Dianthus Therapeutics Highlights Recent Business Achievements and Reports Q1 Financial Results

May 12, 2025

Completed enrollment in Phase 2 MaGic trial of DNTH103 in generalized Myasthenia Gravis (gMG)

Top-line MaGic results anticipated in September 2025 to be the first of three catalysts for the DNTH103 neuromuscular franchise by YE'26

Phase 3 CAPTIVATE trial of DNTH103 in Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) ongoing; interim responder analysis anticipated in 2H'26

Phase 2 MoMeNtum trial of DNTH103 in Multifocal Motor Neuropathy (MMN) ongoing; top-line results anticipated in 2H'26

$331.5 million of cash provides runway into 2H'27

NEW YORK and WALTHAM, Mass., May 12, 2025 (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 first quarter ending March 31, 2025, and provided an update on recent business achievements.

"The first few months of 2025 represent continued excellence in execution by the Dianthus team, including the timely completion of enrollment in our Phase 2 MaGic trial of DNTH103 in gMG, and we look forward to reporting top-line results in September," said Marino Garcia, Chief Executive Officer of Dianthus Therapeutics. "Despite currently approved biologics in the gMG market, significant opportunities remain for improved first-line treatment options. We believe that achieving DNTH103's target profile of effective, consistent symptom control, differentiated safety, and convenient dosing and administration could position it as a preferred first-line biologic therapy across the three neuromuscular indications of gMG, CIDP and MMN."

DNTH103 Clinical Development

DNTH103 is an investigational, clinical-stage, potent monoclonal antibody engineered to selectively target the classical pathway by inhibiting only the active form of the C1s protein, a clinically validated complement target. DNTH103 is designed to enable a more convenient subcutaneous, self-administered injection dosed as infrequently as once every two weeks. DNTH103 has the potential to be a best-in-class pipeline-in-a-product across a range of autoimmune disorders with high unmet need.

Generalized Myasthenia Gravis (gMG)

- **Enrollment complete in Phase 2 MaGic gMG trial:** The MaGic trial is a global, randomized, double-blind, placebo-controlled Phase 2 trial in patients with gMG who are acetylcholine receptor (AChR) antibody positive. Enrollment in this trial is now complete with 65 patients, exceeding the target of 60, and top-line results are anticipated in September 2025.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

- **Phase 3 CAPTIVATE CIDP trial ongoing:** The CAPTIVATE trial is a single, global, two-part, randomized withdrawal Phase 3 trial in patients with CIDP, and it remains on track for an interim responder analysis in 2H'26. The Company believes this single pivotal trial will support a BLA filing in adult patients with CIDP.

Multifocal Motor Neuropathy (MMN)

- **Phase 2 MoMeNtum MMN trial ongoing:** The MoMeNtum trial is a global, randomized, double-blind, placebo-controlled Phase 2 trial in patients with MMN, and it remains on track to report top-line results in 2H'26.

Corporate Updates

- On March 5, 2025, John C. King was announced as Chief Commercial Officer and Sujay Kango joined the Company's Board of Directors. Mr. King brings to Dianthus more than 25 years of global commercial leadership experience in biotechnology, including neuromuscular and hematological rare diseases. Mr. Kango is an experienced executive with more than 26 years of experience in the pharmaceutical and biotechnology sector.

First-Quarter 2025 Financial Results

- **Cash Position** - $331.5 million of cash, cash equivalents and investments as of March 31, 2025 is projected to provide runway into the second half of 2027.

- **R&D Expenses** - Research and development (R&D) expenses for the quarter ended March 31, 2025 were $27.0 million, inclusive of $2.5 million of stock-based compensation, compared to $13.1 million for the quarter ended March 31, 2024, which included $0.8 million of stock-based compensation. This increase in R&D expenses was primarily driven by higher clinical costs, chemistry, manufacturing and controls (CMC) costs, and increased headcount to support DNTH103 Phase 2 and Phase 3 development.

- **G&A Expenses** - General and administrative (G&A) expenses for the quarter ended March 31, 2025 totaled $7.3 million, inclusive of

stock-based compensation of $2.8 million, compared to $5.6 million for the quarter ended March 31, 2024, which included $1.2 million of stock-based compensation. This increase in G&A expenses was primarily due to increased headcount.

- **Net Loss** - Net loss for the quarter ended March 31, 2025 was $29.5 million or $0.82 per share (basic and diluted) compared to $13.7 million or $0.54 per share (basic and diluted) for the quarter ended March 31, 2024.

- **Additional Information** - For additional information on the Company's financial results for the quarter ended March 31, 2025, please refer to the Form 10-Q filed with the SEC.

About DNTH103
DNTH103 is an investigational, clinical-stage, potent monoclonal antibody engineered to selectively target the classical pathway by inhibiting only the active form of the C1s protein, a clinically validated complement target. 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 is building a neuromuscular franchise with DNTH103 and anticipates reporting top-line data from the Phase 2 MaGic trial in generalized Myasthenia Gravis in September 2025, the interim responder analysis of the Phase 3 CAPTIVATE trial in Chronic Inflammatory Demyelinating Polyneuropathy in 2H'26, and top-line data from the Phase 2 MoMeNtum trial in Multifocal Motor Neuropathy in 2H'26.

DNTH103 is an investigational agent that is not approved as a therapy in any indication in any jurisdiction worldwide.

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 and administration of DNTH103; the anticipated timing of the initiation and 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 the Company's Annual Report on Form 10-K for the period ended December 31, 2024, 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)

	March 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 10,116	$ 22,792
Short-term investments	253,114	252,449
Receivable from related party	—	807
Accounts receivable, net	1,000	—
Prepaid expenses and other current assets	6,769	4,856
Total current assets	270,999	280,904
Long-term investments	68,308	81,728

Property and equipment, net	191	194
Right-of-use operating lease assets	1,447	1,553
Other assets and restricted cash	7,635	9,629
Total assets	$ 348,580	$ 374,008
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 8,269	$ 4,579
Accrued expenses	7,979	13,074
Current portion of deferred revenue	479	479
Current portion of operating lease liabilities	226	320
Total current liabilities	16,953	18,452
Deferred revenue	1,851	1,908
Long-term operating lease liabilities	1,170	1,171
Total liabilities	19,974	21,531
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	32	31
Additional paid-in capital	532,207	526,732
Accumulated deficit	(203,903)	(174,392)
Accumulated other comprehensive income	270	106
Total stockholders' equity	328,606	352,477
Total liabilities and stockholders' equity	$ 348,580	$ 374,008

DIANTHUS THERAPEUTICS, INC.

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

	Three Months Ended March 31,	
	2025	**2024**
Revenues:		
License revenue - related party	$ —	$ 874
License revenue	1,163	—
Total revenues	1,163	874
Operating expenses:		
Research and development	27,003	13,078
General and administrative	7,337	5,640
Total operating expenses	34,340	18,718
Loss from operations	(33,177)	(17,844)
Other income/(expense):		
Interest and investment income	3,791	4,222
Loss on investment in related party	(5)	—
Loss on currency exchange, net	(22)	(12)
Other expense	(98)	(114)
Total other income	3,666	4,096
Net loss	$ (29,511)	$ (13,748)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.82)	$ (0.54)
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	35,790,700	25,665,475
Comprehensive loss:		
Net loss	$ (29,511)	$ (13,748)
Other comprehensive income/(loss):		
Unrealized gain/(loss) on marketable securities	164	(74)
Total other comprehensive income/(loss)	164	(74)
Total comprehensive loss	$ (29,347)	$ (13,822)