Dianthus Therapeutics Highlights Recent Business Achievements and Reports Q3 Financial Results

November 07, 2024

Initiation of a single, two-part, pivotal Phase 3 trial of DNTH103 in Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) anticipated by YE'24

Phase 2 MaGic trial of DNTH103 in generalized Myasthenia Gravis (gMG) ongoing; top-line results anticipated in 2H'25

Phase 2 MoMeNtum trial of DNTH103 in Multifocal Motor Neuropathy (MMN) ongoing; top-line results anticipated in 2H'26

Approximately $343 million of cash provides runway into 2H'27

NEW YORK and WALTHAM, Mass., Nov. 07, 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 third quarter ending September 30, 2024 and provided an update on recent business achievements.

"We are excited to expand DNTH103 beyond gMG and MMN into CIDP before year end. Like gMG and MMN, CIDP has significant unmet needs where a best-in-class, potent classical pathway inhibitor can potentially make a meaningful difference in the lives of patients. We believe this single, two-part, pivotal Phase 3 trial will support BLA filing in adult patients with CIDP and we anticipate initiating the trial by year-end 2024," said Marino Garcia, Chief Executive Officer of Dianthus Therapeutics. "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 most recently presented at AANEM and ICNMD and competitor clinical data that further validate targeting the classical pathway and active C1s."

DNTH103 Clinical Development

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.

Generalized Myasthenia Gravis (gMG)

- **Phase 2 MaGic gMG trial ongoing:** 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, and it remains on track to report top-line results in 2H'25.
- **Poster presentations at AANEM and ICNMD:** Encore poster presentations at the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting in Savannah, Georgia and at the 18th International Congress on Neuromuscular Diseases (ICNMD) in Perth, Australia highlighted preclinical and *in vitro* data describing the potentially differentiated profile of DNTH103 in a disease model of gMG.

Multifocal Motor Neuropathy (MMN)

- **Phase 2 MoMeNtum MMN trial ongoing:** The MoMeNtum trial is a global, randomized, double-blind, placebo-controlled Phase 2 trial designed to evaluate the safety, tolerability, and efficacy of DNTH103 in patients with MMN, and it remains on track to report top-line results in 2H'26.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

- **Initiation of a Phase 3 trial in CIDP anticipated by YE'24:** Dianthus plans to initiate a single, two-part, randomized withdrawal Phase 3 trial of DNTH103 in CIDP by YE'24. In the open label Part A of this trial, participants will be administered a loading dose followed by 300mg DNTH103 administered every 2 weeks (Q2W) via subcutaneous (S.C.) injection for up to 13 weeks. Part A includes an interim responder analysis of a pre-defined number of participants. Only participants who respond to DNTH103 in Part A will be randomized into Part B, a double-blind, placebo-controlled treatment period of up to 52 weeks, where they will be assessed for prevention of relapse, safety and tolerability, followed by an open-label extension period. The Company believes this single pivotal trial will support BLA filing in adult patients with CIDP. Additional details regarding Phase 3 trial design and timelines will be provided by YE'24.
- **Poster presentations at AANEM and ICNMD:** Encore poster presentations at the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting in Savannah, Georgia and at the 18th International Congress on Neuromuscular Diseases (ICNMD) in Perth, Australia highlighted preclinical and *in vitro* data describing the potentially differentiated profile of DNTH103 in a disease model of CIDP, in addition to head-to-head affinity and pharmacodynamic (PD) potency data for DNTH103 compared to riliprubart.

Corporate Updates

- Effective September 16, 2024, Steven Romano, M.D., was appointed to the Dianthus Therapeutics Board of Directors. Dr. Romano is a pharmaceutical executive with more than 28 years of experience in drug development across a wide range of therapeutic and disease areas.

He currently serves as Executive Vice President, Chief Research and Development Officer at Silence Therapeutics.

Third-Quarter 2024 Financial Results

- **Cash Position** - $342.6 million of cash, cash equivalents and investments as of September 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 September 30, 2024 were $25.5 million, inclusive of $1.7 million of stock-based compensation, compared to $8.0 million for the quarter ended September 30, 2023, which included $0.4 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 DNTH103 Phase 2 and Phase 3 development.
- **G&A Expenses** - General and administrative (G&A) expenses for the quarter ended September 30, 2024 totaled $6.5 million, inclusive of stock-based compensation of $2.2 million, compared to $8.7 million for the quarter ended September 30, 2023, which included $0.8 million of stock-based compensation. This decrease in G&A expenses was primarily due to lower personnel costs.
- **Net Loss** - Net loss for the quarter ended September 30, 2024 was $25.2 million or $0.74 per share (basic and diluted) compared to $14.8 million or $3.78 per share (basic and diluted) for the quarter ended September 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 and the Phase 2 MoMeNtum trial in Multifocal Motor Neuropathy in 3Q'24, and initiation of a Phase 3 trial in Chronic Inflammatory Demyelinating Polyneuropathy anticipated by YE'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.

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

	September 30, 2024	December 31, 2023
Assets		
Current assets:		

Cash and cash equivalents	$ 33,671	$ 132,325
Short-term investments	247,452	41,393
Receivable from related party	1,390	294
Unbilled receivable from related party	1,293	184
Prepaid expenses and other current assets	3,683	3,255
Total current assets	287,489	177,451
Long-term investments	61,482	—
Property and equipment, net	189	185
Right-of-use operating lease assets	352	615
Other assets and restricted cash	4,736	1,154
Total assets	$ 354,248	$ 179,405
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,572	$ 2,610
Accrued expenses	7,727	6,504
Current portion of deferred revenue - related party	100	100
Current portion of operating lease liabilities	311	417
Total current liabilities	15,710	9,631
Deferred revenue - related party	640	736
Long-term operating lease liabilities	—	168
Total liabilities	16,350	10,535
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	29	15
Additional paid-in capital	483,140	258,231
Accumulated deficit	(145,952)	(89,423)
Accumulated other comprehensive income	681	47
Total stockholders' equity	337,898	168,870
Total liabilities and stockholders' equity	$ 354,248	$ 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 September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenues:				
License revenue - related party	$ 2,172	$ 924	$ 4,909	$ 2,369
Operating expenses:				
Research and development	25,544	7,960	56,692	24,060
General and administrative	6,528	8,723	18,165	13,527
Total operating expenses	32,072	16,683	74,857	37,587
Loss from operations	(29,900)	(15,759)	(69,948)	(35,218)
Other income/(expense):				
Interest income	4,445	1,027	13,375	2,320
Gain on investment in related party	307	—	307	—
Loss on currency exchange, net	(48)	(16)	(91)	(53)
Other income/(expense)	22	(15)	(172)	(41)
Total other income	4,726	996	13,419	2,226
Net loss	$ (25,174)	$ (14,763)	$ (56,529)	$ (32,992)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.74)	$ (3.78)	$ (1.73)	$ (17.40)
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	34,236,728	3,906,886	32,614,771	1,896,605
Comprehensive loss:				
Net loss	$ (25,174)	$ (14,763)	$ (56,529)	$ (32,992)
Other comprehensive income:				
Change in unrealized gains related to available for-sale debt securities	718	15	634	157
Total other comprehensive income	718	15	634	157

Total comprehensive loss	$ (24,456)	$ (14,748)	$ (55,895)	$ (32,835)