



MetaVia Reports First Quarter 2025 Financial Results and Provides Corporate Update

May 14, 2025

Announced Positive Top-Line Phase 1 MAD Trial Results for DA-1726 in Obesity, Demonstrating Compelling Weight Loss and Best-in-Class Potential for Glucose Control, Waist Reduction and Tolerability

Additional Cohorts Planned to Determine Maximum Tolerated Dose of DA-1726

Successfully Completed a Private Placement Resulting in \$10 Million in Gross Proceeds

\$11.2 Million in Cash at End of First Quarter, With the Additional \$10.0 Million From the Private Placement, is Expected to Fund the Company Into 2026

CAMBRIDGE, Mass., May 14, 2025 /PRNewswire/ -- **MetaVia Inc.** (Nasdaq: MTVA), a clinical-stage biotechnology company focused on transforming cardiometabolic diseases, today announced financial results for the first quarter ended March 31, 2025, and provided a corporate strategic update.



"In the first quarter and beyond, we achieved significant progress advancing the clinical development of our two next-generation cardiometabolic assets, highlighted by the positive results from Part 2 of the multiple ascending dose (MAD) Phase 1 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. "We are now well capitalized into 2026 after a successful private placement of \$10 million in aggregate gross proceeds. The data reinforce DA-1726's strong potential as a best-in-class therapy, demonstrating, without titration, a compelling safety and tolerability profile alongside dose-dependent weight loss, reaching a maximum reduction of 6.3% and a mean reduction of 4.3% at the 32 mg dose at Day 26 (p=0.0005). Additionally, at this dose, 83% of patients reported early satiety, and waist circumference decreased by an average of 1.6 inches and a maximum of 3.9 inches by Day 33, consistent with DA-1726's glucagon-driven effects on adipose tissue observed in preclinical models. The drug also achieved fasted glucose reductions of up to -18 mg/dL without hypoglycemic events, further underscoring its potential in obesity and related metabolic diseases. Cardiovascular safety remained favorable, with no QTcF prolongation and a decrease in mean heart rate across most cohorts, despite dual receptor agonism. Gastrointestinal side effects were mild, transient, and infrequent, suggesting a potentially superior tolerability profile compared to existing GLP-1 therapies."

"Building on these encouraging findings, we are initiating higher-dose cohorts to identify the maximum tolerated dose and further unlock DA-1726's full therapeutic potential. Our aim is to deliver a safe, effective and sustainable obesity treatment for patients across a broad range of comorbidities, consistent with guidance from the U.S. Food and Drug Administration (FDA)."

Mr. Kim continued, "This month, we presented compelling 16-week results, in a late-breaking poster, from our 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) at the European Association for the Study of the Liver (EASL) Congress 2025. DA-1241 is the first oral GPR119 agonist to demonstrate both liver-protective and glucose-regulating effects. The data showed that DA-1241 significantly reduced markers of liver injury, inflammation, and fibrosis, improved non-invasive liver assessments, CAP and FAST scores, and enhanced glycemic control in patients with prediabetes or type 2 diabetes. It was well tolerated with a favorable safety profile. These findings suggest DA-1241's benefits extend beyond glycemic control, driven by its anti-inflammatory and anti-fibrotic mechanisms. We believe its novel mechanism of action supports further development as monotherapy or in combination for MASH and metabolic diseases, and we are exploring additional combination therapies. We look forward to discussing these findings with the FDA in the first half of 2025."

Fourth Quarter 2024 and Subsequent Highlights

- May 2025: Closed a private placement, which resulted in aggregate gross proceeds of \$10 million priced at-the-market under Nasdaq rules.
- May 2025: Presented data from the 16-week Phase 2a clinical trial of DA-1241 in patients with presumed MASH in a late-breaking poster presentation at EASL Congress 2025. In this trial, DA-1241 significantly decreased plasma ALT levels, with a mean reduction of 22.8 U/L at 16 weeks, Controlled Attenuation Parameter (CAP) Score improved by 23.0 dB/m,

indicating reduced liver fat content, while an improvement in FibroScan-AST (FAST) score and NIS-4, supports beneficial effects on liver health.

- April 2025: Reported additional positive top-line results from the 4-week MAD Part 2 of its Phase 1 clinical trial of DA-1726 for the treatment of obesity further demonstrating its best-in-class potential. DA-1726 demonstrated a clear dose-responsive trend in body weight reduction across the 8 mg to 32 mg range, indicating potentially greater efficacy at higher doses and longer duration of use. Additionally, body mass index, which shows body weight adjusted for height, showed a difference between the treatment group and the placebo group, which was even more pronounced, further supporting the dose-dependent effect of the drug on weight-related outcomes. Of note, DA-1726 did not show any clinically significant increases in heart rate or QTcF changes up to 32 mg at 4 weeks of administration.
- April 2025: Reported previously issued and outstanding pre-funded warrants were exercised for 1,430,000 shares of the Company's common stock -- leaving no pre-funded warrants outstanding.
- April 2025: Announced positive top-line results from the 4-week MAD Part 2 of its Phase 1 clinical trial of DA-1726 for the treatment of obesity. DA-1726 demonstrated excellent safety and tolerability, with positive clinical activity. The cohort receiving 32 mg of DA-1726 with no titration demonstrated a maximum reduction in body weight from baseline ranging up to -6.3%, and a mean body weight reduction of -4.3% at Day 26 ($p=0.0005$). Four out of six subjects on the 32 mg dose experienced mild gastrointestinal (GI) adverse events (AEs), most of which were resolved after 24 hours of occurrence. There were no treatment-related discontinuations or serious adverse events (SAEs).
- 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.

Anticipated Clinical Milestones

- **DA-1726 in Obesity:**
 - Additional SAD/MAD cohorts to explore the maximum tolerated dose expected to begin in the third quarter of 2025, with data expected in the fourth quarter of 2025.
- **DA-1241 in MASH:**
 - The Company expects to have an end-of-Phase 2 meeting with the FDA in the first half of 2025.

First Quarter Financial and Operating Results

- **Research and Development (R&D) Expenses** were approximately \$2.3 million for the first quarter ended March 31, 2025, as compared to approximately \$4.9 million for the first quarter ended March 31, 2024. The decrease of approximately \$2.6 million was primarily attributable to (i) \$2.9 million in lower direct R&D expenses related to DA-1241 product development and (ii) \$0.2 million in lower direct other R&D costs. These decreases were partially offset by (i) \$0.5 million in higher direct R&D expenses related to DA-1726 product development and (ii) \$0.1 million in higher indirect R&D expenses related to employee compensation and benefits. Included in direct R&D costs were expenses totaling \$1.1 million and \$0.2 million for the three months ended March 31, 2025 and 2024, respectively, related to investigational drug manufacturing, non-clinical and preclinical costs incurred under the Shared Services Agreement with Dong-A (related party).
- **General and Administrative Expenses** were approximately \$1.6 million for the first quarter ended March 31, 2025, compared to approximately \$2.0 million for the first quarter ended March 31, 2024. The decrease of approximately \$0.4 million was primarily due to (i) \$0.4 million in lower consulting expenditures and (ii) \$0.2 million in lower other G&A expenses. These decreases were partially offset by \$0.2 million in higher employee compensation and benefits.
- **Total Operating Expenses** were approximately \$3.9 million for the first quarter ended March 31, 2025, compared to approximately \$6.9 million for the first quarter ended March 31, 2024. The approximately \$3.0 million decrease was attributable to lower R&D and general and administrative expenses.
- **Total Other Income** for the three months ended March 31, 2025 and 2024 remained relatively consistent at \$0.2 million. The net increase in the gain from the change in fair value of warrant liabilities during the three months ended March 31, 2025 was partially offset by a decrease in interest income earned on the Company's cash balance during the three months ended March 31, 2025.
- **Net Loss** for the first quarter ended March 31, 2025, was \$3.7 million, or \$0.36 per basic and diluted share, based on 10,264,202 weighted average shares of common stock outstanding, compared with a net loss of \$6.7 million, or \$1.32 per basic and diluted share, based on 5,089,408 weighted average shares of common stock outstanding for the first quarter ended March 31, 2025.
- **Cash** was \$11.2 million as of March 31, 2025, compared with \$16.0 million as of December 31, 2024. The company expects its cash position, together with the proceeds from the private placement transaction, will be adequate to fund operations into 2026.

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. In a Phase 1 multiple ascending dose (MAD) trial in obesity, DA-1726 demonstrated best-in-class potential for weight loss, glucose control, and waist reduction. 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 and its subsequent Quarterly Reports on Form 10-Q. 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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MetaVia Inc.
Consolidated Balance Sheets
(In thousands, except per share amounts)

	As of	
	March 31, 2025	December 31, 2024
(Unaudited)		
Assets		
Current assets		
Cash	\$ 11,190	\$ 16,017
Prepaid expenses and other current assets	771	55
Total current assets	11,961	16,072
Property and equipment, net	30	34
Right-of-use asset	115	133
Other assets	21	21
Total assets	\$ 12,127	\$ 16,260

Liabilities and stockholders' equity			
Current liabilities			
Accounts payable	\$	3,054	\$ 3,879
Clinical trial accrued liabilities		1,230	1,696
Accrued expenses and other current liabilities		696	785
Warrant liabilities		274	361
Related party payable		2,375	1,472
Lease liability, short-term		81	78
Total current liabilities		7,710	8,271
Lease liability, long-term		37	58
Total liabilities		7,747	8,329
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 March 31, 2025 and December 31, 2024		—	—
Common stock, \$0.001 par value per share, 100,000 shares authorized as of March 31, 2025 and December 31, 2024; 8,655 and 8,637 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively		9	9
Additional paid-in capital		143,899	143,779
Accumulated deficit		(139,528)	(135,857)
Total stockholders' equity		4,380	7,931
Total liabilities and stockholders' equity	\$	12,127	\$ 16,260

MetaVia Inc.

Consolidated Statements of Operations

(Unaudited - In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2025	2024
Operating expenses		
Research and development	\$ 2,327	\$ 4,904
General and administrative	1,559	1,977
Total operating expenses	3,886	6,881
Loss from operations	(3,886)	(6,881)
Other income (expense)		
Change in fair value of warrant liabilities	87	(70)
Interest income	128	237
Total other income	215	167
Loss before income taxes	(3,671)	(6,714)
Provision for income taxes	—	—
Net loss and comprehensive net loss	\$ (3,671)	\$ (6,714)
Loss per share of common stock, basic and diluted	\$ (0.36)	\$ (1.32)
Weighted average shares of common stock, basic and diluted	10,264,202	5,089,408

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