Dianthus Therapeutics Highlights Recent Business Achievements and Reports Q2 Financial Results

August 08, 2024

Phase 2 MaGic trial in generalized Myasthenia Gravis (gMG) ongoing; top-line results anticipated in 2H'25

IND for Phase 2 MoMeNtum trial in Multifocal Motor Neuropathy (MMN) cleared by FDA in June; top-line results anticipated in 2H'26

Phase 2 trial in Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) to initiate 2H'24 Approximately $361 million of cash provides runway into 2H'27

NEW YORK and WALTHAM, Mass., Aug. 08, 2024 (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, 2024, and provided an update on recent business achievements.

"The second quarter of 2024 highlighted the Dianthus team's continued focus on execution and operational excellence as we advance our clinical programs for DNTH103 in generalized Myasthenia Gravis, Multifocal Motor Neuropathy, and Chronic Inflammatory Demyelinating Polyneuropathy," said Marino Garcia, Chief Executive Officer of Dianthus Therapeutics. "We believe DNTH103 may be a potentially best-in-class, potent classical complement pathway inhibitor with infrequent, subcutaneous self-administration and a differentiated safety profile across our three initial indications of gMG, MMN and CIDP. We continue to be confident in the pipeline-in-a-product potential of DNTH103 across multiple autoimmune diseases, supported by our proof-of-concept *in vitro* data presented at EAN and recent competitor clinical data that further validate targeting the classical pathway and active C1s."

Recent Business Highlights and Upcoming Milestones

DNTH103

DNTH103 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. DNTH103 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. DNTH103 has the potential to be a best-in-class pipeline-in-a-product across a range of autoimmune disorders with high unmet need.

- **Phase 2 MaGic gMG trial ongoing:** The MaGic trial is a global, randomized, double-blind, placebo-controlled Phase 2 study in patients with gMG who are acetylcholine receptor (AChR) antibody positive. Initial top-line results from this trial are anticipated to be available in the second half of 2025.
- **Phase 2 IND cleared for MoMeNtum MMN trial:** The MoMeNtum trial is a global, randomized, double-blind, placebo-controlled Phase 2 study designed to evaluate the safety, tolerability, and efficacy of DNTH103 in patients with MMN. Initial top-line results from this trial are anticipated to be available in the second half of 2026.
- **One oral presentation highlighted DNTH103 at AAN 2024:** An oral presentation at the American Academy of Neurology (AAN) Annual Meeting in Denver highlighted preclinical and *in vitro* data describing the differentiated safety profile and neurotransmission activity of DNTH103 and a review of previously released Phase 1 healthy volunteer data.
- **Two DNTH103 posters presented at EAN 2024:** Two poster presentations at the 10th Congress of the European Academy of Neurology (EAN) in Helsinki highlighted preclinical and *in vitro* data describing the potentially differentiated profile of DNTH103 in disease models of gMG and CIDP, in addition to head-to-head affinity and pharmacodynamic (PD) potency data for DNTH103 compared to riliprubart.
- **Planning for CIDP Phase 2 trial ongoing:** Dianthus remains on track to initiate a Phase 2 trial of DNTH103 in CIDP in the second half of 2024.

Corporate

- Effective July 1, 2024, Alison Lawton was appointed Chair of the Dianthus Therapeutics Board of Directors. She succeeded Lonnie Moulder, who remains on the Board of Directors.

Second-Quarter 2024 Financial Results

- **Cash Position** - $360.7 million of cash, cash equivalents and short-term investments as of June 30, 2024 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, 2024 were $18.1 million, inclusive of $1.4 million of stock-based compensation, compared to $10.3 million for the quarter ended June 30, 2023, which included $0.1 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 DNTH103 Phase 1 and Phase 2 development.
- **G&A Expenses** - General and administrative (G&A) expenses for the quarter ended June 30, 2024 totaled $6.0 million, inclusive of stock-based compensation of $1.8 million, compared to $2.5 million for the quarter ended June 30, 2023, which included $0.3 million of stock-based compensation. This increase in G&A expenses was primarily due to higher headcount and consulting and professional fees.
- **Net Loss** - Net loss for the quarter ended June 30, 2024 was $17.6 million or $0.51 per share (basic and diluted) compared to $11.1 million or $12.73 per share (basic and diluted) for the quarter ended June 30, 2023.

About DNTH103

DNTH103 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. DNTH103 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, DNTH103 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 DNTH103 following the initiation of the Phase 2 MaGic trial in generalized Myasthenia Gravis in 1Q'24, regulatory clearance for Multifocal Motor Neuropathy in 2Q'24, and planned initiation of a Phase 2 trial in Chronic Inflammatory Demyelinating Polyneuropathy in 2H'24.

DNTH103 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 DNTH103, and any developments or results in connection therewith, including the target product profile of DNTH103; 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 DNTH103. 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 DNTH103 and data from clinical trials may not be predictive of the results or success of ongoing or later clinical trials, that the development of DNTH103 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, 2023, 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, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 314,169	$ 132,325
Short-term investments	46,538	41,393
Receivable from related party	840	294
Unbilled receivable from related party	835	184
Prepaid expenses and other current assets	3,305	3,255
Total current assets	365,687	177,451
Property and equipment, net	189	185
Right-of-use operating lease assets	442	615
Other assets and restricted cash	2,641	1,154
Total assets	$ 368,959	$ 179,405
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,695	$ 2,610

Accrued expenses	5,857	6,504
Current portion of deferred revenue – related party	100	100
Current portion of operating lease liabilities	377	417
Total current liabilities	10,029	9,631
Deferred revenue – related party	682	736
Long-term operating lease liabilities	30	168
Total liabilities	10,741	10,535
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	-	-
Common stock	29	15
Additional paid-in capital	479,004	258,231
Accumulated deficit	(120,778)	(89,423)
Accumulated other comprehensive income/(loss)	(37)	47
Total stockholders' equity	358,218	168,870
Total liabilities and stockholders' equity	$ 368,959	$ 179,405

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,	
	2024	2023	2024	2023
Revenues:				
License revenue - related party	$ 1,863	$ 969	$ 2,737	$ 1,445
Operating expenses:				
Research and development	18,070	10,253	31,148	16,100
General and administrative	5,997	2,492	11,637	4,804
Total operating expenses	24,067	12,745	42,785	20,904
Loss from operations	(22,204)	(11,776)	(40,048)	(19,459)
Other income/(expense):				
Interest income	4,708	687	8,930	1,293
Loss on currency exchange, net	(31)	(28)	(43)	(37)
Other expense	(80)	(23)	(194)	(26)
Total other income	4,597	636	8,693	1,230
Net loss	$ (17,607)	$ (11,140)	$ (31,355)	$ (18,229)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.51)	$ (12.73)	$ (0.99)	$ (20.84)
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	34,227,038	874,900	31,794,881	874,805
Comprehensive loss:				
Net loss	$ (17,607)	$ (11,140)	$ (31,355)	$ (18,229)
Other comprehensive (loss)/income:				
Change in unrealized (losses)/gains related to available-for-sale debt securities	(10)	38	(84)	142
Total other comprehensive (loss)/income	(10)	38	(84)	142
Total comprehensive loss	$ (17,617)	$ (11,102)	$ (31,439)	$ (18,087)