



DIANTHUS THERAPEUTICS

Dianthus Therapeutics Highlights Recent Business Achievements and Reports Q4 and FY 2024 Financial Results

March 11, 2025

Phase 2 MaGic trial of DNTH103 in generalized Myasthenia Gravis (gMG) ongoing; top-line results on track for 2H'25

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

\$357.0 million of cash provides runway into 2H'27

NEW YORK and WALTHAM, Mass., March 11, 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 fourth quarter and full year ending December 31, 2024 and provided an update on recent business achievements.

"We remain on track to report top-line data in 2H'25 from our Phase 2 clinical trial of DNTH103 in gMG, an indication where a best-in-class, potent active C1s and classical pathway inhibitor with the potential for effective and consistent symptom control along with improved safety and convenience could meaningfully advance the standard of care," said Marino Garcia, Chief Executive Officer of Dianthus Therapeutics. "We are excited to have initiated our pivotal Phase 3 CAPTIVATE trial in CIDP, which is on track for an interim responder analysis in 2H'26, along with top-line results from our Phase 2 trial in 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 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. 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)

- **Phase 2 MaGic gMG trial ongoing:** 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, and it remains on track to report top-line results in 2H'25.

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.

Full Year 2024 Financial Results

- **Cash Position** - \$357.0 million of cash, cash equivalents and investments as of December 31, 2024 is projected to provide runway into the second half of 2027.
- **R&D Expenses** - Research and development (R&D) expenses for the year ended December 31, 2024 were \$83.1 million, inclusive of \$5.6 million of stock-based compensation, compared to \$32.8 million for the year ended December 31, 2023, which included \$0.9 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 year ended December 31, 2024 totaled \$25.0 million, inclusive of stock-based compensation of \$7.3 million, compared to \$18.2 million for the year ended December 31, 2023, which included \$2.0 million of stock-based compensation. This increase in G&A expenses was primarily due to increased headcount and higher professional services costs.

- **Net Loss** - Net loss for the year ended December 31, 2024 was \$85.0 million or \$2.55 per share (basic and diluted) compared to \$43.6 million or \$8.45 per share (basic and diluted) for the year ended December 31, 2023.
- **Additional Information** - For additional information on the Company's financial results for the year ended December 31, 2024, please refer to the Form 10-K 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 2H'25, the interim responder analysis of the Phase 3 CAPITIVATE 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](https://www.linkedin.com/company/dianthus-therapeutics).

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 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.

Contact

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

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 22,792	\$ 132,325
Short-term investments	252,449	41,393
Receivable from related party	807	294
Unbilled receivable from related party	—	184
Prepaid expenses and other current assets	4,856	3,255
Total current assets	280,904	177,451
Long-term investments	81,728	—
Property and equipment, net	194	185
Right-of-use operating lease assets	1,553	615

Other assets and restricted cash	9,629	1,154
Total assets	<u>\$ 374,008</u>	<u>\$ 179,405</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,579	\$ 2,610
Accrued expenses	13,074	6,504
Current portion of deferred revenue	479	—
Current portion of deferred revenue – related party	—	100
Current portion of operating lease liabilities	320	417
Total current liabilities	<u>18,452</u>	<u>9,631</u>
Deferred revenue	1,908	—
Deferred revenue – related party	—	736
Long-term operating lease liabilities	1,171	168
Total liabilities	<u>21,531</u>	<u>10,535</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	31	15
Additional paid-in capital	526,732	258,231
Accumulated deficit	(174,392)	(89,423)
Accumulated other comprehensive income	106	47
Total stockholders' equity	<u>352,477</u>	<u>168,870</u>
Total liabilities and stockholders' equity	<u>\$ 374,008</u>	<u>\$ 179,405</u>

Dianthus Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
Revenues:				
License revenue – related party	\$ 999	\$ 457	\$ 5,909	\$ 2,826
License revenue	326	—	326	—
Total revenues	<u>1,325</u>	<u>457</u>	<u>6,235</u>	<u>2,826</u>
Operating expenses:				
Research and development	26,413	8,781	83,105	32,841
General and administrative	6,828	4,632	24,994	18,159
Total operating expenses	<u>33,241</u>	<u>13,413</u>	<u>108,099</u>	<u>51,000</u>
Loss from operations	(31,916)	(12,956)	(101,864)	(48,174)
Other income/(expense):				
Interest income	3,991	2,444	17,365	4,764
Gain/(loss) on investment in related party	(160)	—	148	—
Gain/(loss) on currency exchange, net	27	(32)	(64)	(85)
Other expense	(380)	(19)	(554)	(60)
Total other income	<u>3,478</u>	<u>2,393</u>	<u>16,895</u>	<u>4,619</u>
Net loss	<u>\$ (28,438)</u>	<u>\$ (10,563)</u>	<u>\$ (84,969)</u>	<u>\$ (43,555)</u>
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.81)	\$ (0.71)	\$ (2.55)	\$ (8.45)
Weighted-average number of shares of common stock outstanding, used in computing net loss per share of common stock, basic and diluted	<u>35,033,773</u>	<u>14,817,676</u>	<u>33,313,849</u>	<u>5,153,423</u>

Comprehensive loss:				
Net Loss	\$ (28,438)	\$ (10,563)	\$ (84,969)	\$ (43,555)
Other comprehensive income/(loss):				
Unrealized gains/(losses) on marketable securities	<u>(575)</u>	<u>51</u>	<u>59</u>	<u>208</u>
Total other comprehensive income/(loss)	<u>(575)</u>	<u>51</u>	<u>59</u>	<u>208</u>
Total comprehensive loss	<u>\$ (29,013)</u>	<u>\$ (10,512)</u>	<u>\$ (84,910)</u>	<u>\$ (43,347)</u>