Dianthus Therapeutics Highlights Recent Business Achievements and Reports Q4 and FY2023 Financial Results

March 21, 2024

Phase 2 MaGic trial in generalized Myasthenia Gravis (gMG) initiated in Q1'24 with top-line results anticipated in 2H'25

$389 million of pro forma cash, including $216 million of net proceeds from a successful PIPE financing completed in January 2024, provides runway into 2H 2027

Building a neuromuscular franchise with DNTH103 through additional planned Phase 2 trials in Multifocal Motor Neuropathy (MMN) and Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) starting in 2024

NEW YORK and WALTHAM, Mass., March 21, 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 fourth quarter and full year ending December 31, 2023, and provided an update on recent business achievements.

"2023 was a transformative year for Dianthus, highlighted by becoming a public company, closing on a financing, and reporting out positive top-line data from our Phase 1 study that supports DNTH103 as a potentially best-in-class complement inhibitor," said Marino Garcia, Chief Executive Officer of Dianthus Therapeutics. "DNTH103 is an investigational potent active C1s inhibitor of the classical pathway with an extended half-life that has the potential to offer a more convenient, safer treatment option for patients with infrequent, subcutaneous self-administration. With our Phase 2 MaGic trial now underway in patients with generalized Myasthenia Gravis (gMG) and cash runway into the second half of 2027 following successful completion of a $230 million PIPE financing in January, we are very well positioned to build a neuromuscular franchise around DNTH103 and reach key data readouts in our three initial indications of gMG, Multifocal Motor Neuropathy (MMN) and Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)."

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 will be presented by Sankalp Gokhale, M.D., Dianthus Therapeutics' Head of Clinical Development, Neurology, at the AAN 2024 Annual Meeting, being held April 13-18, 2024, in Denver and online. (Program number S15.001)
- **Planning for MMN and CIDP Phase 2 trials ongoing:** Dianthus expects to initiate additional Phase 2 trials of DNTH103 in Multifocal Motor Neuropathy (MMN) in the second quarter of 2024 and Chronic Inflammatory Demyelinating Polyneuropathy (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.
- Jeffrey Stavenhagen, Ph.D., was appointed as Chief Scientific Officer in November 2023 to lead the Company's discovery and preclinical research and translational science initiatives.

Full-Year 2023 Financial Results

- **Cash Position** – $389 million of pro forma cash includes cash, cash equivalents and short-term investments as of December 31, 2023 of $173.7 million plus estimated net proceeds of approximately $216 million from the PIPE offering, which closed in January 2024. Net proceeds from the PIPE are unaudited and preliminary.
- **R&D Expenses** – Research and development (R&D) expenses for the year ended December 31, 2023 were $32.8 million, inclusive of $0.9 million of stock-based compensation, compared to $29.4 million for the year ended December 31, 2022, which included $0.4 million of stock-based compensation. This increase in R&D expenses was primarily driven by increased clinical costs and higher headcount to support DNTH103 Phase 1 and Phase 2 development partially offset by lower chemistry, manufacturing and controls (CMC) costs.
- **G&A Expenses** – General and administrative (G&A) expenses for the year ended December 31, 2023 were $18.2 million, inclusive of stock-based compensation of $2.0 million, compared to $6.7 million for the year ended December 31, 2022, which included $1.1 million of stock-based compensation. This increase in G&A expenses was primarily due to costs related to the reverse merger with Magenta and higher headcount and professional fees.
- **Net Loss** – Net loss for the year ended December 31, 2023 was $43.6 million or $8.45 net loss per share (basic and diluted) compared to

$28.5 million or $32.57 net loss for the year ended December 31, 2022.

- **Additional Information** – For additional information on the Company's financial results for the year ended December 31, 2023, please refer to the Form 10-K 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 "Risk Factors" section of our 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.
Consolidated Balance Sheets
(in thousands, except share and per share data)
(unaudited)

ASSETS	**December 31, 2023**	**December 31, 2022**
Current assets:		
Cash and cash equivalents	$ 132,325	$ 15,365
Short-term investments	41,393	60,125
Receivable from related party	294	4,700
Unbilled receivable from related party	184	938
Prepaid expenses and other current assets	3,255	905
Total current assets	177,451	82,033
Property and equipment, net	185	142
Right-of-use operating lease assets	615	814
Other assets and restricted cash	1,154	121

Total assets	$ 179,405	$ 83,110
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY/(DEFICIT)		
Current liabilities:		
Accounts payable	$ 2,610	$ 1,167
Accrued expenses	6,504	6,608
Current portion of deferred revenue – related party	100	100
Current portion of operating lease liabilities	417	350
Total current liabilities	9,631	8,225
Deferred revenue – related party	736	791
Long-term operating lease liabilities	168	438
Total liabilities	10,535	9,454
Commitments and contingencies		
Convertible preferred stock	-	118,024
Stockholders' equity/(deficit):		
Preferred stock	-	-
Common stock	15	-
Additional paid-in capital	258,231	1,661
Accumulated deficit	(89,423)	(45,868)
Accumulated other comprehensive income/(loss)	47	(161)
Total stockholders' equity/(deficit)	168,870	(44,368)
Total liabilities, convertible preferred stock and stockholders' equity/(deficit)	$ 179,405	$ 83,110

Dianthus Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Revenues:				
License revenue – related party	$ 457	$ 1,175	$ 2,826	$ 6,417
Operating expenses:				
Research and development	8,781	9,831	32,841	29,379
General and administrative	4,632	2,037	18,159	6,743
Total operating expenses	13,413	11,868	51,000	36,122
Loss from operations	(12,956)	(10,693)	(48,174)	(29,705)
Other income/(expense):				
Interest income	2,444	640	4,764	1,145
(Loss)/gain on currency exchange, net	(32)	(20)	(85)	136
Other expense	(19)	(43)	(60)	(52)
Total other income	2,393	577	4,619	1,229
Net loss	$ (10,563)	$ (10,116)	$ (43,555)	$ (28,476)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.71)	$ (11.57)	$ (8.45)	$ (32.57)
Weighted-average number of shares of common stock outstanding, used in computing net loss per share of common stock, basic and diluted	14,817,676	874,519	5,153,423	874,234
Comprehensive loss:				
Net Loss	$ (10,563)	$ (10,116)	$ (43,555)	$ (28,476)
Other comprehensive income/(loss):				
Change in unrealized gains/(losses) related to available-for-sale debt securities	51	(11)	208	(161)
Total other comprehensive income/(loss)	51	(11)	208	(161)
Total comprehensive loss	$ (10,512)	$ (10,127)	$ (43,347)	$ (28,637)