Dianthus Therapeutics Highlights Recent Business Achievements and Reports Q2 2026 Financial Results

August 04, 2026

Advancing a neuromuscular franchise with claseprubart, a highly potent investigational classical pathway inhibitor, with best-in-disease potential across generalized Myasthenia Gravis (gMG), Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), and Multifocal Motor Neuropathy (MMN)

Phase 3 EMERGE registrational trial of claseprubart in gMG evaluating 300mg/2mL Q2W and 300mg/2mL Q4W initiated in June '26, with top-line results anticipated in 2H'28

75% response rate observed in Interim Responder Analysis from first 40 participants completing Part A of Phase 3 CAPTIVATE trial of claseprubart in CIDP, with Part B top-line guidance expected by YE'26

Phase 2 MoMeNtum trial of claseprubart in MMN exceeded its original enrollment target of 36 patients; top-line results with 46 patients on track for December '26

Building a rheumatology franchise with DNTH212 across our first three prioritized indications of Sjögren's Disease (SjD), Systemic Lupus Erythematosus (SLE), and Dermatomyositis (DM); Phase 1 healthy volunteer data anticipated by YE'26

Advancing DNTH312, an internally developed, first-in-class, next-generation bifunctional fusion protein combining claseprubart and TACI to target potent inhibition of aC1s and BAFF/APRIL for severe autoimmune diseases; DNTH312 aims to be Phase 1 ready by YE'27

Approximately $1.2 billion of cash as of June 30, 2026 provides expected runway into 2030

NEW YORK and WALTHAM, Mass., Aug. 04, 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 second quarter ending June 30, 2026, and provided an update on other recent business achievements.

"Our strong execution in the first half of 2026 reflects the continued focus and discipline of the Dianthus team as we advance both claseprubart and DNTH212 for severe autoimmune diseases," said Marino Garcia, Chief Executive Officer of Dianthus Therapeutics. "With the initiation of our Phase 3 EMERGE registrational trial in gMG, excellent interim results from Part A of our Phase 3 CAPTIVATE trial in CIDP, and completion of enrollment in the Phase 2 MoMeNtum trial in MMN with top-line results expected in December, claseprubart continues to demonstrate its potential as a best-in-disease, pipeline-in-a-product opportunity. In addition, we anticipate Phase 1 healthy volunteer data for DNTH212 by year end. We continue to strengthen our leadership position in autoimmune diseases with today's announcement of the addition of our innovative, internally developed, first-in-class, next generation, highly potent and half-life extended bifunctional fusion protein, DNTH312."

Claseprubart: Potential Best-in-Disease aC1s Inhibitor for Neuromuscular Diseases

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 initiated, with top-line results expected in 2H'28:** A Phase 3 registrational trial of claseprubart evaluating 300mg/2mL Q2W S.C. and 300mg/2mL Q4W S.C. in gMG patients was initiated in June, with top-line results expected in 2H'28.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

- **75% response rate observed in Interim Responder Analysis from first 40 participants completing Part A of Phase 3 CAPTIVATE trial**, exceeding the target response rate of 50% or greater based on precedent set with aC1s inhibition. Results were consistent and clinically meaningful across multiple efficacy measures. Claseprubart was generally well tolerated with no related serious infections, no clinical symptoms of drug-induced lupus (DIL), no related serious adverse events (SAEs) or discontinuations due to safety. Dianthus expects to provide CAPTIVATE Part B top-line guidance by YE'26.

Multifocal Motor Neuropathy (MMN)

- **Enrollment completed, exceeding the enrollment target, in the Phase 2 MoMeNtum trial, with top-line results on track for December '26:** The MoMeNtum trial, a global, randomized, double-blind, placebo-controlled Phase 2 trial in patients with MMN, exceeded its original enrollment target of 36 patients. Top-line results with 46 patients are on track for December '26.

All Programs

- Claseprubart presentations at the American Academy of Neurology (AAN), Peripheral Nerve Society (PNS), and European Academy of

Neurology (EAN) meetings described the design of the pivotal Phase 3 CAPTIVATE study in CIDP, Phase 2 MaGic trial results in gMG, Minimal Symptom Expression (MSE) results for claseprubart from MaGic, and potential mechanistic advantages of targeting aC1s in gMG. Presentations are available in the Investors section of the Dianthus website.

- 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: Potential Best-in-Disease, Bifunctional BDCA2 and BAFF/APRIL Inhibitor for Rheumatology Conditions

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 by year end:** 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 Phase 1 healthy volunteer data anticipated by year end. Upon completion of the Phase 1 study, Dianthus plans to provide an update on next steps for advancing its priority indications in clinical development.

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

DNTH312: An Internally Developed, First-in-class, Next-generation Bifunctional Fusion Protein Combining Claseprubart and TACI to Target Potent Inhibition of aC1s and BAFF/APRIL for Autoimmune Diseases

- DNTH312 is an internally developed, investigational, first-in-class, next-generation bifunctional fusion protein combining claseprubart and TACI to target potent inhibition of aC1s and BAFF/APRIL. By targeting two validated pathways with complementary disease modifying mechanisms, DNTH312 expands Dianthus' leadership position in autoimmune diseases with its potential for best-in-disease efficacy by targeting deeper responses and broader symptom control, while also addressing larger patient populations.
- DNTH312 demonstrated comparable *in vitro* potency and aC1s inhibition to claseprubart across several functional assays of Classical Pathway inhibition and a similar depth of IgM, IgA, and IgG reductions vs. published values for povetacicept following a single dose in non-human primates (NHPs).
- Additionally, DNTH312 is enhanced with YTE half-life extension technology, and has a similar NHP half-life (22 days) to claseprubart, which has an approximately 60-day half-life in humans.
- DNTH312 aims to be Phase 1 ready by YE'27.

Second-Quarter 2026 Financial Results

- **Cash Position** – Approximately $1.2 billion of cash, cash equivalents and investments as of June 30, 2026 is projected to provide runway into 2030.

- **R&D Expenses** – Research and development (R&D) expenses for the quarter ended June 30, 2026 were $48.7 million, inclusive of $5.6 million of stock-based compensation, compared to $26.3 million for the quarter ended June 30, 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 June 30, 2026 totaled $13.6 million, inclusive of stock-based compensation of $6.3 million, compared to $8.9 million for the quarter ended June 30, 2025, which included $3.2 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 June 30, 2026 was $50.2 million or $0.90 per share (basic and diluted) compared to $31.6 million or $0.88 per share (basic and diluted) for the quarter ended June 30, 2025.

- **Additional Information** – For additional information on the Company's financial results for the quarter ended June 30, 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. Claseprubart was granted Orphan Drug Designation by the FDA for the treatment of Myasthenia Gravis in May 2026.

Dianthus is building a neuromuscular franchise with claseprubart and expects to report top-line data from the Phase 2 MoMeNtum trial in Multifocal Motor Neuropathy in December '26, to 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, and to report top-line results from the Phase 3 EMERGE trial in generalized Myasthenia Gravis in 2H'28.

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 healthy volunteer data expected by YE'26.

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

About DNTH312
DNTH312 is an internally developed, investigational, first-in-class, next-generation bifunctional fusion protein combining claseprubart and TACI to target potent inhibition of aC1s and BAFF/APRIL. DNTH312 is enhanced with YTE half-life extension technology, similar to claseprubart. By targeting two validated pathways with complementary disease modifying mechanisms, DNTH312 is designed to expand Dianthus' leadership position in autoimmune diseases with potential for best-in-disease efficacy by targeting deeper responses and broader symptom control, while also addressing larger patient populations. DNTH312 aims to be Phase 1 ready by YE'27.

DNTH312 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, DNTH212, and DNTH312, and any developments or results in connection therewith, including the target product profile and administration of claseprubart, DNTH212, and DNTH312; 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 market opportunities, in particular with respect to claseprubart, DNTH212 and DNTH312. Claseprubart, DNTH212, and DNTH312 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, DNTH212, and DNTH312 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, DNTH212, or DNTH312 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.

Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)
(unaudited)

	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 110,549	$ 51,087
Short-term investments	776,264	353,208
Accounts receivable, net	106	52
Prepaid expenses and other current assets	10,618	5,091

Total current assets	897,537	409,438
Long-term investments	303,633	110,135
Property and equipment, net	418	296
Right-of-use operating lease assets	1,223	1,337
Other assets and restricted cash	10,460	9,716
Total assets	$ 1,213,271	$ 530,922
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,390	$ 9,725
Accrued expenses	26,101	19,452
Current portion of deferred revenue	1,524	1,188
Current portion of operating lease liabilities	374	367
Total current liabilities	34,389	30,732
Deferred revenue	5,944	5,770
Long-term operating lease liabilities	913	1,019
Total liabilities	41,246	37,521
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	55	43
Additional paid-in capital	1,601,876	829,598
Accumulated deficit	(427,778)	(336,729)
Accumulated other comprehensive (loss)/income	(2,128)	489
Total stockholders' equity	1,172,025	493,401
Total liabilities and stockholders' equity	$ 1,213,271	$ 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 June 30,		Six Months Ended June 30,	
	2026	**2025**	**2026**	**2025**
Revenues:				
License revenue	$ 761	$ 193	$ 1,224	$ 1,356
Operating expenses:				
Research and development	48,686	26,251	83,214	53,254
General and administrative	13,557	8,869	26,025	16,206
Total operating expenses	62,243	35,120	109,239	69,460
Loss from operations	(61,482)	(34,927)	(108,015)	(68,104)
Other income/(expense):				
Interest and investment income	11,542	3,403	17,807	7,194
Gain/(loss) on investment in former related party	105	32	(197)	27
Loss on currency exchange, net	(10)	(30)	(25)	(52)
Other expense	(370)	(107)	(619)	(205)
Total other income	11,267	3,298	16,966	6,964
Net loss	$ (50,215)	$ (31,629)	$ (91,049)	$ (61,140)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.90)	$ (0.88)	$ (1.75)	$ (1.71)
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	56,029,124	35,822,308	52,053,022	35,806,591
Comprehensive loss:				
Net loss	$ (50,215)	$ (31,629)	$ (91,049)	$ (61,140)
Other comprehensive loss:				
Unrealized loss on marketable securities	(1,553)	(172)	(2,617)	(8)
Total other comprehensive loss	(1,553)	(172)	(2,617)	(8)
Total comprehensive loss	$ (51,768)	$ (31,801)	$ (93,666)	$ (61,148)