets for cash and cash equivalents are valued at cost, which approximates fair value.

#### **Concentration of Credit Risk**

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and 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 investments and management believes the Company is not exposed to significant risks of losses.

As of September 30, 2024 and December 31, 2023, 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 and Long-Term Investments**

Short-term and long-term investments consist of investments in U.S. treasury, U.S. government agency and corporate debt 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 and long-term investments as available-for-sale pursuant to ASC 320, *Investments – Debt and Equity Securities*, and reports them at fair value in short-term or long-term investments with unrealized gains and losses reported as a component of accumulated other comprehensive income/(loss) on the unaudited condensed consolidated balance sheets. 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.

When the fair value is below the amortized cost of a marketable security, an estimate of expected credit losses is made in accordance with ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The credit-related impairment amount is recognized in the unaudited condensed consolidated statements of operations and comprehensive loss. Credit losses are recognized through the use of an allowance for credit losses account in the unaudited condensed consolidated balance sheet and subsequent improvements in expected credit losses are recognized as a reversal of an amount in the allowance account. If the Company has the intent to sell the security or it is more likely than not that the Company will be required to sell the security prior to recovery of its amortized cost basis, then the allowance for the credit loss is written-off and the excess of the amortized cost basis of the asset over its fair value is recorded in the unaudited condensed consolidated statements of operations and comprehensive loss. There were no credit losses recorded during the nine months ended September 30, 2024 or 2023.

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

**Receivable from Related Party and Unbilled Receivable from Related Party**

The receivable from related party and unbilled receivable from related party results from option and license agreements with Zenas BioPharma, Inc. (formerly Zenas BioPharma Limited) ("Zenas"), a related party. See Notes 13 and 16 for more information. The receivable represents amounts earned and billed to Zenas but not yet collected while unbilled receivable represents amounts earned but not yet billed to Zenas. The receivable and unbilled receivable are reported at net realizable value. The Company regularly evaluates the creditworthiness of Zenas and their financial condition and does not require collateral from Zenas. As of September 30, 2024 and December 31, 2023, 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 unaudited condensed consolidated statements of operations and comprehensive loss of the respective period.

**Leases**

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

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

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

**Restricted Cash**

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

**Fair Value Measurements**

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

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

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

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

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

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

Management has segregated all financial assets and liabilities that are measured at fair value on a recurring basis into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date. 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 estimated fair value of receivable from related party, unbilled receivable from related party, accounts payable and accrued expenses approximate their carrying amounts due to the relatively short maturity of these instruments.

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

#### ***Classification of Convertible Preferred Stock***

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

#### ***Segment Information***

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

#### ***License Revenue – Related Party***

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

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

The Company evaluates the performance obligations promised in a contract that are based on goods and services that will be transferred to the customer and determines 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 unaudited condensed consolidated balance sheets. If the related performance obligation is expected to be satisfied within the next twelve months this will be classified in current liabilities.

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

#### **Research and Development Costs**

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

The Company enters into consulting, research, and other agreements with commercial firms, researchers, and others for the provision of goods and services. Under such agreements, the Company may pay for services on a monthly, quarterly, project or other basis. Such arrangements are generally cancelable upon reasonable notice and payment of costs incurred. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided by the service providers and vendors or our estimate of the level of service that has been performed at each reporting date, whereas payments are dictated by the terms of each agreement. As such, depending on the timing of payment relative to the receipt of goods or services, 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 September 30, 2024 and December 31, 2023, 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 unaudited condensed consolidated statements of operations and comprehensive loss based on their fair values. All of the stock-based awards are subject only to service-based vesting conditions. Management estimates the fair value of the stock option awards using the Black-Scholes option pricing model, which requires the input of assumptions, including (a) the fair value of the Company's common stock, (b) the expected stock price volatility, (c) the calculation of expected term of the award, (d) the risk-free interest rate and (e) expected dividends. Management estimates the fair value of the restricted stock awards, if any, using the fair value of the Company's common stock. Forfeitures are recognized as they are incurred.

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

Prior to the Reverse Merger, due to 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 had sufficiently similar economic and industry characteristics and includes companies that are most representative of the Company. Following the Reverse Merger, expected volatility at the date of grant is estimated using a "look-back" period, which coincides with the expected term, of the Company's stock price as reported on the Nasdaq Capital Market.

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

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

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

### **Comprehensive Loss**

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

### **Net Loss per Share**

Basic and diluted net loss per share attributable to common stockholders is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. The weighted average number of shares of common stock outstanding includes the weighted average effect of outstanding pre-funded warrants for the purchase of shares of common stock for which the remaining unfunded exercise price is \$0.001 or less per share.

Basic and diluted net loss per share attributable to common stockholders are calculated in conformity with the two-class method required for participating securities. Convertible preferred stock is a participating security in distributions of the Company. During the three and nine months ended September 30, 2023, the net loss attributable to common stockholders was not allocated to the convertible preferred shares as the holders of convertible preferred shares did not have a contractual obligation to share in losses. Under the two-class method, basic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during each period. During the three and nine months ended September 30, 2023, the weighted-average number of shares of common stock outstanding used in the basic net loss per share calculation did not include unvested restricted common stock as these shares were considered contingently issuable shares until they vested.

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

Additional information is included in Note 14.

### Recently Issued Accounting Pronouncements

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

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

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. The amendments in ASU 2024-03 address investor requests for more detailed expense information and require additional disaggregated disclosures in the notes to financial statements for certain categories of expenses that are included on the face of the income statement. This guidance is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating this guidance to determine the impact it may have on the unaudited condensed consolidated financial statements.

### 3. Reverse Merger

As described in Note 1, Merger Sub merged with and into Former Dianthus, with Former Dianthus surviving as a wholly owned subsidiary of the Company on September 11, 2023. The Reverse Merger was accounted for as a reverse asset acquisition accounted for as a reverse recapitalization in accordance with U.S. GAAP with Former Dianthus as the accounting acquirer of Magenta. At the effective time of the Reverse Merger, substantially all of the assets of Magenta consisted of cash and cash equivalents, marketable securities, as well as other nominal non-operating assets. Under such reverse recapitalization accounting, the assets and liabilities of Magenta were recorded at their fair value in Magenta's financial statements at the effective time of the Reverse Merger, which approximated book value due to the short-term nature. No goodwill or intangible assets were recognized.

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

Cash and cash equivalents	\$	69,738
Other current assets		2,473
Accrued liabilities		(616)
Net assets acquired	\$	<u>71,595</u>

With respect to the CVRs issued in connection with the Reverse Merger, the Company believes that the achievement of the milestones outlined in the CVR Agreement are highly susceptible to factors outside the Company's influence that are not expected to be resolved for a long period of time, if at all. In particular, these amounts are primarily influenced by the actions and judgments of third parties and the buyers of such assets and are based on the buyers of such assets progressing the in-process research and development assets into clinical trials, and in the case of one of the agreements, to a regulatory milestone. If the Company were to record a receivable for such contingent payments, it would also record a corresponding liability. As of September 30, 2024, no receivables are recorded on the unaudited condensed consolidated balance sheet relating to such contingent payments.

#### 4. Short-Term and Long-Term Investments

The following table provides a summary of short-term and long-term investments:

		September 30, 2024			Classification	
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value	Short-term Investments	Long-term Investments
<u>Available-for-sale investments:</u>						
U.S. treasury securities	\$ 250,942	\$ 543	\$ (6)	\$ 251,479	\$ 195,441	\$ 56,038
U.S. government agency securities	1,013	1	—	1,014	1,014	—
Corporate debt securities	56,298	143	—	56,441	50,997	5,444
Total available-for-sale investments	<u>\$ 308,253</u>	<u>\$ 687</u>	<u>\$ (6)</u>	<u>\$ 308,934</u>	<u>\$ 247,452</u>	<u>\$ 61,482</u>
		December 31, 2023			Classification	
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value	Short-term Investments	Long-term Investments
<u>Available-for-sale investments:</u>						
U.S. treasury securities	\$ 36,370	\$ 48	\$ —	\$ 36,418	\$ 36,418	\$ —
U.S. government agency securities	4,976	—	(1)	4,975	4,975	—
Total available-for-sale investments	<u>\$ 41,346</u>	<u>\$ 48</u>	<u>\$ (1)</u>	<u>\$ 41,393</u>	<u>\$ 41,393</u>	<u>\$ —</u>

#### 5. Prepaid Expenses and Other Current Assets

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

	September 30, 2024	December 31, 2023
Prepaid materials, supplies and research and development services	\$ 2,675	\$ 2,155
Prepaid subscriptions, software and other administrative services	958	504
Prepaid insurance	50	596
Prepaid expenses and other current assets	<u>\$ 3,683</u>	<u>\$ 3,255</u>

#### 6. Property and Equipment

The following table provides a summary of property and equipment:

	September 30, 2024	December 31, 2023
Computer equipment	\$ 302	\$ 234
Furniture and fixtures	54	48
Subtotal	356	282
Less: accumulated depreciation	(167)	(97)
Property and equipment, net	<u>\$ 189</u>	<u>\$ 185</u>

Depreciation expense was \$25 thousand and \$70 thousand during the three and nine months ended September 30, 2024, respectively, and \$19 thousand and \$47 thousand during the three and nine months ended September 30, 2023, respectively.

## 7. Fair Value of Financial Instruments

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

Description	Fair Value at September 30, 2024	Level 1	Level 2	Level 3
<b>Recurring Assets:</b>				
Cash equivalents:				
Money market funds	\$ 7,203	\$ 7,203	\$ —	\$ —
U.S. treasury securities	9,965	9,965	—	—
Corporate debt securities	8,905	—	8,905	—
Short-term investments:				
U.S. treasury securities	195,441	195,441	—	—
U.S. government agency securities	1,014	—	1,014	—
Corporate debt securities	50,997	—	50,997	—
Long-term investments:				
U.S. treasury securities	56,038	56,038	—	—
Corporate debt securities	5,444	—	5,444	—
Other assets and restricted cash:				
Investment in related party	307	307	—	—
Total assets measured at fair value	<u>\$ 335,314</u>	<u>\$ 268,954</u>	<u>\$ 66,360</u>	<u>\$ —</u>

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

There were no transfers between levels for the nine months ended September 30, 2024 or for the year ended December 31, 2023.

The weighted-average maturity of the securities held at September 30, 2024 were 12 months or less.

## 8. Accrued Expenses

The following table provides a summary of accrued expenses:

	September 30, 2024	December 31, 2023
Accrued compensation	\$ 4,009	\$ 5,361
Accrued external research and development	2,892	456
Accrued professional fees	353	422
Other accrued expenses	473	265
Accrued expenses	<u>\$ 7,727</u>	<u>\$ 6,504</u>

## 9. Leases

The Company leases space under operating leases for administrative offices in New York, New York, and Waltham, Massachusetts and wet laboratory space in Watertown, Massachusetts.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating lease cost	\$ 104	\$ 88	\$ 310	\$ 263
Variable lease cost	7	7	22	20
Total operating lease costs	<u>\$ 111</u>	<u>\$ 95</u>	<u>\$ 332</u>	<u>\$ 283</u>

The Company recorded operating lease costs of \$0.1 million and \$0.3 million during each of the three and nine months ended September 30, 2024 and 2023, respectively, within the general and administrative expenses line item in the unaudited condensed consolidated statements of operations and comprehensive loss. The Company recorded operating lease costs of \$14 thousand and \$44 thousand during the three and nine months ended September 30, 2024, respectively, and nil during the three and nine months ended September 30, 2023 within the research and development expenses line item in the unaudited condensed consolidated statements of operations and comprehensive loss.

Maturities of operating lease liabilities as of September 30, 2024, are as follows:

2024 (remaining 3 months)	\$ 106
2025	222
Total undiscounted operating lease payments	328
Less: imputed interest	(17)
Present value of operating lease liabilities	<u>\$ 311</u>
<u>Balance sheet classification:</u>	
Current portion of operating lease liabilities	\$ 311
Long-term operating lease liabilities	—
Total operating lease liabilities	<u>\$ 311</u>

The weighted-average remaining term of operating leases was 10 months and the weighted-average discount rate used to measure the present value of operating lease liabilities was 11% as of September 30, 2024.

## 10. Common Stock

At the closing of the private placement on January 24, 2024, the Company issued 14,500,500 shares of common stock and pre-funded warrants to purchase 4,666,332 shares of common stock with a \$0.001 per share exercise price. The pre-funded warrants are exercisable at any time after the date of issuance and will not expire. As of September 30, 2024, there were 4,666,332 pre-funded warrants outstanding related to this private placement.

At the effective time of the Reverse Merger on September 11, 2023, the Company issued an aggregate of 11,021,248 shares of Company common stock to the Former Dianthus stockholders, based on the exchange ratio of approximately 0.2181 shares of Company common stock for each share of Former Dianthus common stock, including those shares of Former Dianthus common stock issued upon the conversion of Former Dianthus preferred stock and those shares of the Former Dianthus common stock issued in the pre-closing financing. In conjunction with the pre-closing financing, the Company also issued pre-funded warrants to purchase 210,320 shares of common stock with a \$0.001 per share exercise price. The pre-funded warrants are exercisable at any time after the date of issuance and will not expire. As of September 30, 2024, there were 210,320 pre-funded warrants outstanding related to this financing.

As of September 30, 2024 and December 31, 2023, the Company was authorized to issue up to 150,000,000 shares of \$0.001 par value of Company common stock. As of September 30, 2024 and December 31, 2023, the Company had issued and outstanding shares of common stock of 29,366,352 and 14,817,696, respectively.

Each share of Company common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the Company's board of directors, if any. No dividends have been declared or paid by the Company through September 30, 2024.

The Company had the following shares of Company common stock reserved for future issuance as of September 30, 2024 and December 31, 2023:

	As of September 30, 2024	As of December 31, 2023
Issuance of common stock upon exercise of stock options	4,499,964	1,749,475
Equity awards available for grant under stock award plans	1,952,204	879,461
Shares available for issuance under the Employee Stock Purchase Plan	99,578	37,078
Issuance of common stock upon exercise of warrants	4,881,329	214,997
Total common stock reserved for future issuance	<u>11,433,075</u>	<u>2,881,011</u>

## 11. Preferred Stock and Convertible Preferred Stock

### *Preferred Stock*

As of September 30, 2024, the Company was authorized to issue up to 10,000,000 shares of preferred stock at a par value of \$0.001. As of September 30, 2024, no shares of preferred stock were issued and outstanding.

### *Convertible Preferred Stock*

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

## 12. Stock-Based Compensation

### *2018 Stock Option and Incentive Plan*

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

The 2018 Incentive Plan provides that the number of shares reserved and available for issuance under the 2018 Incentive Plan will automatically increase each January 1 by 4% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31 (the "Evergreen Provision") or such lesser number of shares as determined by the Company's board of directors or compensation committee of the board of directors. The number of shares reserved for issuance under the 2018 Incentive Plan increased by 592,707 on January 1, 2024. Shares of common stock underlying any awards under the 2018 Incentive Plan, the 2019 Stock Plan and the 2016 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) will be available for future awards under the 2018 Incentive Plan.

On May 23, 2024, the Company's stockholders approved an amendment and restatement of the 2018 Incentive Plan (the "2018 Amended Plan") to:

- provide for an increase in the number of shares of common stock reserved for issuance thereunder by 2,931,820 shares;
- increase the Evergreen Provision (as described above) from 4% to 5% of issued and outstanding shares of common stock on December 31 of the preceding calendar year; and
- extend the expiration date until March 14, 2034.

As of September 30, 2024, 1,860,204 shares of the Company's common stock were available for grant under the 2018 Amended Plan.

The 2018 Amended Plan is administered by either the board of directors or the compensation committee of the board of directors. The exercise prices, vesting and other restrictions are determined at the discretion of the administrator, except that the term of stock options and stock appreciation rights may not be greater than ten years (or five years for certain incentive stock options). Awards typically vest over 12 months to four years. The exercise price for stock options granted may not be less than the fair value of common stock as of the date of grant (or 110% of the fair value of common stock for certain incentive stock options). The fair value of common stock is based on quoted market prices.

### **2019 Stock Plan**

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

### **2019 Employee Stock Purchase Plan**

Employees may elect to participate in the Dianthus Therapeutics, Inc. 2019 Employee Stock Purchase Plan, as amended (the "ESPP"). The purchase price of common stock under the ESPP is equal to 85% of the lower of the fair market value of the common stock on the offering date or the exercise date. The six-month offering periods previously began in December and June of each year. During the nine months ended September 30, 2024 and 2023, there were no shares of common stock purchased under the ESPP. As of September 30, 2024, 99,578 shares remained available for issuance under the ESPP.

The ESPP provides that the number of shares reserved and available for issuance under the ESPP will automatically increase each January 1 through January 1, 2029, by the lesser of (i) 1% of the number of shares issued and outstanding on the immediately preceding December 31, (ii) 62,500 shares and (iii) such number of shares as determined by the Company's board of directors or its appointed administrator. The number of shares reserved for issuance under the ESPP increased by 62,500 on January 1, 2024.

### **Stock Option Inducement Grant and Inducement Plan**

In December 2023, the Company's board of directors granted an option to purchase 96,000 shares of common stock to a new hire as an inducement grant. In February 2024, the Company's board of directors approved the Dianthus Therapeutics, Inc. Equity Inducement Plan (the "Inducement Plan"), which provides for up to 300,000 shares of common stock for inducement awards. As of September 30, 2024, there were 92,000 shares available to be granted under the Inducement Plan.

### Stock Options

The following table summarizes stock option activity for the nine months ended September 30, 2024:

	Number of Stock Options Outstanding	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance at January 1, 2024	1,749,475	\$ 10.61	8.4	\$ 3,181
Options granted, fair value of \$15.91 per share	2,888,000	20.55		20,062
Options exercised	(48,156)	12.60		629
Options forfeited	(89,355)	15.21		1,037
Balance at September 30, 2024	4,499,964	\$ 16.88	8.9	\$ 49,026
Exercisable options at September 30, 2024	1,251,732	\$ 12.82	8.1	\$ 19,657
Unvested options at September 30, 2024	3,248,232	\$ 18.44	9.2	\$ 29,369

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 nine months ended September 30, 2024 was \$15.91 per share.

The table below summarizes the assumptions used to determine the grant-date fair value of stock options issued, presented on a weighted average basis during the three and nine months ended September 30, 2024 and 2023.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Risk-free interest rate	3.7 %	4.3 %	4.2 %	3.9 %
Expected term (in years)	6.0	5.8	6.0	6.0
Expected volatility	92.2 %	91.7 %	92.7 %	86.4 %
Expected dividend yield	0.0 %	0.0 %	0.0 %	0.0 %

### Stock Warrants

In April 2021, Former Dianthus issued 4,677 warrants for the purchase of common stock at an exercise price of \$1.65 per share. The warrants vested on July 30, 2023 and had a grant date fair value of \$1.16 per warrant. As of September 30, 2024, the warrants have a weighted average remaining contractual term of 6.6 years.

### Stock-based Compensation Expense

The following table provides a summary of stock-based compensation expense:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 1,688	\$ 379	\$ 3,877	\$ 711
General and administrative	2,152	800	5,099	1,463
Total stock-based compensation expense	<u>\$ 3,840</u>	<u>\$ 1,179</u>	<u>\$ 8,976</u>	<u>\$ 2,174</u>

As of September 30, 2024, there was \$43.9 million of total unrecognized compensation cost related to granted stock options. The Company expects to recognize that cost over a remaining weighted-average period of 3.2 years.



### 13. License Revenue – Related Party

In September 2020, the Company entered into an Option Agreement with Zenas ("Zenas Option"), a related party (See Note 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 \$1.0 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; (iv) reimbursement of a portion of all non-CMC-related costs and expenses for the development of the first antibody sequence through the first regulatory approval; (v) development milestones totaling up to \$11.0 million; and (vi) royalties on net sales ranging from the mid-single digits to the low teen percentages.

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 September 30, 2024, 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 September 30, 2024, no royalty revenue had been recognized.

The Company recognized related party license revenue totaling \$2.2 million and \$0.9 million for the three months ended September 30, 2024 and 2023, respectively, and \$4.9 million and \$2.4 million for the nine months ended September 30, 2024 and 2023, respectively, associated with the Zenas Agreements. As of September 30, 2024, the Company recorded a related party receivable of \$1.4 million, unbilled related party receivable of \$1.3 million, current deferred related party revenue of \$0.1 million and noncurrent deferred related party revenue of \$0.6 million on its unaudited condensed consolidated balance sheet. As of December 31, 2023, the Company recorded a related party receivable of \$0.3 million, unbilled related party receivable of \$0.2 million, current deferred related party revenue of \$0.1 million and noncurrent deferred related party revenue of \$0.7 million on its unaudited condensed consolidated balance sheet.

#### 14. Net Loss Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net loss	\$ (25,174)	\$ (14,763)	\$ (56,529)	\$ (32,992)
Denominator:				
Weighted-average shares of common stock outstanding including shares issuable under equity-classified pre-funded warrants	34,236,728	3,907,075	32,614,771	1,896,983
Less: weighted-average unvested restricted shares of common stock	—	(189)	—	(378)
Weighted-average shares used to compute net loss per share of common stock, basic and diluted	<u>34,236,728</u>	<u>3,906,886</u>	<u>32,614,771</u>	<u>1,896,605</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.74)</u>	<u>\$ (3.78)</u>	<u>\$ (1.73)</u>	<u>\$ (17.40)</u>

Pre-funded warrants totaling 4,876,652 shares have been included in the computation of basic and diluted net loss per share of common stock for the three and nine months ended September 30, 2024 as the pre-funded warrants are issuable for nominal consideration pursuant to their terms.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Stock options outstanding	4,499,964	1,772,179	4,499,964	1,772,179
Unvested restricted shares of common stock	—	63	—	63
Warrants for the purchase of common stock	4,677	214,997	4,677	214,997
Total	<u>4,504,641</u>	<u>1,987,239</u>	<u>4,504,641</u>	<u>1,987,239</u>

## 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 and \$0.6 million during the three and nine months ended September 30, 2024, respectively, and \$50 thousand and \$0.1 million during the three and nine months ended September 30, 2023, respectively, for amounts owed under the Alloy license agreement within the research and development expenses line item in the unaudited condensed consolidated statements of operations and comprehensive loss.

### ***OmniAb, Inc.***

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

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

Upon the achievement of certain development milestones, the Company is obligated to make additional payments to OmniAb of up to \$12.2 million. Upon the achievement of certain commercial milestones, the Company is obligated to make royalty payments in the low to mid-single digit percentages. The Company recorded \$0.1 million during each of the three and nine months ended September 30, 2024 for amounts owed under the OmniAb license agreement within the research and development expenses line item in the unaudited condensed consolidated statements of operations and comprehensive loss. The Company recorded nil and \$0.2 million during the three and nine months ended September 30, 2023, respectively, for amounts owed under the OmniAb license agreement within the research and development expenses line item in the unaudited condensed consolidated statements of operations and comprehensive loss.

### ***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 \$4.1 million based on the September 30, 2024 exchange rate) and £2.3 million (approximately \$3.1 million based on the September 30, 2024 exchange rate), 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 \$3.3 million based on the September 30, 2024 exchange rate). The Company recorded \$1.0 million and \$2.0 million during the three and nine months ended September 30, 2024, respectively, and \$0.6 million and \$2.0 million during the three and nine months ended September 30, 2023, respectively, for amounts owed under the IONTAS collaborative research license agreement within the research and development expenses line item in the unaudited condensed consolidated statements of operations and comprehensive loss.

#### **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 condensed consolidated financial statements as of September 30, 2024 and December 31, 2023.

#### **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 September 30, 2024 and December 31, 2023, the Company had standing agreements with consultants, contractors or service providers whose terms do not yield material long-term commitments.

### **16. Related Party Transactions**

#### **Zenas BioPharma, Inc.**

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 a member 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 whose investment manager is a member of 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 September 30, 2024, Tellus and affiliated entities owned approximately 5%, and the Fairmount Funds and affiliated entities owned approximately 9% of the Company's outstanding shares. See Note 13 for more information. In connection with these agreements, the Company recognized \$2.2 million and \$0.9 million for the three months ended September 30, 2024 and 2023, respectively, and \$4.9 million and \$2.4 million for the nine months ended September 30, 2024 and 2023, respectively, within the license revenue – related party line item in the unaudited condensed consolidated statements of operations and comprehensive loss. As of September 30, 2024, the Company recorded a related party receivable of \$1.4 million, unbilled related party receivable of \$1.3 million, current deferred related party revenue of \$0.1 million and noncurrent deferred related party revenue of \$0.6 million on its unaudited condensed consolidated balance sheet. As of December 31, 2023, the Company recorded a related party receivable of \$0.3 million, unbilled related party receivable of \$0.2 million, current deferred related party revenue of \$0.1 million and noncurrent deferred related party revenue of \$0.7 million on its unaudited condensed consolidated balance sheet.

In 2020, Zenas issued 156,848 shares of common stock to the Company in exchange for the Zenas Option. Previously, the Company used the measurement alternative as the measurement attribute for accounting for the Zenas common stock which did not require it to assess the fair value of the common stock at each reporting period as the fair value of the Zenas common stock was not readily determinable nor was there a reliable source for observable transactions from which the Company could determine a fair value. On September 12, 2024, Zenas announced the pricing of its initial public offering (the "Zenas IPO") of \$17.00 per share, which also included a 1-for-8.6831 reverse stock split of its capital stock. Upon the Zenas IPO, the fair value of the Zenas common stock was deemed readily determinable and the Company recorded a noncurrent asset of \$0.3 million within other assets and restricted cash on its unaudited condensed consolidated balance sheet. The Company will reassess the fair value of the investment at the end of each reporting period. Any adjustments to the fair value will be recorded as unrealized gains or losses within other income (loss) in the unaudited condensed consolidated statements of operations and comprehensive loss.

#### ***Fairmount Funds***

On March 13, 2023, the Fairmount Funds issued promissory notes in the aggregate principal amount of \$0.4 million to Former Dianthus at an interest rate of 4.5% per annum. On March 15, 2023, Former Dianthus repaid principal and interest in the amount of \$0.4 million to the Fairmount Funds in satisfaction of its obligations under the promissory notes.

#### **17. Subsequent Events**

##### ***Leases***

On October 1, 2024, the Company entered into an amended lease agreement for its offices in Waltham, Massachusetts to extend the term of the lease (the "Waltham Extension"). Pursuant to the Waltham Extension, the lease will expire on January 31, 2026. The aggregate estimated base rent payments due over the Lease Extension Period is approximately \$0.2 million.

On October 29, 2024, the Company entered into a lease agreement for its office in New York, New York to extend the term of the lease (the "New York Extension"). Pursuant to the New York Extension, the lease will now expire on February 28, 2031. The aggregate estimated base rent payments due over the New York Extension is approximately \$1.6 million.

##### ***Shelf Registration Statement and At-the-Market Offering Program***

On October 1, 2024, the Company filed a registration statement with the SEC for the issuance of common stock, preferred stock, warrants, debt securities, rights and units up to an aggregate of \$500.0 million. On October 9, 2024, the registration statement was declared effective by the SEC. The registration statement includes an at-the-market ("ATM") offering program for the sale of up to \$200.0 million of shares of the Company's common stock. The Company has not sold any shares of its common stock or received any proceeds from the ATM offering program as of the date of this report.

##### ***Collaboration Agreement***

On October 21, 2024, Zenas assigned the Zenas Agreements to its affiliated entity, Zenas BioPharma (HK) Limited ("Zenas HK"). After the assignment, the Company entered into a novation agreement (the "Novation Agreement") with Zenas HK and Tenacia Biotechnology (Hong Kong) Co., Limited ("Tenacia"), and an amendment to the License Agreement with Tenacia (the "Tenacia License Agreement"), pursuant to which Tenacia replaced Zenas HK as a party to the Zenas Agreements, and certain economic terms under the License Agreement with respect to cost sharing and development milestones were amended.

The Tenacia License Agreement provides Tenacia 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 identified under the agreement, which has been identified as DNTH103. Under the Zenas Option, as now held by Tenacia pursuant to the Novation Agreement, Tenacia also has the right to exercise an option with respect to a second antibody sequence. If Tenacia exercises the option and pays the Company the option exercise fee related to the second antibody sequence, the Company will grant Tenacia an exclusive license to the sequences and products under this second antibody sequence.

The consideration under the Tenacia License Agreement related to the first antibody sequence includes the following payments by Tenacia to the Company: (i) a \$2.5 million upfront payment upon execution of the Tenacia License Agreement; (ii) reimbursement of a portion of certain clinical costs; (iii) development milestones totaling up to \$15.0 million; and (v) royalties on net sales ranging from the mid-single digits to the low teen percentages. Tenacia is also responsible for paying local development costs in the Tenacia Territory.

The Company will record the accounting impact of the transaction in the fourth quarter of 2024.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements that involve risks and uncertainties, including those described in the section titled "*Special Note Regarding Forward-Looking Statements*" included elsewhere in this Quarterly Report on Form 10-Q. Our actual results and the timing of selected events could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth under the section titled "*Risk Factors*" included elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 21, 2024.

### Overview

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

Our most advanced product candidate, DNTH103, is a clinical-stage, highly potent, highly selective and fully human monoclonal immunoglobulin G4 with picomolar binding affinity that is designed to selectively bind only to the active form of the C1s complement protein, while leaving the lectin and alternative pathways intact. DNTH103 is also engineered withYTE 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. As a result of its more targeted profile, we aim to demonstrate that DNTH103 may have a reduced risk of infections from encapsulated bacteria when compared to C5 terminal inhibitors, thus potentially avoiding a FDA Boxed Warning and associated Risk Evaluation and Mitigation Strategy ("REMS"). The active form of C1s is generated during complement activation by cleavage of the inactive proenzyme C1s. As a validated complement target in the autoimmune and inflammatory field, C1s inhibition prevents further progression of the classical pathway cascade. We believe that DNTH103 has the potential to yield therapeutic benefit in multiple autoimmune and inflammatory disease indications where inappropriate activation of the classical pathway cascade drives or exacerbates the disease pathology by inhibiting the ability of activated C1s to effect downstream complement activity, ameliorating complement mediated cell death and disruption of normal cellular function.

Data reported from DNTH103's Phase 1 clinical trial in 60 healthy volunteers across eight dose cohorts validates the extended half-life and potent classical pathway inhibition and supports a potentially differentiated safety profile of DNTH103. The topline data confirmed its approximately 60-day half-life and highly potent classical pathway inhibition with every two weeks S.C. dosing of 300mg/2mL surpassing the calculated IC90 of 87ug/mL, establishing DNTH103's best-in-class potential to be the first self-administered subcutaneous injection dosed as infrequently as every two weeks to treat a range of autoimmune disorders. Based on the clinical data available to date, DNTH103 was generally well tolerated with no serious adverse events or complement-related infections.

In February 2024, we announced the initiation of our Phase 2 MaGic trial of DNTH103 in patients with generalized Myasthenia Gravis ("gMG"). The initiation followed clearance by the U.S. Food and Drug Administration ("FDA") of the Phase 2 Investigational New Drug ("IND") application for DNTH103. The Phase 2 MaGic trial is a global, randomized, double-blind, placebo-controlled Phase 2 trial in up to 60 patients with gMG who are acetylcholine receptor antibody positive. Following an initial loading dose, DNTH103 will be administered every two weeks via S.C. injection. The S.C. treatment duration will initially be 12 weeks with a 52-week open-label extension. The primary endpoint of the trial is safety and tolerability. Secondary endpoints include Myasthenia Gravis Activities of Daily Living Scale ("MG-ADL") and Quantitative Myasthenia Gravis ("QMg") score assessments. Initial top-line results from this trial are anticipated to be available in the second half of 2025.

In June 2024, we announced clearance of our Phase 2 IND application by the FDA for the MoMeNtum trial of DNTH103 in patients with Multifocal Motor Neuropathy ("MMN"). The MoMeNtum trial is a global, randomized, double-blind, placebo-controlled Phase 2 trial designed to evaluate the safety, tolerability, and efficacy of DNTH103 in 36 patients with MMN. Following determination of immunoglobulin ("Ig") dependency and responsiveness, patients will be randomized to receive a placebo or DNTH103, administered every two weeks via S.C. injection. The initial S.C. treatment duration is expected to be 17 weeks followed by a 52-week open-label extension. The primary endpoint of this trial is safety and tolerability. Secondary endpoints include time to intravenous Ig retreatment, time to relapse, and assessments of muscle and grip strength. Initial top-line results from this trial are anticipated to be available in the second half of 2026.

We plan to initiate a single, two-part (Part A and Part B) Phase 3 trial of DNTH103 in patients with Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP") by the end of 2024. The planned trial will be a global, randomized withdrawal, double-blind, placebo-controlled Phase 3 trial in adult patients with CIDP. In the open-label Part A of this trial, participants will be administered a loading dose followed by 300mg of DNTH103 administered every two weeks via S.C. injection for up to 13 weeks. Part A includes an interim responder analysis of a pre-defined number of participants. Only participants who respond to DNTH103 in Part A will be randomized into Part B, a double-blind, placebo-controlled treatment period of up to 52 weeks, where they will be assessed for prevention of relapse, safety and tolerability, followed by an open-label extension period. We believe this single pivotal trial may support a Biologics License Application ("BLA") filing in adult patients with CIDP. We anticipate providing additional information regarding the Phase 3 trial design and timelines by the end of 2024.

#### **Shelf Registration Statement and ATM Offering Program**

On October 1, 2024, we filed a registration statement with the SEC for the issuance of common stock, preferred stock, warrants, debt securities, rights and units up to an aggregate of \$500.0 million. On October 9, 2024, the registration statement was declared effective by the SEC. The registration statement includes an ATM offering program for the sale of up to \$200.0 million of shares of our common stock.

#### **2024 Private Placement**

On January 22, 2024, in order to provide us with additional capital for our development programs, we entered into a securities purchase agreement for a private placement with certain institutional and accredited investors. At the closing of the private placement on January 24, 2024, we sold and issued 14,500,500 shares of common stock at a price per share of \$12.00, and pre-funded warrants to purchase 4,666,332 shares of common stock at a purchase price of \$11.999 per pre-funded warrant, which represents the per share purchase price of the common stock less the \$0.001 per share exercise price for each pre-funded warrant, for an aggregate purchase price of approximately \$230 million.

#### **Completion of the Reverse Merger and Pre-Closing Financing**

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

Concurrently with the execution and delivery of the Merger Agreement, and in order to provide Former Dianthus with additional capital for its development programs, Former Dianthus entered into a subscription agreement, as amended, with certain investors named therein. Immediately prior to the effective time of the Reverse Merger, Former Dianthus sold and issued 2,873,988 shares of Former Dianthus common stock and 210,320 pre-funded warrants, exercisable for 210,320 shares of Former Dianthus common stock, at a purchase price of approximately \$23.34 per share or \$23.34 per warrant, for an aggregate purchase price of approximately \$72 million (the "pre-closing financing").

See Item 1 of Part I "*Financial Statements—Note 1 – Organization, Description of Business and Liquidity*" for additional information.

## Background

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

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

To date, we have funded our operations primarily with proceeds from the sale of capital stock and have raised aggregate gross proceeds of \$423.5 million from private placements. As of September 30, 2024, we had cash, cash equivalents and investments of \$342.6 million. Based on our current operating plan, we believe that our existing cash, cash equivalents and investments should be sufficient to fund our operations into the second half of 2027. Until we achieve profitability, we plan to fund our operations and capital expenditures with cash on hand and expect to seek to raise any necessary additional capital through private or public equity or debt financings, loans or other capital sources, which could include income from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. There can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us. If we are unable to raise sufficient additional capital, we will be required to seek other alternatives which may include, among others, a delay or termination of our clinical trials or the development of our product candidates, temporary or permanent curtailment of our operations, a sale of our assets, or other alternatives with strategic or financial partners.

We have incurred significant recurring losses. We generated net losses of \$56.5 million and \$33.0 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of \$146.0 million. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on a variety of factors, including the timing, scope and results of our research and development activities. We expect our expenses and capital requirements will increase substantially in connection with our ongoing activities, if and as we:

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



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

## **Global and Macroeconomic Developments**

Uncertainty in the global economy presents significant risks to our business. We are subject to continuing risks and uncertainties in connection with legislative, regulatory, political, geopolitical and macroeconomic developments beyond our control, including inflationary pressures, general economic slowdown or a recession, high interest rates, changes in monetary policy or foreign currency exchange rates, instability in financial institutions, the prospect of a shutdown of the U.S. federal government, the ongoing conflict in Ukraine, conflict in the Middle East, rising tensions between China and Taiwan, the attacks on marine vessels traversing the Red Sea and the responses thereto, pandemics or other public health crises and supply chain disruptions. While we are closely monitoring the impact of the current macroeconomic conditions on all aspects of our business, including the impacts on participants in our clinical trials, employees, suppliers, vendors, business partners and regulators, the ultimate extent of the impact on our business remains highly uncertain and will depend on future developments and factors that continue to evolve. Most of these developments and factors are outside of our control and could exist for an extended period of time. We will continue to evaluate the nature and extent of the potential impacts to Dianthus' business, results of operations, liquidity and capital resources. For additional information, see the section titled “*Risk Factors*” found elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 21, 2024.

## **Components of Results of Operations**

### **Revenue**

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

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

Under the Zenas Agreements, the consideration payable by Zenas BioPharma includes the following: (i) a \$1.0 million upfront payment upon execution of the Zenas License Agreement; (ii) an approximate \$1.1 million payment representing reimbursement for a portion of development costs previously incurred by us; (iii) reimbursement of a portion of costs related to 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"), we determined that there is one combined performance obligation that consists of the license and data transfer, the CMC and non-CMC services and the participation in a joint steering committee, and that the combined performance obligation is satisfied over time. Therefore, we will recognize the transaction price from the license agreement over our estimated period to complete our activities. We concluded that we would utilize a cost-based input method to measure our progress toward completion of our performance obligation and to calculate the corresponding amount of revenue to recognize each period. We believe this is the best measure of progress because other measures do not reflect how we transfer our performance obligation to Zenas BioPharma. In applying the cost-based input method of revenue recognition, we use actual costs incurred relative to budgeted costs expected to be incurred for the combined performance obligation. These costs consist primarily of third-party contract costs. Revenue will be recognized based on the level of costs incurred relative to the total budgeted costs for the performance obligations. A cost-based input method of revenue recognition requires us to make estimates of costs to complete the performance obligation. In making such estimates, judgment is required to evaluate assumptions related to cost estimates.

There is a sales or usage-based royalty exception within ASC 606 that applies when a license of intellectual property is the predominant item to which the royalty relates. In accordance with this royalty exception, we will recognize royalty revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). As of September 30, 2024 and December 31, 2023, no royalty revenue had been recognized.

We also determined that the milestone payments of \$11.0 million are variable consideration under ASC 606, which need to be added to the transaction price when it is probable that a significant revenue reversal will not occur. Based on the nature of the milestones, such as the regulatory approvals which are generally not within our control, we will not consider achievement of this milestone to be probable until the uncertainty associated with such milestone has been resolved. When it is probable that a significant reversal of revenue will not occur, the milestone payment will be added to the transaction price for which we recognize revenue. As of September 30, 2024 and December 31, 2023, no milestones had been achieved.

For the three months ended September 30, 2024 and 2023, we recognized related party license revenue totaling \$2.2 million and \$0.9 million, respectively, associated with the Zenas Agreements. For the nine months ended September 30, 2024 and 2023, we recognized related party license revenue totaling \$4.9 million and \$2.4 million, respectively, associated with the Zenas Agreements.

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

## **Operating Expenses**

### *Research and Development*

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

External expenses include:

- payments to third parties in connection with research and development, including agreements with third parties such as contract research organizations ("CROs"), clinical trial sites and consultants;
- the cost of manufacturing products for use in our clinical trials and preclinical studies, including payments to contract development and manufacturing organizations ("CDMOs") and consultants; and

- payments to third parties in connection with the preclinical development of 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.

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

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

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

- the timing and progress of our preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we pursue;
- our ability to establish a favorable safety profile with IND-enabling toxicology studies to enable clinical trials;
- successful patient enrollment in, and the initiation and completion of, larger and later-stage clinical trials;
- per subject trial costs;
- the number and extent of our clinical trials required for regulatory approval;
- the countries in which our clinical trials are conducted;
- the length of time required to enroll eligible subjects in our clinical trials;
- the number of subjects that participate in our clinical trials;
- the drop-out and discontinuation rate of subjects in our clinical trials;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in our clinical trials and follow-up;
- the extent to which we encounter any serious adverse events in our clinical trials;
- the timing of receipt of regulatory approvals from applicable regulatory authorities;
- the timing, receipt and terms of any marketing approvals and post-marketing approval commitments from applicable regulatory authorities;
- the extent to which we establish collaborations, strategic partnerships, or other strategic arrangements with third parties, if any, and the performance of any such third party;
- hiring and retaining research and development personnel;
- our arrangements with our CDMOs and CROs;

- development and timely delivery of commercial-grade drug formulations that can be used in our planned clinical trials and for commercial launch;
- the impact of any business interruptions to our operations or to those of the third parties with whom we work; and
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights.

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

#### *General and Administrative Expenses*

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

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

#### *Other Income/(Expense)*

Other income/(expense) consists primarily of interest income generated from earnings on invested cash equivalents and investment securities.

#### *Income Tax*

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

## Results of Operations

### Comparison of the Three Months Ended September 30, 2024 and September 30, 2023

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

	Three Months Ended September 30,	
	2024	2023
	(in thousands)	
<b>Revenues:</b>		
License revenue - related party	\$ 2,172	\$ 924
<b>Operating expenses:</b>		
Research and development	25,544	7,960
General and administrative	6,528	8,723
Total operating expenses	32,072	16,683
Loss from operations	(29,900)	(15,759)
Other income/(expense):		
Interest income	4,445	1,027
Gain on investment in related party	307	—
Loss on currency exchange, net	(48)	(16)
Other income/(expense)	22	(15)
Total other income	4,726	996
Net loss	<u>\$ (25,174)</u>	<u>\$ (14,763)</u>

#### License Revenue—Related Party

Under the terms of the Zenas Agreements, we recognized related party license revenue of \$2.2 million and \$0.9 million for the three months ended September 30, 2024 and 2023, respectively. The increase was primarily due to increased clinical operations activity costs associated with the commencement of DNTH103's Phase 2 clinical trials in gMG and MMN in 2024, along with preparations to initiate a Phase 3 clinical trial in CIDP by the end of 2024.

#### Research and Development Expenses

Research and development expenses were \$25.5 million for the three months ended September 30, 2024, as compared to \$8.0 million for the three months ended September 30, 2023, an increase of \$17.5 million. This increase was due to (1) a \$14.0 million increase in external research and development costs, consisting of preclinical study costs, CMC activities, third-party consulting services, clinical operation activities, licensing and milestone payments and discovery activities and (2) a \$3.5 million increase in internal research and development costs, consisting of personnel and related costs and stock-based compensation expense.

The \$14.0 million increase in external research and development costs was due to a \$13.8 million increase in expenses related to our lead product candidate, DNTH103, and a \$0.2 million increase in discovery activities. For the three months ended September 30, 2024, as compared to the three months ended September 30, 2023, there were increases in expenses related to DNTH103 of \$6.8 million in CMC activities, \$5.8 million in clinical operations activities, \$0.9 million in preclinical study costs and \$0.4 million in licensing and milestone payments, which were partially offset by a decrease of \$0.1 million in third-party consulting services related to DNTH103. The increased DNTH103-related costs in CMC activities, clinical operations, preclinical study costs and licensing and milestone payments were primarily due to activities related to the commencement of DNTH103's Phase 2 clinical trials in gMG and MMN in 2024, along with preparations to initiate a Phase 3 clinical trial in CIDP by the end of 2024. The \$0.2 million increase in expenses related to our discovery activities was due to development activities of potential molecules beyond DNTH103 in the three months ended September 30, 2024.

The \$3.5 million increase in internal research and development costs was due to a \$2.2 million increase in personnel and related costs and a \$1.3 million increase in stock-based compensation expense. The increases were due to the buildout of our internal research and development function to support our ongoing and planned Phase 2 and Phase 3 clinical trials.

### General and Administrative Expenses

General and administrative expenses were \$6.5 million for the three months ended September 30, 2024, as compared to \$8.7 million for the three months ended September 30, 2023, a decrease of \$2.2 million. The decrease in general and administrative expenses was primarily due to decreases of \$3.4 million in personnel-related costs related to severance costs to former employees of Magenta in the prior period and \$1.1 million in director and officer insurance costs related to the Reverse Merger in the prior period. These decreases were partially offset by increases of \$1.4 million in stock-based compensation expense, \$0.7 million in professional services costs and \$0.2 million in facilities costs as we continue to build out our general and administrative function to support our operations as a public company and to support our ongoing and planned Phase 2 and Phase 3 clinical trials.

### Other Income/(Expense)

Other income was \$4.7 million for the three months ended September 30, 2024, as compared to \$1.0 million for the three months ended September 30, 2023, an increase of \$3.7 million. The increase was primarily due to an increase of \$3.4 million in interest income from a larger investment balance and higher interest rates on investments and a \$0.3 million gain on an investment in a related party.

### Comparison of the Nine Months Ended September 30, 2024 and September 30, 2023

The following table summarizes our results of operations for the periods indicated:

	Nine Months Ended September 30,	
	2024	2023
	(in thousands)	
<b>Revenues:</b>		
License revenue - related party	\$ 4,909	\$ 2,369
<b>Operating expenses:</b>		
Research and development	56,692	24,060
General and administrative	18,165	13,527
Total operating expenses	74,857	37,587
Loss from operations	(69,948)	(35,218)
<b>Other income/(expense):</b>		
Interest income	13,375	2,320
Gain on investment in related party	307	—
Loss on currency exchange, net	(91)	(53)
Other income/(expense)	(172)	(41)
Total other income	13,419	2,226
Net loss	<u>\$ (56,529)</u>	<u>\$ (32,992)</u>

### License Revenue—Related Party

Under the terms of the Zenas Agreements, we recognized related party license revenue of \$4.9 million and \$2.4 million for the nine months ended September 30, 2024 and 2023, respectively. The increase was primarily due to increased clinical operations activity costs associated with the commencement of DNTH103's Phase 2 clinical trials in gMG and MMN in 2024, along with preparations to initiate a Phase 3 clinical trial in CIDP by the end of 2024.

### Research and Development Expenses

Research and development expenses were \$56.7 million for the nine months ended September 30, 2024, as compared to \$24.1 million for the nine months ended September 30, 2023, an increase of \$32.6 million. This increase was due to (1) a \$23.7 million increase in external research and development costs, consisting of preclinical study costs, CMC activities, third-party consulting services, clinical operation activities, licensing and milestone payments and discovery activities and (2) a \$8.9 million increase in internal research and development costs, consisting of personnel and related costs, stock-based compensation expense, and other costs.

The \$23.7 million increase in external research and development costs was due to a \$23.5 million increase in expenses related to our lead product candidate, DNTH103, and a \$0.2 million increase in expenses related to our discovery activities. For the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023, there were increases in expenses related to DNTH103 of \$11.9 million in clinical operations activities, \$9.9 million in CMC activities, \$0.9 million in licensing and milestone payments, \$0.5 million in third-party consulting services and \$0.3 million in preclinical study costs related to DNTH103. The increased DNTH103-related costs in clinical operations, CMC activities, licensing and milestone payments, third-party consulting services and preclinical study costs were primarily due to activities related to the commencement of DNTH103's Phase 2 clinical trials in gMG and MMN in 2024, along with preparations to initiate a Phase 3 clinical trial in CIDP by the end of 2024. The \$0.2 million increase in expenses related to our discovery activities was due to development activities of potential molecules beyond DNTH103 in the nine months ended September 30, 2024.

The \$8.9 million increase in internal research and development costs was due to a \$5.2 million increase in personnel and related costs, a \$3.2 million increase in stock-based compensation expense and a \$0.5 million increase in other costs. The increases were due to the buildout of our internal research and development function to support our ongoing and planned Phase 2 and Phase 3 clinical trials.

#### *General and Administrative Expenses*

General and administrative expenses were \$18.2 million for the nine months ended September 30, 2024, as compared to \$13.5 million for the nine months ended September 30, 2023, an increase of \$4.7 million. The increase was primarily due to increases of \$3.6 million in stock-based compensation expense, \$1.8 million in professional services costs, \$1.0 million in third-party consulting services costs and \$0.3 million in facilities costs. The increases in costs were due to the buildout of our general and administrative function to support our operations as a public company and to support our ongoing and planned Phase 2 and Phase 3 clinical trials. These increases were partially offset by decreases of \$1.7 million in personnel-related costs related to severance costs to former employees of Magenta in the prior period and \$0.3 million in other costs related to the Reverse Merger in the prior period.

#### *Other Income/(Expense)*

Other income was \$13.4 million for the nine months ended September 30, 2024, as compared to \$2.2 million for the nine months ended September 30, 2023, an increase of \$11.2 million. The increase was primarily due to an increase of \$11.1 million in interest income from a larger investment balance and higher interest rates on investments and a \$0.3 million gain on an investment in a related party, partially offset by an increase in other expenses of \$0.2 million.

### **Liquidity and Capital Resources**

#### ***Sources of Liquidity***

Since inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from operations. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of our lead product candidate, DNTH103, or any future product candidates. We expect that our research and development and general and administrative costs will continue to increase significantly, including in connection with conducting clinical trials and manufacturing for our lead product candidate or any future product candidates to support potential future commercialization and providing general and administrative support for our operations, including the costs associated with operating as a public company. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources. See the section titled "Risk Factors" found elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 21, 2024 for additional risks associated with our substantial capital requirements.

We have an open market sales agreement with TD Securities (USA) LLC ("TD Cowen") (the "ATM Agreement") pursuant to which, we may sell from time to time, through TD Cowen, shares of our common stock for an aggregate sales price of up to \$200 million. Any sales of our common stock pursuant to the ATM Agreement are made under our registration statement on Form S-3 which was deemed effective by the SEC on October 9, 2024. We have not sold any shares of our common stock or received any proceeds from the ATM offering program as of the date of this report.

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

## Future Capital Requirements

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

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

To date, we have funded our operations primarily with proceeds from the sale of capital stock and have raised aggregate gross proceeds of \$423.5 million. However, we have incurred significant recurring losses. We had an accumulated deficit of \$146.0 million as of September 30, 2024. As of September 30, 2024, we had cash, cash equivalents and investments of \$342.6 million. Based on our current operating plan, we believe that our existing cash, cash equivalents and investments should be sufficient to fund our operations into the second half of 2027. Until we achieve profitability, we plan to fund our operations and capital expenditures with cash on hand and expect to seek to raise any necessary additional capital through private or public equity or debt financings, loans or other capital sources, which could include income from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. There can be no assurance that we will be successful in raising additional capital or that such capital, if available, will be on terms that are acceptable to us. Our failure to obtain sufficient capital on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to seek other alternatives which may include, among others, a delay or termination of our clinical trials or the development of our product candidates, temporary or permanent curtailment of our operations, a sale of our assets, or other alternatives with strategic or financial partners.

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

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

- the scope, timing, progress, results, and costs of researching and developing DNTH103, and conducting larger and later-stage clinical trials;
- the scope, timing, progress, results, and costs of researching and developing other future product candidates that we may pursue;
- the costs, timing, and outcome of regulatory review of our product candidates;



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

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

### Cash Flows

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

	Nine Months Ended September 30,	
	2024	2023
	(in thousands)	
Net cash used in operating activities	\$ (50,736)	\$ (25,007)
Net cash (used in)/provided by investing activities	(263,702)	28,490
Net cash provided by financing activities	215,947	138,439
(Decrease)/increase in cash, cash equivalents and restricted cash	<u>\$ (98,491)</u>	<u>\$ 141,922</u>

### Cash Flows from Operating Activities

For the nine months ended September 30, 2024, net cash used in operating activities consisted of a net loss of \$56.5 million, partially offset by a decrease in net operating assets and liabilities of \$0.1 million and net non-cash operating expenses of \$5.7 million. The decrease in net operating assets and liabilities was primarily attributable to an increase in accounts payable, accrued expenses and operating lease liabilities of \$5.9 million, partially offset by increases in other assets of \$3.1 million, unbilled receivable from Zenas BioPharma of \$1.1 million, receivable from Zenas BioPharma of \$1.1 million and prepaid expenses and other current assets of \$0.4 million and a decrease in deferred revenue of \$0.1 million. The non-cash operating expenses consisted primarily of stock-based compensation expense of \$9.0 million and amortization of right-of-use operating lease assets of \$0.3 million, partially offset by accretion of discount on investment securities of \$3.3 million and a gain on an investment in related party of \$0.3 million.

For the nine months ended September 30, 2023, net cash used in operating activities consisted of a net loss of \$33.0 million, partially offset by a decrease in net operating assets and liabilities of \$6.5 million and net non-cash operating expenses of \$1.5 million. The decrease in net operating assets and liabilities was primarily attributable to decreases in receivable from Zenas BioPharma of \$4.5 million, unbilled receivable from Zenas BioPharma of \$0.4 million and prepaid expenses and other current assets of \$2.5 million, partially offset by a decrease in accounts payable, accrued expenses and lease liabilities of \$0.9 million. The non-cash operating expenses consisted primarily of stock-based compensation expense of \$2.2 million and amortization of right-of-use lease assets of \$0.2 million, partially offset by accretion of discount on investment securities of \$0.9 million.

### Cash Flows from Investing Activities

For the nine months ended September 30, 2024, net cash used in investing activities consisted primarily of \$305.6 million of purchases of investment securities, partially offset by \$42.0 million of proceeds from maturities of investment securities.

For the nine months ended September 30, 2023, net cash provided by investing activities consisted primarily of \$59.8 million of proceeds from maturities of investment securities, partially offset by \$31.2 million of purchases of investment securities.

#### *Cash Flows from Financing Activities*

For the nine months ended September 30, 2024, net cash provided by financing activities consisted of \$215.3 million of net proceeds from the private placement and \$0.6 million of proceeds from the exercise of stock options.

For the nine months ended September 30, 2023, net cash provided by financing activities primarily consisted of proceeds of \$72.0 million from the sale of shares of Former Dianthus common stock in the pre-closing financing and net cash acquired in connection with the reverse recapitalization of \$69.7 million, partially offset by \$3.3 million of reverse recapitalization transactions costs.

#### **Contractual Obligations and Commitments**

##### *Lease Obligations*

We lease space under operating leases agreements for administrative offices in New York, New York, and Waltham, Massachusetts and wet laboratory space in Watertown, Massachusetts, which expire in February 2031, January 2026 and August 2025, respectively.

##### *Research and Development and Manufacturing Agreements*

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

##### *License and Collaboration Agreements*

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

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

In July 2020, Former Dianthus entered into a collaborative research agreement with IONTAS Limited ("IONTAS") to perform certain milestone-based research and development activities under our first development program. The agreement was amended in January 2023 to extend services to additional development programs. We are obligated to pay development and commercial milestone payments of up to £5.4 million (approximately \$7.2 million based on the September 30, 2024 exchange rate) with the first development program and of up to £2.5 million (approximately \$3.3 million based on the September 30, 2024 exchange rate) with the second development program.

## **Critical Accounting Policies and Estimates**

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States of America ("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 our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate estimates and assumptions on a periodic basis. Our actual results may differ materially from these estimates.

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

### ***Research and Development Expenses***

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

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

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

### ***Stock-Based Compensation***

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

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

Prior to the Reverse Merger, due to a lack of company-specific historical and implied volatility data, we based our estimate of expected volatility on the historical volatility of a representative group of companies with similar characteristics to us, including stage of product development and life science industry focus. We believe the group selected had sufficiently similar economic and industry characteristics and includes companies that were most representative of us. Following the Reverse Merger, expected volatility at the date of grant is estimated using a "look-back" period, which coincides with the expected term, of our stock price as reported on the Nasdaq Capital Market.

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

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

### **Revenue Recognition—Zenas Agreements**

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

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

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

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

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

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

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

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

### **Item 4. Controls and Procedures.**

#### ***Management's Evaluation of Disclosure Controls and Procedures***

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2024. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, due to the previously identified material weaknesses described below, our disclosure controls and procedures were not effective as of September 30, 2024. A material weakness (as defined in Rule 12b-2 under the Exchange Act) is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

As previously disclosed in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, filed with the SEC on November 9, 2023, we previously identified material weaknesses in our internal control over financial reporting related to: (a) our general segregation of duties, including the review and approval of journal entries as well as system access that was not designed to allow for effective segregation of duties, which limits our ability to perform sufficient reviews and approve journal entries posted to the general ledger and to consistently execute review procedures over general ledger account reconciliations, financial statement preparation and accounting for vendor and payroll transactions; and (b) our accounting software system, which has certain system limitations, including limited user access controls and change management controls, which limits our ability to ensure appropriate authorization and segregation of duties when processing transactions. We have concluded that these material weaknesses in our internal control over financial reporting are due to the fact that we have limited resources and do not have the necessary business processes and related internal controls formally designed and implemented coupled with the appropriate resources to oversee our business processes and controls. These material weaknesses did not result in any identified material misstatements to the financial statements, and there were no changes to previously released financial results. However, the deficiencies created a reasonable possibility that material misstatements to the unaudited condensed consolidated financial statements would not be prevented or detected on a timely basis.

Management has analyzed the material weaknesses and performed additional analysis and procedures in preparing our unaudited condensed consolidated financial statements. We have concluded that our unaudited condensed consolidated financial statements fairly present, in all material respects, our financial condition, results of operations and cash flows at and for the periods presented.

#### ***Remediation Efforts to Address Material Weaknesses***

We are in the process of implementing measures designed to improve our internal control over financial reporting to remediate the material weaknesses identified above. Our planned remediation actions include the following:

- Formalizing our internal control documentation and strengthening supervisory reviews by our management;
- Adding additional accounting personnel and segregating duties among accounting personnel; and
- Implementing new applications and systems that focus on creating strong internal controls, including user access controls and defined approval processes for the posting of journal entries and recording of vendor invoices, payments of expenses, payroll processing and general ledger maintenance.

We are currently working to improve our internal processes and implement enhanced controls, as described above, to address the material weaknesses in our internal control over financial reporting and to remedy the ineffectiveness of our disclosure controls and procedures. These material weaknesses will not be considered to be remediated until the applicable controls have operated for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. We are committed to continuing to improve our internal control processes, and, as we continue to evaluate and work to improve our internal control over financial reporting, we may take additional measures to address control deficiencies, or we may modify certain of the remediation measures described above.

***Changes in Internal Control over Financial Reporting***

There have been no changes in our internal control over financial reporting during the quarter ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings.

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

### Item 1A. Risk Factors.

You should carefully consider the risks, uncertainties and other factors contained in the risks factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023, as well as the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and related notes and the section titled “*Management's Discussion and Analysis of Financial Condition and Results of Operations*,” and in our other public filings, in evaluating our business. The occurrence of any of the events or developments described in the above-mentioned risk factors could materially harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline. Additional risks, uncertainties and other factors not presently known to us or that we currently deem immaterial also may harm our business, financial condition, results of operations and growth prospects.



**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

***Recent Sales of Unregistered Equity Securities***

There were no sales of unregistered equity securities during the quarter ended September 30, 2024.

***Issuer Purchases of Equity Securities***

We did not repurchase any of our equity securities during the quarter ended September 30, 2024.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

(c) *Trading Plans*. During the quarter ended September 30, 2024, no director or Section 16 officer adopted or terminated any Rule 10b5-1 trading arrangements or non-Rule 10b5-1 trading arrangements (in each case, as defined in Item 408(a) of Regulation S-K).

## Item 6. Exhibits.

Exhibit Number	Description
2.1†	<a href="#"><u>Agreement and Plan of Merger, dated as of May 2, 2023, by and among Magenta Therapeutics, Inc., Dio Merger Sub, Inc. and Dianthus Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed with the SEC on May 3, 2023).</u></a>
3.1	<a href="#"><u>Fifth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on September 12, 2023).</u></a>
3.2	<a href="#"><u>Third Amended and Restated By-laws (incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 21, 2024).</u></a>
4.1	<a href="#"><u>Form of Pre-Funded Warrant of Dianthus Therapeutics, Inc. (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on January 22, 2024).</u></a>
4.2	<a href="#"><u>Registration Rights Agreement, dated January 22, 2024, by and among Dianthus Therapeutics, Inc. and certain parties thereto (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on January 22, 2024).</u></a>
31.1*	<a href="#"><u>Principal Executive Officer Certification Pursuant to Rules 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
31.2*	<a href="#"><u>Principal Financial Officer Certification Pursuant to Rules 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
32.1**	<a href="#"><u>Certifications Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

\* Filed herewith.

\*\* Furnished herewith. The certifications on Exhibit 32.1 hereto are deemed not "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section. Such certifications will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

† The annexes, schedules and certain exhibits to the Merger Agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Dianthus Therapeutics, Inc. hereby agrees to furnish supplementally a copy of any omitted annex, schedule or exhibit to the SEC upon request.

# Management contract or compensatory plan or arrangement.

## 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 thereunto duly authorized.

DIANTHUS THERAPEUTICS, INC.

Date: November 7, 2024

By: /s/ Marino Garcia  
Name: Marino Garcia  
Title: President and Chief Executive Officer  
(Principal Executive Officer)

DIANTHUS THERAPEUTICS, INC.

Date: November 7, 2024

By: /s/ Ryan Savitz  
Name: Ryan Savitz  
Title: Chief Financial Officer and Chief Business Officer  
(Principal Financial Officer)

PRINCIPAL EXECUTIVE OFFICER CERTIFICATION PURSUANT TO RULES 13a-14(a) OR 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT  
OF 1934, AS ADOPTED PURSUANT TO SECTION 302  
OF THE SARBANES-OXLEY ACT OF 2002

I, Marino Garcia, certify that:

1. I have reviewed this report on Form 10-Q of Dianthus Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2024

By: /s/ Marino Garcia  
Marino Garcia  
President and Chief Executive Officer  
(Principal Executive Officer)

PRINCIPAL FINANCIAL OFFICER CERTIFICATION PURSUANT TO RULES 13a-14(a) OR 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT  
OF 1934, AS ADOPTED PURSUANT TO SECTION 302  
OF THE SARBANES-OXLEY ACT OF 2002

I, Ryan Savitz, certify that:

1. I have reviewed this report on Form 10-Q of Dianthus Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2024

By: /s/ Ryan Savitz  
Ryan Savitz  
Chief Financial Officer and Chief Business Officer  
(Principal Financial Officer)

CERTIFICATIONS PURSUANT TO 18 U.S.C.  
SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906  
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Dianthus Therapeutics, Inc. (the "Company") on Form 10-Q for the three months ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Marino Garcia, President and Chief Executive Officer of the Company, and Ryan Savitz, Chief Financial Officer and Chief Business Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to our knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2024

By: /s/ Marino Garcia  
Marino Garcia  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: November 7, 2024

By: /s/ Ryan Savitz  
Ryan Savitz  
Chief Financial Officer and Chief Business Officer  
(Principal Financial Officer)

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