Dianthus Therapeutics Highlights Recent Business Achievements and Reports Q3 2026 Financial Results

November 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 on track, with top-line results expected in 2H'28

Phase 3 CAPTIVATE trial of claseprubart in CIDP evaluating 300mg/2mL Q2W now conservatively projected to require less than 200 participants in the open-label Part A in order to randomize 128 responders into the placebo-controlled withdrawal Part B portion of the study, with Part A top-line results expected by YE'27 and Part B top-line results expected by YE'28

Phase 2 MoMeNtum trial of claseprubart in MMN top-line results on track for December '26

DNTH212 continues to advance with Phase 1 single ascending dose (SAD) Part A healthy volunteer preliminary data expected in Q1'27. First SLE patient in Part B of the Phase 1 SAD study was dosed in October, with preliminary results from Part B expected in 2H'27. The Dianthus-led Phase 1 multiple ascending dose (MAD) study is planned to initiate in Q2'27 with preliminary data expected in 2H'27

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, on track to be Phase 1 ready by YE'27

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

NEW YORK and WALTHAM, Mass., Nov. 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 third quarter ending September 30, 2026, and provided an update on other recent business achievements.

"The Dianthus team continues to execute on our strategy to build a best-in-disease neuromuscular franchise with claseprubart across gMG, CIDP, and MMN, while advancing an exciting pipeline of potentially best-in-disease bifunctional fusion proteins with DNTH212 and DNTH312," said Marino Garcia, Chief Executive Officer of Dianthus Therapeutics. "Following top-line results from our Phase 2 MoMeNtum trial of claseprubart in December, we plan to quickly initiate a Phase 3 trial in MMN in 2027. MMN represents a significant market opportunity, characterized by high unmet needs and limited competition. IVIg is the only approved treatment for patients with MMN, and the lack of patient and physician satisfaction with IVIg presents a meaningful opportunity for claseprubart, given its unique potential for a differentiated, best-in-disease profile due to potent inhibition of the classical pathway and preservation of the lectin and alternative pathways while targeting a patient-friendly, 300mg/2mL, self-administered subcutaneous autoinjector once every two weeks."

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 on track with top-line results expected in 2H'28:** A Phase 3 registrational trial of claseprubart evaluating 300mg/2mL S.C. Q2W and 300mg/2mL S.C. Q4W in gMG patients was initiated in June, with top-line results expected in 2H'28.
- **MaGic OLE data presented at AANEM:** Results from the Phase 2 MaGic open-label extension (OLE) were presented at the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) Annual Meeting, September 29 to October 2, 2026, and demonstrated sustained efficacy and a continued favorable safety profile for claseprubart in gMG.

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.
- **CAPTIVATE Part A top-line results expected by YE'27 and Part B top-line results expected by YE'28:** The Phase 3 CAPTIVATE trial of claseprubart 300mg/2mL S.C. Q2W is now conservatively projected to require less than 200 participants in the open-label Part A in order to randomize 128 responders into the placebo-controlled withdrawal Part B portion of the study. Top-line results from all participants completing Part A are expected by YE'27, and top-line results from Part B are expected by YE'28.

Multifocal Motor Neuropathy (MMN)

- **Phase 2 MoMeNtum trial 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. Following top-line results, a Phase 3 trial in MMN is planned to initiate in 2027.

All Programs

- Multiple claseprubart data presentations were made at the 18th International Congress on Neuromuscular Diseases (ICNMD), American Academy of Neurology (AAN) Autoimmune Neurology Conference, American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) Annual Meeting, and American Neurological Association (ANA) Annual Meeting. Among the data presented were results demonstrating a sustained safety and efficacy profile for claseprubart in the Phase 2 MaGic open-label extension, and a 75% response rate observed in the interim responder analysis of the first 40 participants completing unblinded Part A of the Phase 3 CAPTIVATE trial. Presentations are available in the Investors section of the Dianthus website.

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.

- **Dosing of SLE patients in Phase 1 Part B initiated in October:** DNTH212 is being evaluated in a two-part Phase 1 study in China in healthy volunteers (Part A) and patients with Systemic Lupus Erythematosus (SLE, Part B). Part A is evaluating single ascending doses of DNTH212, with preliminary healthy volunteer data expected in Q1’27. Based upon data seen to date and as previously announced by Leads Biolabs, dosing of SLE patients in Part B of the Phase 1 SAD study was initiated in October, with preliminary Part B SLE data expected in 2H’27.
- **Dianthus-led MAD study planned to initiate in Q2’27:** Dianthus plans to initiate a Phase 1 multiple ascending dose (MAD) study outside of China in healthy volunteers in Q2’27 to support the continued global development of DNTH212, with preliminary data expected in 2H’27.
- **Update on next steps in prioritized indications by YE’27:** Dianthus plans to provide an update on next steps for advancing its first three prioritized indications of Sjögren’s Disease (SjD), SLE, and Dermatomyositis (DM) in clinical development by YE’27.

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 is on track to be Phase 1 ready by YE’27.**

Corporate Updates

- Dianthus was selected by Great Place To Work® and *Fortune* magazine for the 2026 *Fortune* Best Workplaces in BioPharma™ ListThis was Dianthus’ inaugural appearance on the list, ranking among the top 30 small- and medium-sized biotechnology and pharmaceutical companies in the United States. The Company was recognized for fostering a high-trust and engaging workplace culture.

Third-Quarter 2026 Financial Results

- **Cash Position** – Approximately $1.2 billion of cash, cash equivalents and investments as of September 30, 2026, is projected to provide runway into 2030.
- **R&D Expenses** – Research and development (R&D) expenses for the quarter ended September 30, 2026 were $45.6 million, inclusive of $6.3 million of stock-based compensation, compared to $32.5 million for the quarter ended September 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, in addition to costs related to DNTH212 and DNTH312 development.
- **G&A Expenses** – General and administrative (G&A) expenses for the quarter ended September 30, 2026 totaled $14.1 million, inclusive of stock-based compensation of $6.4 million, compared to $8.2 million for the quarter ended September 30, 2025, which included $3.3 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 September 30, 2026 was $46.6 million or $0.81 per share (basic and diluted), compared to $36.8 million or $0.97 per share (basic and diluted) for the quarter ended September 30, 2025.
- **Additional Information** – For additional information on the Company’s financial results for the quarter ended September 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 results from the Phase 2 MoMeNtum trial in Multifocal Motor Neuropathy in December ’26, report top-line results from the Phase 3 CAPTIVATE trial Part A in CIDP by YE’27 and from Part B by YE’28, and 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 SLE (Part B) is ongoing, with

preliminary healthy volunteer data expected in Q1'27 and preliminary Part B SLE data expected in 2H'27. Dianthus plans to initiate a Phase 1 multiple ascending dose (MAD) study outside of China in healthy volunteers in Q2'27 to support the continued global development of DNTH212, with preliminary data expected in 2H'27. Dianthus plans to provide an update on next steps for advancing its first three prioritized indications in clinical development by YE'27.

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 is on track 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)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 55,686	$ 51,087
Short-term investments	782,097	353,208
Accounts receivable, net	582	52
Prepaid expenses and other current assets	17,673	5,091
Total current assets	856,038	409,438
Long-term investments	406,040	110,135
Property and equipment, net	749	296
Right-of-use operating lease assets	1,151	1,337

Other assets and restricted cash	12,274	9,716
Total assets	$ 1,276,252	$ 530,922
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,498	$ 9,725
Accrued expenses	21,079	19,452
Current portion of deferred revenue	1,589	1,188
Current portion of operating lease liabilities	349	367
Total current liabilities	28,515	30,732
Deferred revenue	5,449	5,770
Long-term operating lease liabilities	859	1,019
Total liabilities	34,823	37,521
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	56	43
Additional paid-in capital	1,722,069	829,598
Accumulated deficit	(474,421)	(336,729)
Accumulated other comprehensive (loss)/income	(6,275)	489
Total stockholders' equity	1,241,429	493,401
Total liabilities and stockholders' equity	$ 1,276,252	$ 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 September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Revenues:				
License revenue	$ 1,210	$ 396	$ 2,434	$ 1,752
Operating expenses:				
Research and development	45,600	32,489	128,814	85,743
General and administrative	14,082	8,195	40,107	24,401
Total operating expenses	59,682	40,684	168,921	110,144
Loss from operations	(58,472)	(40,288)	(166,487)	(108,392)
Other income/(expense):				
Interest and investment income	12,143	3,658	29,950	10,852
Gain/(loss) on investment in former related party	28	227	(169)	254
Loss on currency exchange, net	(24)	(2)	(49)	(54)
Other expense	(318)	(360)	(937)	(565)
Total other income	11,829	3,523	28,795	10,487
Net loss	$ (46,643)	$ (36,765)	$ (137,692)	$ (97,905)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.81)	$ (0.97)	$ (2.56)	$ (2.68)
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	57,341,193	37,794,088	53,835,116	36,476,370
Comprehensive loss:				
Net loss	$ (46,643)	$ (36,765)	$ (137,692)	$ (97,905)
Other comprehensive (loss)/income:				
Unrealized (loss)/gain on marketable securities	(4,147)	65	(6,764)	57
Total other comprehensive (loss)/income	(4,147)	65	(6,764)	57
Total comprehensive loss	$ (50,790)	$ (36,700)	$ (144,456)	$ (97,848)