Dianthus Therapeutics Highlights Recent Business Achievements and Reports Q1 Financial Results

May 09, 2024

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

Building a neuromuscular franchise with DNTH103; Phase 2 trial in Multifocal Motor Neuropathy (MMN) to initiate 2Q'24 and Phase 2 trial in Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) to initiate 2H'24

$377 million of cash, including proceeds from a successful $230 million PIPE financing completed in January 2024, provides runway into 2H 2027

NEW YORK and WALTHAM, Mass., May 09, 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 first quarter ending March 31, 2024, and provided an update on recent business achievements.

"The first quarter of 2024 was highlighted by the initiation of our Phase 2 MaGic trial of DNTH103 for patients with gMG. We are also encouraged by recently published proof-of-concept clinical trial data that continues to validate active C1s as a target for treating CIDP, enhancing our confidence in the pipeline-in-a-product potential for DNTH103 across multiple autoimmune diseases," said Marino Garcia, Chief Executive Officer of Dianthus Therapeutics. "We remain on track to initiate our Phase 2 clinical trials in MMN and CIDP this year as well."

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 initiated in February:** The MaGic trial is a global, randomized, double-blind, placebo-controlled Phase 2 study in up to 60 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.
- **Oral presentation at the American Academy of Neurology (AAN) 2024 Annual Meeting on April 15, 2024:** An oral presentation describing key attributes of DNTH103 and its differentiation in gMG was presented at the AAN 2024 Annual Meeting.
- **Planning for MMN and CIDP Phase 2 trials ongoing:** Dianthus expects to initiate additional Phase 2 trials of DNTH103 in MMN in the second quarter of 2024 and CIDP in the second half of 2024.

Corporate

- Dianthus successfully completed a private investment in public equity ("PIPE") financing in January 2024 that resulted in gross proceeds of approximately $230 million. This PIPE financing included participation from both new and existing investors, including Bain Capital Life Sciences, RA Capital Management, Avidity Partners, Fairmount, Venrock Healthcare Capital Partners, RTW Investments, Great Point Partners LLC, Octagon Capital, Janus Henderson Investors, Vestal Point Capital, Logos Capital, Catalio Capital Management, Woodline Partners LP, Ally Bridge Group, Tellus BioVentures, StemPoint Capital LP and a large investment management firm.

First-Quarter 2024 Financial Results

- **Cash Position** - $377.0 million of cash, cash equivalents and short-term investments as of March 31, 2024 is projected to provide runway into 2H 2027.
- **R&D Expenses** - Research and development (R&D) expenses for the quarter ended March 31, 2024 were $13.1 million, inclusive of $0.8 million of stock-based compensation, compared to $5.8 million for the quarter ended March 31, 2023, which included $0.2 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, partially offset by lower pre-clinical costs.
- **G&A Expenses** - General and administrative (G&A) expenses for the quarter ended March 31, 2024 totaled $5.6 million, inclusive of stock-based compensation of $1.2 million, compared to $2.3 million for the quarter ended March 31, 2023, which included $0.3 million of stock-based compensation. This increase in G&A expenses was primarily due to higher headcount and professional fees.
- **Net Loss** - Net loss for the quarter ended March 31, 2024 was $13.7 million or $0.54 net loss per share (basic and diluted) compared to $7.1 million or $8.10 net loss per share (basic and diluted) for the quarter ended March 31, 2023.
- **Additional Information** - For additional information on the Company's financial results for the quarter ended March 31, 2024, please refer to the Form 10-Q filed with the SEC.

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 has initiated a Phase 2 trial in generalized Myasthenia Gravis and plans to initiate additional Phase 2 trials in other neuromuscular indications, including Multifocal Motor Neuropathy and Chronic Inflammatory Demyelinating Polyneuropathy, in 2024.

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.

Dianthus has initiated a Phase 2 trial of DNTH103, a potential best-in-class active C1s inhibitor, in generalized Myasthenia Gravis and plans to initiate additional Phase 2 trials in other neuromuscular indications, including Multifocal Motor Neuropathy and Chronic Inflammatory Demyelinating Polyneuropathy, in 2024.

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)
(unaudited)

	March 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 329,724	$ 132,325
Short-term investments	47,312	41,393
Receivable from related party	435	294
Unbilled receivable from related party	441	184
Prepaid expenses and other current assets	3,014	3,255
Total current assets	380,926	177,451
Property and equipment, net	195	185
Right-of-use operating lease assets	530	615
Other assets and restricted cash	811	1,154
Total assets	$ 382,462	$ 179,405
LIABILITIES AND STOCKHOLDERS’ EQUITY		
Current liabilities:		
Accounts payable	$ 2,612	$ 2,610
Accrued expenses	5,847	6,504
Current portion of deferred revenue – related party	100	100
Current portion of operating lease liabilities	400	417

Total current liabilities	8,959	9,631
Deferred revenue – related party	719	736
Long-term operating lease liabilities	97	168
Total liabilities	9,775	10,535
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	-	-
Common stock	29	15
Additional paid-in capital	475,856	258,231
Accumulated deficit	(103,171)	(89,423)
Accumulated other comprehensive (loss)/income	(27)	47
Total stockholders' equity	372,687	168,870
Total liabilities and stockholders' equity	$ 382,462	$ 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 March 31,	
	2024	**2023**
Revenues:		
License revenue – related party	$ 874	$ 476
Operating expenses:		
Research and development	13,078	5,847
General and administrative	5,640	2,312
Total operating expenses	18,718	8,159
Loss from operations	(17,844)	(7,683)
Other income/(expense):		
Interest income	4,222	606
Loss on currency exchange, net	(12)	(9)
Other expense	(114)	(3)
Total other income	4,096	594
Net loss	$ (13,748)	$ (7,089)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.54)	$ (8.10)
Weighted-average number of common shares outstanding, used in computing net loss per common share, basic and diluted	25,665,475	874,709
Comprehensive loss:		
Net Loss	$ (13,748)	$ (7,089)
Other comprehensive (loss)/income:		
Change in unrealized (losses)/gains related to available-for-sale debt securities	(74)	104
Total other comprehensive (loss)/income	(74)	104
Total comprehensive loss	$ (13,822)	$ (6,985)