Dianthus Therapeutics Highlights Recent Business Achievements and Reports Q1 2026 Financial Results

May 05, 2026

Early GO decision reached in CAPTIVATE in March 2026 based on GO criteria of 20 confirmed responders achieved with less than 40 planned participants completing open-label Part A

Claseprubart granted Orphan Drug Designation by FDA for Myasthenia Gravis

Phase 3 registrational trial of claseprubart evaluating 300mg/2mL Q2W and 300mg/2mL Q4W in generalized Myasthenia Gravis (gMG) on track 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 Q4'26

Phase 1 healthy volunteer data for DNTH212 anticipated in 2H'26

Building a rheumatology franchise around DNTH212 with first three priority indications of Sjögren's Disease (SjD), Systemic Lupus Erythematosus (SLE), and Dermatomyositis (DM)

Further strengthened the balance sheet with approximately $719 million in gross proceeds from an underwritten public offering of common stock and pre-funded warrants

Approximately $1.2 billion of cash as of March 31, 2026 provides expected runway into 2030

NEW YORK and WALTHAM, Mass., May 05, 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 first quarter ending March 31, 2026, and provided an update on other recent business achievements.

"Q1 of this year was a pivotal period for Dianthus as we were able to make an early GO decision in PART A of the claseprubart CIDP CAPTIVATE study. In CAPTIVATE, we targeted 40 patients completing Part A and a response rate of approximately 50% based on precedent set with aC1s inhibition. We were able to make an early GO decision after 20 confirmed responders were identified with less than the 40 planned participants completing Part A. Claseprubart potency and early efficacy and safety results in CAPTIVATE Part A further build our confidence in claseprubart as a potentially best-in-disease therapy for neuromuscular diseases," said Marino Garcia, Chief Executive Officer of Dianthus Therapeutics. "We are also excited to announce the first three priority indications selected for DNTH212, our first-in-class bifunctional fusion protein and next potential best-in-disease pipeline therapeutic: Sjögren's Disease, Systemic Lupus Erythematosus, and Dermatomyositis. These are areas of high unmet need, where compelling biological rationale and clinical data support the complementary potential of targeting both BDCA2 and BAFF/APRIL to drive differentiated efficacy compared to single-mechanism approaches. Together, these indications represent a strong foundation for establishing a synergistic rheumatology franchise around DNTH212, alongside the synergistic neuromuscular franchise we are building with claseprubart in 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-disease pipeline-in-a-product across a range of autoimmune disorders with high unmet need.

Generalized Myasthenia Gravis (gMG)

- **Phase 3 EMERGE trial on track to initiate in 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 on track to initiate in mid-2026, with top-line results expected in 2H'28.
- **Orphan Drug Designation granted:** Claseprubart was granted Orphan Drug Designation by the FDA for the treatment of Myasthenia Gravis. The FDA's Office of Orphan Products Development grants orphan designation to drugs and biologics intended to treat rare diseases affecting fewer than 200,000 people in the United States. Orphan Drug Designation qualifies sponsors for incentives including tax credits for qualified clinical trials, exemption from user fees, and potential seven years of market exclusivity after approval.
- **Claseprubart data presented at the 2026 American Academy of Neurology (AAN) Annual Meeting:** Two presentations describing results from the Phase 2 MaGic trial of claseprubart in gMG and *in vitro* data supporting the potential mechanistic advantages of aC1s inhibition 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** in March 2026**:** 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 trial on track for top-line results in Q4'26:** The MoMeNtum trial is an ongoing global, randomized, double-blind, placebo-controlled Phase 2 trial in patients with MMN, with top-line results on track for Q4'26.

All Programs
In March 2026, the Company filed an 8K indicating receipt of written feedback from FDA agreeing to three proposals for all ongoing and planned future claseprubart trials:

- Removal of anti-nuclear antibodies ("ANAs") as a screening criteria, a common reason for screen failure across all three claseprubart programs;
- Removal of routine ANA testing during claseprubart clinical trials; and
- Reclassification of the hypothetical risk of SLE to drug-induced lupus (DIL), a side effect in several classes of widely used medications characterized by the reversal of symptoms upon discontinuation of the precipitating medication.

Of note, there have been no cases of either SLE or DIL to date in any claseprubart program.

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.

- **Initial indications selected for DNTH212 clinical development:** SjD, SLE, and DM have been selected as the first three priority indications for DNTH212 clinical development and will serve as the foundation of a synergistic rheumatology franchise for DNTH212.

- **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. Upon completion of the Phase 1 study, Dianthus plans to provide an update on next steps for advancing its priority indications in clinical development.

Corporate Updates:

On March 12, Dianthus announced the closing of an upsized underwritten public offering of common stock and pre-funded warrants, with aggregate gross proceeds of approximately $719 million.

First-Quarter 2026 Financial Results

- **Cash Position** – Approximately $1.2 billion of cash, cash equivalents and investments as of March 31, 2026 is projected to provide runway into 2030.

- **R&D Expenses** – Research and development (R&D) expenses for the quarter ended March 31, 2026 were $34.5 million, inclusive of $4.8 million of stock-based compensation, compared to $27.0 million for the quarter ended March 31, 2025, which included $2.5 million of stock-based compensation. This increase in R&D expenses was primarily driven by higher clinical costs and increased headcount to support claseprubart Phase 2 and Phase 3 development.

- **G&A Expenses** – General and administrative (G&A) expenses for the quarter ended March 31, 2026 totaled $12.5 million, inclusive of stock-based compensation of $5.8 million, compared to $7.3 million for the quarter ended March 31, 2025, which included $2.8 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, 2026 was $40.8 million or $0.85 per share (basic and diluted) compared to $29.5 million or $0.82 per share (basic and diluted) for the quarter ended March 31, 2025.

- **Additional Information** – For additional information on the Company's financial results for the quarter ended March 31, 2026, please refer to the Form 10-Q filed with the SEC.

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-disease 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 Q4'26, 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. Dianthus is building a rheumatology franchise with DNTH212 and has selected Sjögren's Disease (SjD), Systemic Lupus Erythematosus (SLE), and Dermatomyositis (DM) as the first three prioritized indications for clinical development. 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)

	March 31, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 627,667	$ 51,087
Short-term investments	483,592	353,208
Accounts receivable, net	1,230	52
Prepaid expenses and other current assets	7,422	5,091
Total current assets	1,119,911	409,438
Long-term investments	113,868	110,135
Property and equipment, net	274	296
Right-of-use operating lease assets	1,293	1,337
Other assets and restricted cash	11,538	9,716
Total assets	$ 1,246,884	$ 530,922
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,274	$ 9,725
Accrued expenses	31,125	19,452
Current portion of deferred revenue	1,485	1,188
Current portion of operating lease liabilities	399	367
Total current liabilities	38,283	30,732
Deferred revenue	6,322	5,770
Long-term operating lease liabilities	965	1,019
Total liabilities	45,570	37,521
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	54	43
Additional paid-in capital	1,579,398	829,598
Accumulated deficit	(377,563)	(336,729)

Accumulated other comprehensive (loss)/income	(575)	489
Total stockholders' equity	1,201,314	493,401
Total liabilities and stockholders' equity	$ 1,246,884	$ 530,922

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,	
	2026	**2025**
Revenues:		
License revenue	$ 463	$ 1,163
Operating expenses:		
Research and development	34,528	27,003
General and administrative	12,468	7,337
Total operating expenses	46,996	34,340
Loss from operations	(46,533)	(33,177)
Other income/(expense):		
Interest and investment income	6,265	3,791
Loss on investment in former related party	(302)	(5)
Loss on currency exchange, net	(15)	(22)
Other expense	(249)	(98)
Total other income	5,699	3,666
Net loss	$ (40,834)	$ (29,511)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.85)	$ (0.82)
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	48,032,742	35,790,700
Comprehensive loss:		
Net loss	$ (40,834)	$ (29,511)
Other comprehensive (loss)/income:		
Unrealized (loss)/gain on marketable securities	(1,064)	164
Total other comprehensive (loss)/income	(1,064)	164
Total comprehensive loss	$ (41,898)	$ (29,347)