



DIANTHUS THERAPEUTICS

Dianthus Therapeutics Highlights Recent Business Achievements and Reports Q2 Financial Results

August 07, 2025

Phase 2 MaGic trial of claseprubart (DNTH103) in generalized Myasthenia Gravis (gMG) top-line results anticipated in September 2025; the first of three catalysts for the claseprubart neuromuscular franchise by YE'26

Phase 3 CAPTIVATE trial of claseprubart in Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) ongoing; interim responder analysis anticipated in 2H'26

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

\$309.1 million of cash provides runway into 2H'27

NEW YORK and WALTHAM, Mass., Aug. 07, 2025 (GLOBE NEWSWIRE) -- Dianthus Therapeutics, Inc. (Nasdaq: DNTH), a clinical-stage biotechnology company dedicated to advancing the next generation of antibody complement therapeutics to treat severe autoimmune diseases, today reported financial results for the second quarter ending June 30, 2025, and provided an update on recent business achievements.

"We look forward to reporting top-line Phase 2 results from our MaGic trial with claseprubart in gMG in September. We believe the multibillion-dollar gMG market has significant potential to expand, as only approximately 10% of AChR+ patients in the U.S. are currently on FcRn or complement therapies today," said Marino Garcia, Chief Executive Officer of Dianthus Therapeutics. "Our recently completed quantitative market research with gMG treating neurologists in the U.S. clearly highlights their desire for new, improved therapies, specifically those with greater durability of symptom control, a differentiated safety profile by eliminating the boxed warning and REMS of C5 inhibitors, and a more convenient, patient-friendly delivery like an infrequent, self-administered autoinjector. We believe claseprubart has the potential to effectively address these unmet needs and help expand the use of biologics earlier in the treatment paradigm with patients that would otherwise delay the use of more burdensome biologics."

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 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)

- **Top-line Phase 2 MaGic gMG trial results anticipated in September:** The [MaGic trial](#) is a global, randomized, double-blind, placebo-controlled Phase 2 trial in patients with gMG who are acetylcholine receptor (AChR) antibody positive. As previously announced in May, [enrollment in this trial was completed](#) with 65 patients, exceeding the target of 60.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

- **Phase 3 CAPTIVATE CIDP trial ongoing:** The [CAPTIVATE trial](#) is a single, global, two-part, randomized withdrawal Phase 3 trial in patients with CIDP, and it remains on track for an interim responder analysis in 2H'26. 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 ongoing:** The [MoMeNtum trial](#) is a global, randomized, double-blind, placebo-controlled Phase 2 trial in patients with MMN, and it remains on track to report top-line results in 2H'26.

Corporate Updates

- The International Nonproprietary Name (INN) has been finalized and DNTH103, a potentially best-in-class investigational classical pathway inhibitor, is now called claseprubart.
- On May 22, 2025, Simon Read, Ph.D., [joined the Company's Board of Directors](#). Dr. Read is a serial entrepreneur with more than 30 years of biopharmaceutical experience. He served as CEO and Founder of Mariana Oncology until its acquisition by Novartis in 2024 and CSO of Ra Pharma until its acquisition by UCB in 2020.

Second-Quarter 2025 Financial Results

- **Cash Position** - \$309.1 million of cash, cash equivalents and investments as of June 30, 2025 is projected to provide runway into the second half of 2027.

- **R&D Expenses** - Research and development (R&D) expenses for the quarter ended June 30, 2025 were \$26.3 million, inclusive of \$2.5 million of stock-based compensation, compared to \$18.1 million for the quarter ended June 30, 2024, which included \$1.4 million of stock-based compensation. This increase in R&D expenses was primarily driven by higher clinical costs, chemistry, manufacturing and controls (CMC) 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, 2025 totaled \$8.9 million, inclusive of stock-based compensation of \$3.2 million, compared to \$6.0 million for the quarter ended June 30, 2024, which included \$1.8 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 June 30, 2025 was \$31.6 million or \$0.88 per share (basic and diluted) compared to \$17.6 million or \$0.51 per share (basic and diluted) for the quarter ended June 30, 2024.
- **Additional Information** - For additional information on the Company's financial results for the quarter ended June 30, 2025, please refer to the Form 10-Q filed with the SEC.

About Claseprubart

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, self-administered injection dosed as infrequently as once every two weeks. 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 anticipates reporting top-line data from the Phase 2 MaGic trial in generalized Myasthenia Gravis in September 2025, the interim responder analysis of the Phase 3 CAPTIVATE trial in Chronic Inflammatory Demyelinating Polyneuropathy in 2H'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 Dianthus Therapeutics

Dianthus Therapeutics is a clinical-stage biotechnology company dedicated to designing and delivering novel, best-in-class monoclonal antibodies with improved selectivity and potency. Based in New York City and Waltham, Mass., Dianthus is comprised of an experienced team of biotech and pharma executives who are leading the development of next-generation antibody complement therapeutics, aiming 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 any developments or results in connection therewith, including the target product profile and administration of claseprubart; the anticipated timing of the initiation and results from those studies and trials; 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 the market and potential opportunities for complement therapies, in particular with respect to claseprubart. Claseprubart is an investigational agent that is not approved as a therapy 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 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 the Company's other compounds may take longer and/or cost more than planned, that the Company may be unable to successfully complete the clinical development of the Company's compounds, that the Company 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.

Contact

Jennifer Davis Ruff
Dianthus Therapeutics
jdavisruff@dianthustx.com

DIANTHUS THERAPEUTICS, INC.

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

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 13,237	\$ 22,792
Short-term investments	244,152	252,449
Receivable from former related party	—	807
Accounts receivable, net	39	—
Prepaid expenses and other current assets	6,177	4,856
Total current assets	263,605	280,904
Long-term investments	51,705	81,728
Property and equipment, net	207	194
Right-of-use operating lease assets	1,378	1,553
Other assets and restricted cash	9,181	9,629
Total assets	<u>\$ 326,076</u>	<u>\$ 374,008</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 5,404	\$ 4,579
Accrued expenses	13,999	13,074
Current portion of deferred revenue	479	479
Current portion of operating lease liabilities	211	320
Total current liabilities	20,093	18,452
Deferred revenue	1,785	1,908
Long-term operating lease liabilities	1,119	1,171
Total liabilities	<u>22,997</u>	<u>21,531</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	32	31
Additional paid-in capital	538,481	526,732
Accumulated deficit	(235,532)	(174,392)
Accumulated other comprehensive income	98	106
Total stockholders' equity	<u>303,079</u>	<u>352,477</u>
Total liabilities and stockholders' equity	<u>\$ 326,076</u>	<u>\$ 374,008</u>

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,	
	2025	2024	2025	2024
Revenues:				
License revenue – former related party	\$ —	\$ 1,863	\$ —	\$ 2,737
License revenue	193	—	1,356	—
Total revenues	193	1,863	1,356	2,737
Operating expenses:				
Research and development	26,251	18,070	53,254	31,148
General and administrative	8,869	5,997	16,206	11,637
Total operating expenses	<u>35,120</u>	<u>24,067</u>	<u>69,460</u>	<u>42,785</u>
Loss from operations	(34,927)	(22,204)	(68,104)	(40,048)
Other income/(expense):				
Interest and investment income	3,403	4,708	7,194	8,930
Gain on investment in former related party	32	—	27	—
Loss on currency exchange, net	(30)	(31)	(52)	(43)
Other expense	(107)	(80)	(205)	(194)
Total other income	<u>3,298</u>	<u>4,597</u>	<u>6,964</u>	<u>8,693</u>
Net loss	<u>\$ (31,629)</u>	<u>\$ (17,607)</u>	<u>\$ (61,140)</u>	<u>\$ (31,355)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.88)</u>	<u>\$ (0.51)</u>	<u>\$ (1.71)</u>	<u>\$ (0.99)</u>
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	<u>35,822,308</u>	<u>34,227,038</u>	<u>35,806,591</u>	<u>31,794,881</u>

Comprehensive loss:				
Net loss	\$ (31,629)	\$ (17,607)	\$ (61,140)	\$ (31,355)
Other comprehensive loss:				
Unrealized loss on marketable securities	<u>(172)</u>	<u>(10)</u>	<u>(8)</u>	<u>(84)</u>
Total other comprehensive loss	<u>(172)</u>	<u>(10)</u>	<u>(8)</u>	<u>(84)</u>
Total comprehensive loss	<u>\$ (31,801)</u>	<u>\$ (17,617)</u>	<u>\$ (61,148)</u>	<u>\$ (31,439)</u>