Dianthus Therapeutics Highlights Recent Business Achievements and Reports Q3 Financial Results

November 05, 2025

Claseprubart achieved statistically significant and clinically meaningful improvements in Myasthenia Gravis Activities of Daily Living (MG-ADL), Quantitative Myasthenia Gravis (QMG), and other efficacy measures at Week 13 in Phase 2 MaGic trial in gMG

New claseprubart data from the MaGic open-label extension supporting potential for 300mg/2mL Q4W dosing and new in vitro data highlighting potential efficacy benefits of upstream (aC1s, claseprubart) vs. downstream (C5, ravulizumab) complement inhibition were presented during the AANEM Annual Meeting in October 2025

Phase 3 gMG trial including two claseprubart treatment arms, 300mg/2mL Q2W and 300mg/2mL Q4W, vs. placebo anticipated to initiate in 2026

Accelerated timing for interim responder analysis for Phase 3 CAPTIVATE trial of claseprubart in Chronic Inflammatory Demyelinating Polyneuropathy (CIDP); now anticipated in Q2'26 (formerly 2H'26) due to faster than expected enrollment

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

Announced exclusive license agreement for DNTH212, a bifunctional BDCA2 and BAFF/APRIL inhibitor; Phase 1 healthy volunteer data anticipated in 2H'26

Estimated ~$525 million of cash after DNTH212 upfront and near-term milestone payments provides runway into 2028

NEW YORK and WALTHAM, Mass., Nov. 05, 2025 (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, 2025, and provided an update on recent business achievements.

"I'm extremely proud of our team's outstanding track record of execution against our vision to become a leading biotech company in the I&I field. Just in the past 2 months, we delivered impressive results from the gMG MaGic trial, accelerated the timing of the interim responder analysis from our CIDP CAPTIVATE trial from 2H'26 to Q2'26, and in-licensed DNTH212, a new and exciting clinical-stage bifunctional fusion protein. Both claseprubart and DNTH212 have validated mechanisms of action with pipeline-in-a-product potential, and aim to deliver best-in-class efficacy, safety, and convenience with infrequent, subcutaneous self-administration," said Marino Garcia, Chief Executive Officer of Dianthus Therapeutics. "The claseprubart efficacy and safety data from the MaGic trial, including the recently presented data for placebo patients transitioning to claseprubart in the OLE and the post-hoc analyses highlighting the impact of QMG screening criteria on MG-ADL results, strongly support our Phase 3 plans to advance both 300mg/2mL Q2W and 300mg/2mL Q4W as a potential best-in-class treatment option in gMG. We remain focused on execution as we aim to deliver first-line biologic therapies that can meaningfully improve the lives of patients with severe autoimmune diseases."

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, 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)

- **Positive Phase 2 data reported in September and presented at AANEM:** Results from the MaGic trial, a global, randomized, double-blind, placebo-controlled Phase 2 trial in patients with gMG who are acetylcholine receptor (AChR) antibody positive, were reported in September and presented at the American Association of Neuromuscular and Electromagnetic Medicine (AANEM) Annual Meeting. Claseprubart 300mg/2mL and 600mg/4mL Q2W demonstrated rapid, statistically significant and clinically meaningful improvements over placebo as measured by both MG-ADL and QMG, including at Week 1 and at Week 13. The claseprubart 300mg/2mL Q2W dose was also statistically significant and clinically meaningful across other key efficacy endpoints, including Minimal Symptom Expression (MSE), Myasthenia Gravis Composite (MGC) Score and the Myasthenia Gravis Quality of Life Scale (MG-QoL-15r). Claseprubart was generally well tolerated with no drug-related Serious Adverse Events (SAEs) or discontinuations due to any related adverse event.

- **New MaGic data presented during AANEM:** New claseprubart data were presented during AANEM and in a Virtual Industry Forum titled *Upstream Targeting: Rethinking MG Treatment Through Active C1s Inhibition*, which included:
  - A robust MG-ADL decline at week 4 in the open-label extension (OLE) of -2.5 points and QMG score reduction of -3.2 points for patients on placebo during the RCT who received only two doses of claseprubart 600mg/4mL Q2W without a loading dose and achieved a PK level far below the steady state of 300mg/2mL Q2W, supporting potential for Q4W dosing of 300mg/2mL
  - A subgroup analysis of patients enrolled in the MaGic trial with a QMG score ≥10 at baseline which demonstrated a 3-point difference from placebo in MG-ADL treatment effect for 300mg/2mL Q2W
  - *In vitro* data demonstrating the benefits of upstream (active C1s with claseprubart) vs. downstream (C5 with ravulizumab) inhibition in the prevention of pro-inflammatory split products C3a and C3b

- **Phase 3 trial expected to begin in 2026:** An end-of-Phase 2 meeting is planned with the FDA to align on the proposed design of a Phase 3 trial for claseprubart in gMG that investigates both 300mg/2mL Q2W and 300mg/2mL Q4W doses vs. placebo and includes QMG ≥10

screening criteria.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

- **Phase 3 CAPTIVATE CIDP trial interim responder analysis now expected in Q2'26:** The CAPTIVATE trial is a single, global, two-part, randomized withdrawal Phase 3 trial in patients with CIDP, and an interim responder analysis (n=40) from Part A of this trial is now expected in Q2'26, accelerated from previous guidance of 2H'26 due to faster than expected enrollment. 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 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) is expected to initiate by year-end 2025, with top-line results in healthy volunteers expected in the second half of 2026. An update on indication prioritization for DNTH212 is planned for 2026.

Corporate Updates

- On September 11, Dianthus announced the closing of an upsized underwritten public offering of common stock, with aggregate gross proceeds of approximately $288 million.

- On October 16, Dianthus entered into an exclusive licensing agreement with Nanjing Leads Biolabs Co., Ltd. ("Leads" (9887.HK)) for DNTH212 (being developed in China by Leads Biolabs as LBL-047), a first and potentially best-in-class bifunctional BDCA2 and BAFF/APRIL inhibitor.

Third-Quarter 2025 Financial Results

- **Cash Position** – An estimated $525 million of adjusted cash, cash equivalents and investments as of September 30, 2025 is projected to provide runway into 2028. This $525 million estimate includes cash, cash equivalents and investments as of September 30, 2025 of approximately $555.5 million, less $30 million of upfront and near-term milestone payments payable to Leads Biolabs.

- **R&D Expenses** - Research and development (R&D) expenses for the quarter ended September 30, 2025 were $32.5 million, inclusive of $2.5 million of stock-based compensation, compared to $25.5 million for the quarter ended September 30, 2024, which included $1.7 million of stock-based compensation. This increase in R&D expenses was primarily driven by higher clinical costs, milestone 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 September 30, 2025 totaled $8.2 million, inclusive of stock-based compensation of $3.3 million, compared to $6.5 million for the quarter ended September 30, 2024, which included $2.2 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 September 30, 2025 was $36.8 million or $0.97 per share (basic and diluted) compared to $25.2 million or $0.74 per share (basic and diluted) for the quarter ended September 30, 2024.

- **Additional Information** - For additional information on the Company's financial results for the quarter ended September 30, 2025, 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-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 gMG in 2026, the interim responder analysis of the Phase 3 CAPTIVATE trial in Chronic Inflammatory Demyelinating Polyneuropathy in Q2'26, and top-line data from the Phase 2 MoMeNtum trial in Multifocal Motor Neuropathy in 2H'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 expected to initiate by year-end 2025, with top-line results in healthy volunteers expected in the second half of 2026.

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 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, 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.

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DIANTHUS THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)
(unaudited)

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 55,984	$ 22,792
Short-term investments	346,629	252,449
Receivable from former related party	—	807
Accounts receivable, net	5,000	—
Prepaid expenses and other current assets	6,212	4,856
Total current assets	413,825	280,904
Long-term investments	152,874	81,728
Property and equipment, net	185	194
Right-of-use operating lease assets	1,306	1,553
Other assets and restricted cash	9,255	9,629
Total assets	$ 577,445	$ 374,008
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,705	$ 4,579
Accrued expenses	15,979	13,074
Current portion of deferred revenue	954	479
Current portion of operating lease liabilities	217	320
Total current liabilities	23,855	18,452
Deferred revenue	6,068	1,908
Long-term operating lease liabilities	1,068	1,171
Total liabilities	30,991	21,531
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	43	31
Additional paid-in capital	818,545	526,732
Accumulated deficit	(272,297)	(174,392)

Accumulated other comprehensive income	163	106
Total stockholders' equity	546,454	352,477
Total liabilities and stockholders' equity	$ 577,445	$ 374,008

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,	
	2025	2024	2025	2024
Revenues:				
License revenue – former related party	$ —	$ 2,172	$ —	$ 4,909
License revenue	396	—	1,752	—
Total revenues	396	2,172	1,752	4,909
Operating expenses:				
Research and development	32,489	25,544	85,743	56,692
General and administrative	8,195	6,528	24,401	18,165
Total operating expenses	40,684	32,072	110,144	74,857
Loss from operations	(40,288)	(29,900)	(108,392)	(69,948)
Other income/(expense):				
Interest and investment income	3,658	4,445	10,852	13,375
Gain on investment in former related party	227	307	254	307
Loss on currency exchange, net	(2)	(48)	(54)	(91)
Other (expense)/income	(360)	22	(565)	(172)
Total other income	3,523	4,726	10,487	13,419
Net loss	$ (36,765)	$ (25,174)	$ (97,905)	$ (56,529)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.97)	$ (0.74)	$ (2.68)	$ (1.73)
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	37,794,088	34,236,728	36,476,370	32,614,771
Comprehensive loss:				
Net loss	$ (36,765)	$ (25,174)	$ (97,905)	$ (56,529)
Other comprehensive income:				
Unrealized gain on marketable securities	65	718	57	634
Total other comprehensive income	65	718	57	634
Total comprehensive loss	$ (36,700)	$ (24,456)	$ (97,848)	$ (55,895)