Dianthus Therapeutics Highlights Recent Business Achievements and Third Quarter 2023 Financial Results

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Began trading on Nasdaq under the ticker symbol DNTH following the successful completion of our merger with Magenta Therapeutics

Completed concurrent $72 million financing with a syndicate of leading life-science investors

Announced positive top-line Phase 1 data for lead clinical program, DNTH103, confirming potent classical complement pathway inhibition, extended half-life, and a potentially differentiated safety profile

On track to advance DNTH103 into Phase 2 trials targeting multiple neuromuscular indications in 2024, starting with generalized Myasthenia Gravis in Q1 2024

Robust balance sheet, closing the quarter with over $189 million of cash runway expected to fund operations into Q2 2026

NEW YORK and WALTHAM, Mass., Nov. 09, 2023 (GLOBE NEWSWIRE) -- Dianthus Therapeutics, Inc. (Nasdaq: DNTH), a clinical-stage biotechnology company dedicated to advancing the next generation of antibody complement therapeutics to treat severe autoimmune diseases, today reported financial results for the third quarter ending September 30, 2023 and provided an update on recent business achievements.

“This was a landmark quarter of progress and momentum for Dianthus, marked by the positive top-line results for our lead clinical program, DNTH103, validating its best-in-class potential as well as our exciting transition to the public markets with a robust balance sheet,” said Marino Garcia, President and Chief Executive Officer of Dianthus Therapeutics. “As we look ahead, we remain on track to progress DNTH103 into Phase 2 trials for multiple neuromuscular indications where we have the potential to develop a new standard of care, beginning with generalized Myasthenia Gravis in the first quarter of 2024, followed by Multifocal Motor Neuropathy and Chronic Inflammatory Demyelinating Polyneuropathy. We’re particularly energized by the high level of engagement and interest we’ve seen from leading clinicians and investigators globally due to DNTH103’s potentially differentiated profile as a potent active C1s inhibitor with infrequent, subcutaneous self-administration. We are encouraged by the potential of DNTH103 to address both the disease and treatment burdens that disrupt the lives of patients suffering from severe autoimmune diseases, and we look forward to providing updates on our progress in the coming months.”

Recent Business Highlights and Upcoming Milestones

DNTH103
DNTH103 is an investigational, potent monoclonal antibody designed to selectively target the active form of the C1s protein, a clinically validated complement target within the classical pathway. Selective inhibition of the classical complement pathway may lower patient risk of infection from encapsulated bacteria by preserving immune activity of the lectin and alternative pathways. Engineered with validated YTE half-life extension technology, DNTH103 is intended to be the first subcutaneous complement therapy that can be self-administered as infrequently as once every two weeks for a range of severe, classical pathway-driven autoimmune disorders, beginning with generalized Myasthenia Gravis (gMG), Multifocal Motor Neuropathy (MMN), and Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).

- Top-line Phase 1 data across seven single and multiple ascending dose cohorts with 52 healthy volunteers establish DNTH103’s best-in-class potential. Results confirmed:
  - Approximately 60-day half-life and highly potent classical pathway inhibition
  - A potentially differentiated safety profile, with no serious adverse events or complement-related infections
- In a well-established, functional in vitro AChR-positive model of gMG disease, DNTH103 improved neurotransmission and muscle contraction, providing further scientific rationale and support for targeting the classical pathway with DNTH103 in AChR-positive gMG patients.
- Dianthus intends to initiate Phase 2 trials of DNTH103 for gMG in the first quarter of 2024, followed by MMN in the first half of 2024 and CIDP in the second half of 2024.

Corporate

- Successfully completed merger with Magenta Therapeutics and began trading on Nasdaq under the new ticker symbol “DNTH” with over $189 million of cash runway expected to fund operations into Q2 2026.
- Concurrent with the closing of the merger, completed a $72 million private investment in

common stock and pre-funded warrants from a syndicate of healthcare investors led by Fidelity Management & Research Company, Catalio Capital Management, 5AM Ventures, Avidity Partners, Wedbush Healthcare Partners and founding investors Fairmount, Tellus BioVentures and Venrock Healthcare Capital Partners.
- Further strengthened Board of Directors with appointments of Alison Lawton and Anne McGeorge.

Third Quarter Financial Results

- Cash, cash equivalents, and investments totaled $189.9 million on September 30, 2023.
- Research and development expenses for the quarter ended September 30, 2023 were $8.0 million, inclusive of $0.4 million of stock-based compensation.
- General and administrative expenses for the quarter ended September 30, 2023 were $8.7 million, inclusive of severance costs for legacy Magenta employees of $4.0 million and stock-based compensation of $0.8 million.
- Net loss for the quarter ended September 30, 2023 was $14.8 million or $3.78 net loss per share (basic and diluted).
- For additional information on the Company's financial results for the quarter ended September 30, 2023, please refer to the Form 10-Q filed with the SEC.

About DNTH103
DNTH103 is an investigational, long-acting monoclonal antibody designed to selectively target the active form of the C1s protein, a clinically validated complement target within the classical pathway. DNTH103 is enhanced with YTE half-life extension technology designed to enable a more convenient subcutaneous, self-administered injection dosed as infrequently as once every two weeks. Additionally, selective inhibition of the classical complement pathway may lower patient risk of infection from encapsulated bacteria by preserving immune activity of the lectin and alternative pathways. As the classical pathway plays a significant role in disease pathology, DNTH103 has the potential to be a best-in-class pipeline-in-a-product across a range of autoimmune disorders with high unmet need. Dianthus plans to initiate Phase 2 trials in multiple neuromuscular indications in 2024, starting with generalized Myasthenia Gravis in the first quarter of 2024.

About Dianthus Therapeutics
Dianthus Therapeutics is a clinical-stage biotechnology company dedicated to designing and delivering novel, best-in-class monoclonal antibodies with improved selectivity and potency. Based in New York City and Waltham, Mass., Dianthus is comprised of an experienced team of biotech and pharma executives who are leading the development of next-generation antibody complement therapeutics, aiming to deliver transformative medicines for people living with severe autoimmune and inflammatory diseases. To learn more, please visit www.dianthustx.com and follow us on LinkedIn.

Cautionary Statement Regarding Forward-Looking Statements
Certain statements in this press release, other than purely historical information, may constitute "forward-looking statements" within the meaning of the federal securities laws, including for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995, express or implied statements regarding future plans and prospects, including statements regarding the expectations or plans for discovery, preclinical studies, clinical trials and research and development programs, in particular with respect to DNTH103, and any developments or results in connection therewith, including the target product profile of DNTH103; the anticipated timing of the results from those studies and trials; expectations regarding the time period over which the Company's capital resources are expected to be sufficient to fund its anticipated operations; and expectations regarding the market and potential opportunities for complement therapies, in particular with respect to DNTH103. The words "opportunity," "potential," "milestones," "runway," "will," "anticipate," "achieve," "near-term," "catalysts," "pursue," "pipeline," "believe," continue," "could," "estimate," "expect," " intend," "may," "might," "plan," "possible," "predict," "project," " should," "strive," "would," "aim," "target," "commit," and similar expressions (including the negatives of these terms or variations of them) generally identify forward-looking statements, but the absence of these words does not mean that statement is not forward looking.

Actual results could differ materially from those included in the forward-looking statements due to various factors, risks and uncertainties, including, but not limited to, that preclinical testing of DNTH103 and data from clinical trials may not be predictive of the results or success of ongoing or later clinical trials, that the development of DNTH103 or the Company's other compounds may take longer and/or cost more than planned, that the Company may be unable to successfully complete the clinical development of the Company's compounds, that the Company may be delayed in initiating, enrolling or completing its planned clinical trials, and that the Company's compounds may not receive regulatory approval or become commercially successful products. These and other risks and uncertainties are identified under the heading "Risk Factors" included in Exhibit 99.1 to the Company's Form 8-K/A filed on September 21, 2023, and other filings that the Company has made and may make with the SEC in the future. Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved.

The forward-looking statements in this press release speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. Dianthus undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

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Dianthus Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)
(unaudited)

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 157,282	$ 15,365
Short-term investments	32,588	60,125
Receivable from related party	232	4,700
Unbilled receivable from related party	519	938
Prepaid expenses and other current assets	832	905
Total current assets	191,453	82,033
Property and equipment, net	195	142
Right-of-use lease assets	698	814
Other assets and restricted cash	116	121
Total assets	$ 192,462	$ 83,110
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY/(DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,369	$ 1,167
Accrued expenses	11,197	6,608
Current portion of deferred revenue – related party	100	100
Current portion of lease liabilities	413	350
Total current liabilities	13,079	8,225
Deferred revenue – related party	745	791
Long-term lease liabilities	257	438
Total liabilities	14,081	9,454
Commitments and contingencies		
Convertible preferred stock	-	118,024
Stockholders' equity/(deficit):		
Preferred stock	-	-
Common stock	15	-
Additional paid-in capital	257,230	1,661
Accumulated deficit	(78,860)	(45,868)
Accumulated other comprehensive loss	(4)	(161)
Total stockholders' equity/(deficit)	178,381	(44,368)
Total liabilities and stockholders' equity/(deficit)	$ 192,462	$ 83,110

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,	
	2023	2022	2023	2022
Revenues:				
License revenue – related party	$ 924	$ 1,173	$ 2,369	$ 5,242
Operating expenses:				
Research and development	7,960	7,218	24,060	19,548
General and administrative	8,723	2,209	13,527	4,706
Total operating expenses	16,683	9,427	37,587	24,254
Loss from operations	(15,759)	(8,254)	(35,218)	(19,012)
Other income/(expense):				
Interest income	1,027	416	2,320	505
(Loss)/gain on currency exchange, net	(16)	56	(53)	156
Other expense	(15)	(2)	(41)	(9)
Total other income	996	470	2,226	652

Net loss	$ (14,763)	$ (7,784)	$ (32,992)	$ (18,360)
Net loss per share attributable to common stockholders, basic and diluted	$ (3.78)	$ (8.90)	$ (17.40)	$ (21.00)
Weighted-average number of common shares outstanding used in computing net loss per common share, basic and diluted	3,906,886	874,327	1,896,605	874,138
Comprehensive loss:				
Net Loss	$ (14,763)	$ (7,784)	$ (32,992)	$ (18,360)
Other comprehensive income/(loss):				
Change in unrealized losses related to available-for-sale debt securities	15	(150)	157	(150)
Total other comprehensive income/(loss)	15	(150)	157	(150)
Total comprehensive loss	$ (14,748)	$ (7,934)	$ (32,835)	$ (18,510)