MetaVia Reports Year End 2024 Financial Results and Provides Corporate Update

March 20, 2025

Top-Line Data From MAD Part 2 of the Phase 1 Trial of DA-1726 Expected in April of 2025

Announced Positive Top-Line 16-Week Results from the Phase 2a Trial of DA-1241 for the Treatment of MASH, in December, Demonstrating Direct Hepatic Action in Addition to Its Glucose Lowering Effect

$16.0 Million in Cash at End of Fourth Quarter Expected to Fund the Company Into the Third Quarter of 2025

CAMBRIDGE, Mass., March 20, 2025 /PRNewswire/ -- **MetaVia Inc.** (Nasdaq: MTVA), a clinical-stage biotechnology company focused on transforming cardiometabolic diseases, today announced financial results for the year ended December 31, 2024 and provided a corporate strategic update.

"Throughout 2024, we made exceptional progress advancing the clinical development of our two, next generation cardiometabolic assets. We eagerly anticipate reporting top-line results from the expanded cohorts of the multiple ascending dose (MAD) Part 2 of our Phase 1 clinical trial of DA-1726, a novel, dual oxyntomodulin (OXM) analog agonist that functions as a glucagon-like peptide-1 receptor (GLP1R) and glucagon receptor (GCGR), for the treatment of obesity," stated Hyung Heon Kim, President and Chief Executive Officer of MetaVia. "In light of the strong safety profile from the planned cohorts of the SAD Part 1 and MAD Part 2 of the study, we are adding additional cohorts to further explore the maximum tolerated dose, which will allow us to realize the full potential of DA-1726. It is important to note that many patients using current GLP-1 agonists discontinue treatment due to tolerability issues, with 20% to 30% stopping within the first two months and up to 70% discontinuing within a year. Based on the preclinical data gathered so far and DA-1726's balanced activation of GLP1R and glucagon receptors, which enhances energy expenditure, we remain confident that DA-1726 has the potential to become a best-in-class obesity drug, offering superior tolerability compared to currently marketed GLP-1 agonists and those in late-stage clinical trials. The top-line data from the MAD Part 2 study, expected shortly, will give us an early read on clinical efficacy. We remain committed to the rapid clinical development of DA-1726 and continue to plan for an early proof-of-concept study to assess the efficacy and safety of DA-1726, which is expected to commence during the fourth quarter of 2025."

Mr. Kim continued, "In December, we reported positive top-line 16-week results from the two-part Phase 2a clinical trial of DA-1241, a novel G-Protein-Coupled Receptor 119 (GPR119) agonist, in patients with presumed metabolic dysfunction-associated steatohepatitis (MASH). DA-1241 met the primary endpoint, achieving a reduction in alanine transaminase (ALT) levels through direct hepatic effects, along with key secondary endpoints, including significantly lower hemoglobin A1C (HbA1C) levels compared to placebo. These are very positive results especially given the small study size. Importantly, DA-1241 demonstrated excellent tolerability, with mostly mild adverse events and no drug-related serious adverse events in the treatment groups. Based on these findings, we remain confident that DA-1241's novel mechanism of action, which targets the inflammation associated with MASH, has the potential to result in a safe and effective treatment for this disease. We continue to conduct preclinical studies with a focus on exploring combination therapies for DA-1241, which has the potential to offer further benefits across the full spectrum of MASH. We look forward to reporting the complete data set, which we intend to present at a major medical meeting. Additionally, we anticipate scheduling an end-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) in the first half of 2025."

Fourth Quarter 2024 and Subsequent Highlights

- January 2025: Held an Advisory Committee meeting at the 9th Annual MASH-TAG 2025 Conference, to discuss the positive top-line 16-week results from the two-part Phase 2a clinical trial of DA-1241.
- December 2024: Announced positive top-line 16-week results from the two-part Phase 2a clinical trial in patients with presumed MASH. In this trial, DA-1241 (100mg) demonstrated a statistically significant reduction in ALT levels at weeks 4 and 8, with a near statistically significant reduction at week 16. Statistically significant results were also achieved in multiple secondary endpoints including reductions in controlled attenuation parameter (CAP) and HbA1c. DA-1241 demonstrated similar trends in other liver enzymes including aminotransferase (AST) and gamma-glutamyl transferase (GGT).
- November 2024: Announced a strategic realignment with a name change from "NeuroBo Pharmaceuticals, Inc." to "MetaVia Inc.", reflecting the Company's focus on cardiometabolic diseases. In parallel, the Company's common stock

began trading on the Nasdaq Stock Market under the new ticker symbol, "MTVA."
- November 2024: Announced completion of the last patient visit in the Company's two-part, Phase 2a clinical trial evaluating the efficacy and safety of DA-1241 for the treatment of patients with presumed MASH.

Anticipated Clinical Milestones

- **DA-1726 in Obesity:** Top-line data from the additional cohorts in the MAD Part 2 is expected in April of 2025. The planned Phase 1 Part 3 will evaluate early proof of concept, with the first patient expected to be enrolled during the fourth quarter of 2025, followed by an interim data readout in or around mid-2026 and top-line results are expected in the second half of 2026.
- **DA-1241 in MASH:** The full data set from the two-part Phase 2a clinical trial of DA-1241 in MASH are expected to be presented at a major medical meeting in 2025. The Company expects to have an end-of-Phase 2 meeting with the FDA in the first half of 2025.

Full Year 2024 Financial and Operating Results

- **Research and Development (R&D) Expenses** were approximately $21.6 million for the year ended December 31, 2024, as compared to approximately $9.2 million for the year ended December 31, 2023. The increase of approximately $12.4 million was primarily attributable to (i) $9.3 million in higher clinical trial expenditures, (ii) $2.5 million in higher expenditures for investigational drug manufacturing, non-clinical and preclinical costs related to expenses incurred under the Shared Services Agreement with Dong-A, and (iii) $1.2 million in higher employee compensation and benefits. These increases were partially offset by (i) $0.2 million in lower consulting expenditures and (ii) $0.4 million in lower other R&D costs.
- **General and Administrative Expenses** were approximately $7.3 million for the year ended December 31, 2024, compared to approximately $6.7 million for the year ended December 31, 2023. The increase of approximately $0.5 million was primarily due to $1.0 million in higher employee compensation and benefits, partially offset by (i) $0.4 million in lower consulting expenditures, and (ii) $0.1 million in legal and professional fees.
- **Total Operating Expenses** were approximately $28.8 million for the year ended December 31, 2024, compared to approximately $15.9 million for the year ended December 31, 2023. The approximately $12.9 million increase was attributable to higher R&D and G&A expenses.
- **Other Income** was approximately $1.2 million for the year ended December 31, 2024, compared to approximately $3.4 million for the year ended December 31, 2023. The decrease of approximately $2.2 million was primarily attributable to a $2.7 million lower gain related to the change in fair value of warrant liabilities due to warrant exercises in 2023 and the impact of the common stock's declining stock price during the last few years, partially offset by $0.5 million in higher interest income primarily due to higher average invested amounts in 2024.
- **Net Loss** for the year ended December 31, 2024, was $27.6 million, or $3.56 per basic and diluted share, based on 7,757,128 weighted average shares of common stock outstanding, compared with a net loss of $12.5 million, or $2.46 per basic and diluted share, based on 5,071,101 weighted average shares of common stock outstanding for the year ended December 31, 2023.
- **Cash** was $16.0 million as of December 31, 2024, compared with $22.4 million as of December 31, 2023. The company expects its cash position will be adequate to fund operations into the third quarter of 2025.

About MetaVia
MetaVia Inc. is a clinical-stage biotechnology company focused on transforming cardiometabolic diseases. The company is currently developing DA-1726 for the treatment of obesity, and is developing DA-1241 for the treatment of Metabolic Dysfunction-Associated Steatohepatitis (MASH). DA-1726 is a novel oxyntomodulin (OXM) analogue that functions as a glucagon-like peptide-1 receptor (GLP1R) and glucagon receptor (GCGR) dual agonist. OXM is a naturally-occurring gut hormone that activates GLP1R and GCGR, thereby decreasing food intake while increasing energy expenditure, thus potentially resulting in superior body weight loss compared to selective GLP1R agonists. DA-1241 is a novel G-protein-coupled receptor 119 (GPR119) agonist that promotes the release of key gut peptides GLP-1, GIP, and PYY. In pre-clinical studies, DA-1241 demonstrated a positive effect on liver inflammation, lipid metabolism, weight loss, and glucose metabolism, reducing hepatic steatosis, hepatic inflammation, and liver fibrosis, while also improving glucose control. In a Phase 2a clinical study, DA-1241 demonstrated direct hepatic action in addition to its glucose lowering effects.

For more information, please visit www.metaviatx.com.

Forward Looking Statements
Certain statements in this press release may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believes", "expects", "anticipates", "may", "will", "should", "seeks", "approximately", "potential", "intends", "projects", "plans", "estimates" or the negative of these words or other comparable terminology (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this press release, including, without limitation, those risks associated with MetaVia's ability to execute on its commercial strategy; our expectations regarding the sufficiency of our existing cash on hand to fund our operations; the timeline for regulatory submissions; the ability to obtain regulatory approval through the development steps of MetaVia's current and future product candidates; the ability to realize the benefits of the license agreement with Dong-A ST Co. Ltd., including the impact on future financial and operating results of

MetaVia; the cooperation of MetaVia's contract manufacturers, clinical study partners and others involved in the development of MetaVia's current and future product candidates; potential negative interactions between MetaVia's product candidates and any other products with which they are combined for treatment; MetaVia's ability to initiate and complete clinical trials on a timely basis; MetaVia's ability to recruit subjects for its clinical trials; whether MetaVia receives results from MetaVia's clinical trials that are consistent with the results of pre-clinical and previous clinical trials; impact of costs related to the license agreement, known and unknown, including costs of any litigation or regulatory actions relating to the license agreement; the effects of changes in applicable laws or regulations; the effects of changes to MetaVia's stock price on the terms of the license agreement and any future fundraising; and other risks and uncertainties described in MetaVia's filings with the Securities and Exchange Commission, including MetaVia's most recent Annual Report on Form 10-K. Forward-looking statements speak only as of the date when made. MetaVia does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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- Tables to Follow -

MetaVia Inc.
Consolidated Balance Sheets
(In thousands, except per share amounts)

	As of December 31,	
	2024	2023
Assets		
Current assets		
Cash	$ 16,017	$ 22,435
Prepaid expenses and other current assets	55	77
Total current assets	16,072	22,512
Property and equipment, net	34	46
Right-of-use asset	133	202
Other assets	21	21
Total assets	$ 16,260	$ 22,781
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,879	$ 821
Clinical trial accrued liabilities	1,696	3,033
Accrued expenses and other current liabilities	785	592
Warrant liabilities	361	658
Related party payable	1,472	789
Lease liability, short-term	78	67
Total current liabilities	8,271	5,960
Lease liability, long-term	58	136
Total liabilities	8,329	6,096
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value per share; 10,000 shares authorized and no shares issued or outstanding as of December 31, 2024 and 2023	—	—
Common stock, $0.001 par value per share, 100,000 shares authorized as of December 31, 2024 and 2023; 8,637 and 4,906 shares issued and outstanding as of December 31, 2024 and 2023, respectively	9	5
Additional paid–in capital	143,779	124,945

Accumulated deficit	(135,857)	(108,265)
Total stockholders' equity	7,931	16,685
Total liabilities and stockholders' equity	$ 16,260	$ 22,781

MetaVia Inc.

Consolidated Statements of Operations

(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2024	2023
Operating expenses		
Research and development	$ 21,553	$ 9,158
General and administrative	7,256	6,728
Total operating expenses	28,809	15,886
Loss from operations	(28,809)	(15,886)
Other income		
Change in fair value of warrant liabilities	297	2,955
Interest income	920	461
Total other income	1,217	3,416
Loss before income taxes	(27,592)	(12,470)
Provision for income taxes	—	—
Net loss and comprehensive net loss	(27,592)	(12,470)
Loss per share of common stock, basic and diluted	$ (3.56)	$ (2.46)
Weighted average shares of common stock, basic and diluted	7,757,128	5,071,101

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