Dianthus Therapeutics Highlights Recent Business Achievements, Including GO Decision for Phase 3 CAPTIVATE CIDP Trial, and Reports Q4 and FY 2025 Financial Results

March 09, 2026

Early GO decision reached in CAPTIVATE ahead of Q2'26 guidance based on GO criteria of 20 confirmed responders achieved with less than 40 planned participants completing open-label Part A

Phase 3 registrational trial of claseprubart evaluating 300mg/2mL Q2W and 300mg/2mL Q4W in generalized Myasthenia Gravis (gMG) expected to initiate in mid-2026; top-line results anticipated in 2H'28

Phase 2 MoMeNtum trial of claseprubart in Multifocal Motor Neuropathy (MMN) ongoing; top-line results on track for 2H'26

Phase 1 healthy volunteer data for DNTH212 anticipated in 2H'26; update on indication prioritization planned for 1H'26

$514.4 million of cash as of December 31, 2025 provides runway into 2028

Investor conference call and webcast to be held to discuss the CAPTIVATE trial interim responder analysis today, March 9, 2026 at 8:00 a.m. ET

NEW YORK and WALTHAM, Mass., March 09, 2026 (GLOBE NEWSWIRE) -- Dianthus Therapeutics, Inc. (Nasdaq: DNTH), a clinical-stage biotechnology company dedicated to developing next-generation therapies to transform the treatment of severe autoimmune diseases, today reported financial results for the fourth quarter and full year ending December 31, 2025, announced a GO decision in the Phase 3 CAPTIVATE trial of claseprubart in Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), and provided an update on other recent business achievements.

"It is truly exciting to be part of a company developing potential best-in-disease therapies for patients suffering from severe autoimmune diseases. I am very proud of the impressive level of execution the Dianthus team continues to deliver against our ambitious goals," said Marino Garcia, Chief Executive Officer of Dianthus Therapeutics. "With claseprubart, we are building a leading neuromuscular franchise with a target product profile that aims to combine best-in-class efficacy and safety with the convenience of an infrequent, subcutaneous, self-administered autoinjector that has the potential to meaningfully shift the treatment paradigm and standard of care for more than 150,000 patients in the U.S. living with gMG, CIDP and MMN."

Claseprubart (DNTH103) Clinical Development

Claseprubart 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. Claseprubart is designed to enable a more convenient, subcutaneous (S.C.), self-administered injection dosed as infrequently as once every two or four weeks. Claseprubart 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 3 trial expected to initiate mid-2026, with top-line results expected in 2H'28:** Following the successful completion of our end-of-Phase 2 meeting with the FDA in the first quarter of 2026, a Phase 3 registrational trial of claseprubart evaluating 300mg/2mL Q2W S.C. and 300mg/2mL Q4W S.C. in gMG patients is expected to initiate in mid-2026, with top-line results expected in 2H'28.
- **Claseprubart data presented at Muscular Dystrophy Association (MDA) Clinical and Scientific Conference, March 8-11, 2026:** Three poster presentations describing claseprubart Phase 2 MaGic results and *in vitro* data are available on the Investors section of the Dianthus website under Scientific Publications.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

- **Early GO decision announced in Phase 3 CAPTIVATE trial:** The target for the Part A interim responder analysis was a response rate of 50% or greater (i.e., ≥20 confirmed responders out of first 40 participants to complete Part A) based on precedent set with aC1s inhibition. This GO decision was reached early, after 20 confirmed responders were achieved with less than 40 planned participants completing open-label Part A of the trial. Dianthus expects to provide CAPTIVATE Part B top-line guidance by YE'26.

Multifocal Motor Neuropathy (MMN)

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

DNTH212 Clinical Development

DNTH212 is an investigational, extended half-life bifunctional fusion protein targeting plasmacytoid dendritic cell (pDC) BDCA2 to reduce Type 1 interferon production, while simultaneously inhibiting BAFF/APRIL to suppress B cell function. By targeting both the innate and adaptive immune systems via two clinically validated pathways that are known drivers of autoimmune disease pathogenesis, this complementary and differentiated approach has the potential to address multiple autoimmune indications with improved outcomes.

- **Phase 1 data anticipated in 2H'26:** A two-part Phase 1 study in China in healthy volunteers (Part A) and patients with systemic lupus erythematosus (Part B) was initiated in December 2025, with top-line results in healthy volunteers expected in 2H'26. An update on indication prioritization for DNTH212 is planned for 1H'26.

Full Year 2025 Financial Results

- **Cash Position** – $514.4 million of cash, cash equivalents and investments as of December 31, 2025 is projected to provide runway into 2028.
- **R&D Expenses** – Research and development (R&D) expenses for the year ended December 31, 2025 were $145.6 million, inclusive of $10.1 million of stock-based compensation, compared to $83.1 million for the year ended December 31, 2024, which included $5.6 million of stock-based compensation. This increase in R&D expenses was primarily driven by higher clinical costs, upfront and clinical development milestones for DNTH212, and increased headcount to support claseprubart Phase 2 and Phase 3 development.
- **G&A Expenses** – General and administrative (G&A) expenses for the year ended December 31, 2025 totaled $34.3 million, inclusive of stock-based compensation of $12.7 million, compared to $25.0 million for the year ended December 31, 2024, which included $7.3 million of stock-based compensation. This increase in G&A expenses was primarily due to increased headcount.
- **Net Loss** – Net loss for the year ended December 31, 2025 was $162.3 million or $4.20 per share (basic and diluted) compared to $85.0 million or $2.55 per share (basic and diluted) for the year ended December 31, 2024.
- **Additional Information** – For additional information on the Company's financial results for the year ended December 31, 2025, please refer to the Form 10-K filed with the SEC.

CAPTIVATE Investor Conference Call & Webcast to be Held at 8:00 a.m. ET Today
Dianthus Therapeutics will host an investor call and webcast to discuss the CAPTIVATE interim responder analysis today, March 9, 2026 at 8:00 a.m. ET. To access the live conference call by phone, please register here. Conference call participants in the question and answer session should pre-register to receive the dial-in number and personal PIN.

The live webcast may be accessed via the Investors section of the Dianthus Therapeutics website at https://investor.dianthustx.com/. A replay of the webcast will be available following the call. The presentation that will be used on this webcast is available here.

About Claseprubart (DNTH103)
Claseprubart 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. Claseprubart is enhanced with YTE half-life extension technology designed to enable a more convenient subcutaneous, infrequently dosed, self-administered injection. 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, claseprubart 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 claseprubart and expects to initiate a Phase 3 trial in generalized Myasthenia Gravis in mid-2026, with top-line results expected in 2H'28, report top-line data from the Phase 2 MoMeNtum trial in Multifocal Motor Neuropathy in 2H'26, and provide an update on timing of top-line data from Part B of the Phase 3 CAPTIVATE trial in Chronic Inflammatory Demyelinating Polyneuropathy by YE'26.

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

About DNTH212
DNTH212 is an investigational, extended half-life bifunctional fusion protein targeting plasmacytoid dendritic cell (pDC) BDCA2 to reduce Type 1 interferon production, while simultaneously inhibiting BAFF/APRIL to suppress B cell function. By targeting both the innate and adaptive immune systems via two clinically validated pathways that are known drivers of autoimmune disease pathogenesis, this complementary and differentiated approach has the potential to address multiple autoimmune indications with improved outcomes. A two-part Phase 1 study in China in healthy volunteers (Part A) and patients with systemic lupus erythematosus (Part B) is ongoing, with top-line results in healthy volunteers expected in 2H'26.

DNTH212 is an investigational agent that is not approved as a therapy in any indication in any jurisdiction worldwide.

About Dianthus Therapeutics
Dianthus Therapeutics, Inc. is a clinical-stage biotechnology company dedicated to developing next-generation therapies to transform the treatment of severe autoimmune diseases. Based in New York City and Waltham, Mass., Dianthus is comprised of an experienced team of biotech and pharma executives who aim 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 claseprubart and DNTH212, and any developments or results in connection therewith, including the target product profile and administration of claseprubart and DNTH212; the anticipated timing of the initiation and results from those studies and trials; expectations regarding the clinical trial designs or indications; 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 market size, patient population size, and potential opportunities for complement therapies, in particular with respect to claseprubart and DNTH212. Claseprubart and DNTH212 are investigational agents that are not approved as therapies in any indication in any jurisdiction worldwide. 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 claseprubart and DNTH212 and data from clinical trials may not be predictive of the results or success of ongoing or later clinical trials, that the preliminary interim analysis based on a limited number of patients from the Part A open label portion of the claseprubart CAPTIVATE study in patients with CIDP may not be predictive of the results or success of the remaining patients treated in Part A or patients treated in Part B of the CAPTIVATE study, that the development of claseprubart or DNTH212 may take longer and/or cost more than planned,

that the Company or its partner may be unable to successfully complete the clinical development of the Company's compounds, that the Company or its partner 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, 2025, 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.
Consolidated Balance Sheets
(unaudited, in thousands)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 51,087	$ 22,792
Short-term investments	353,208	252,449
Receivable from former related party	—	807
Accounts receivable, net	52	—
Prepaid expenses and other current assets	5,091	4,856
Total current assets	409,438	280,904
Long-term investments	110,135	81,728
Property and equipment, net	296	194
Right-of-use operating lease assets	1,337	1,553
Other assets and restricted cash	9,716	9,629
Total assets	$ 530,922	$ 374,008
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 9,725	$ 4,579
Accrued expenses	19,452	13,074
Current portion of deferred revenue	1,188	479
Current portion of operating lease liabilities	367	320
Total current liabilities	30,732	18,452
Deferred revenue	5,770	1,908
Long-term operating lease liabilities	1,019	1,171
Total liabilities	37,521	21,531
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	43	31
Additional paid-in capital	829,598	526,732
Accumulated deficit	(336,729)	(174,392)
Accumulated other comprehensive income	489	106
Total stockholders' equity	493,401	352,477
Total liabilities and stockholders' equity	$ 530,922	$ 374,008

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

	Three Months Ended December 31, 2025	Three Months Ended December 31, 2024	Year Ended December 31, 2025	Year Ended December 31, 2024
Revenues:				
License revenue – related party	$ —	$ 999	$ —	$ 5,909
License revenue	284	326	2,036	326
Total revenues	284	1,325	2,036	6,235
Operating expenses:				

Research and development	59,895	26,413	145,638	83,105
General and administrative	9,930	6,828	34,331	24,994
Total operating expenses	69,825	33,241	179,969	108,099
Loss from operations	(69,541)	(31,916)	(177,933)	(101,864)
Other income/(expense):				
Interest and investment income	5,267	3,991	16,119	17,365
Gain/(loss) on investment in related party	254	(160)	508	148
Gain/(loss) on currency exchange, net	(3)	27	(57)	(64)
Other expense	(409)	(380)	(974)	(554)
Total other income	5,109	3,478	15,596	16,895
Net loss	$ (64,432)	$ (28,438)	$ (162,337)	$ (84,969)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.43)	$ (0.81)	$ (4.20)	$ (2.55)
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	44,971,383	35,033,773	38,617,580	33,313,849
Comprehensive loss:				
Net Loss	$ (64,432)	$ (28,438)	$ (162,337)	$ (84,969)
Other comprehensive income/(loss):				
Unrealized gain/(loss) on marketable securities	326	(575)	383	59
Total other comprehensive income/(loss)	326	(575)	383	59
Total comprehensive loss	$ (64,106)	$ (29,013)	$ (161,954)	$ (84,910)