MetaVia Reports Second Quarter 2025 Financial Results and Provides Corporate Update

August 7, 2025

Dosed the First Patient in the 8-Week 48 mg MAD Cohort of its Phase 1 Clinical Trial to Further Explore Maximum Tolerated Dose of DA-1726 for the Treatment of Obesity; Top-Line Data Expected in the Fourth Quarter of 2025

Signed AI-Driven Collaboration with Syntekabio to Explore Additional Indications for DA-1241 Beyond MASH

$17.6 Million in Cash at End of Second Quarter is Expected to Fund the Company Into 2026

CAMBRIDGE, Mass., Aug. 7, 2025 /PRNewswire/ -- **MetaVia Inc.** (Nasdaq: MTVA), a clinical-stage biotechnology company focused on transforming cardiometabolic diseases, today announced financial results for the second quarter ended June 30, 2025, and provided a corporate strategic update.

"During the second quarter and recently, we continued to make significant progress advancing the clinical development of our two next-generation cardiometabolic assets," stated Hyung Heon Kim, President and Chief Executive Officer of MetaVia. "A key milestone was the dosing of the first patient in the 48 mg multiple ascending dose (MAD) Phase 1 trial of DA-1726, a novel, dual oxyntomodulin (OXM) analog agonist that targets both the glucagon-like peptide-1 receptor (GLP1R) and glucagon receptor (GCGR), for the treatment of obesity. Most recently, we announced the extension of this 48 mg cohort to 8-weeks, in order to evaluate longer-term early efficacy and safety, while exploring the maximum tolerated dose without the need for titration. Previously reported clinical data from the 32 mg dose cohort highlighted DA-1726's best-in-class potential, demonstrating a compelling safety and tolerability profile without the need for dose titration. The 48 mg cohort is expected to build on a clear dose-dependent trend in weight reduction seen across the 8 to 32 mg range, potentially unlocking greater efficacy with extended use. We expect the 32 mg dose will serve as the starting point for future clinical trials."

"In prior cohorts, DA-1726 at the 32 mg dose demonstrated weight loss (average 4.3%, max 6.3%, p=0.0005 by Day 26), with 83% of patients reporting early satiety. By Day 33, waist circumference decreased by an average of 1.6 inches (max 3.9 inches), aligning with glucagon-driven adipose effects observed in preclinical models. Fasting glucose was reduced by up to 18 mg/dL without hypoglycemia, highlighting its promise in treating obesity and related metabolic disorders. Cardiovascular safety was also favorable—no QTcF prolongation and reduced heart rate across most cohorts—despite dual agonism. GI side effects were mild transient, and infrequent, suggesting better tolerability than current GLP-1 therapies. We look forward to reporting data from the 8-week 48 mg cohort in the fourth quarter of this year. Following our successful private placement for aggregate gross proceeds of $10.0 million in May, we remain well-capitalized to reach this milestone, with our runway now extended into 2026."

Mr. Kim continued, "In June, we presented new pre-clinical data on DA-1241, a first-in-class oral GPR119 agonist, at the American Diabetes Association's (ADA) 85th Scientific Sessions. The new data further underscores the potential of combining DA-1241 with an FGF21 analogue, such as Efruxifermin. For the first time, this combination therapy showed synergistic benefits in reducing liver fat, inflammation, and fibrosis, three key drivers of MASH progression. Additionally, our 16-week Phase 2a results, presented at the EASL Congress 2025, highlighted DA-1241's dual mechanism of action through anti-inflammatory and anti-fibrotic pathways, which demonstrated DA-1241's hepatoprotective and glucose-regulating effects. Together, these findings reinforce our confidence in DA-1241's potential as part of a combination approach to effectively address the complex pathology of MASH. We are currently working to schedule an end-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA). Based on the strong safety data from the Phase 2a trial, we signed a collaboration agreement with Syntekabio to potentially enhance the value of DA-1241 beyond MASH, by using their DeepMatcher® AI platform to screen over 1,700 validated protein targets. This approach aims to identify new, high-potential indications while ensuring specificity and reducing off-target risks. We believe this well-tolerated oral candidate can address significant unmet needs and look forward to early insights later this year."

Second Quarter 2025 and Subsequent Highlights

- August 2025: Administered the fifth dose for the first patient in the 8-week extended 48 mg, MAD cohort of the Phase 1 clinical trial of DA-1726 for the treatment of obesity. The cohort, extended to 8 weeks from 4 weeks, is designed to explore the maximum tolerated dose further, continue to explore safety over a longer treatment duration, and evaluate early efficacy.

- August 2025: Announced a research collaboration with Syntekabio, Inc., a leading artificial intelligence (AI)-driven drug discovery company, to identify additional disease targets beyond MASH, and optimize the therapeutic profile of DA-1241.
- July 2025: Dosed the first patient in the 4-week 48 mg MAD cohort of the Phase 1 clinical trial of DA-1726, for the treatment of obesity, to further explore the maximum tolerated dose.
- June 2025: After the conclusion of the virtual 2025 Annual Meeting of Stockholders on June 30, 2025, all outstanding pre-funded warrants issued in May 2025 were exercised for 4,605,162 shares of the Company's common stock.
- June 2025: Presented preclinical data on DA-1241 in a poster presentation at the ADA's 85th Scientific Sessions. The data demonstrated additive hepatoprotective effects in combination with Efruxifermin, a fibroblast growth factor 21 (FGF21) analogue, in a metabolic dysfunction-associated steatohepatitis (MASH) mouse model.
- May 2025: Closed on a private placement offering with Dong-A ST, a related party, and Dong-A Socio Holdings Co., Ltd., the parent company of Dong-A ST, and received gross proceeds of $10.0 million, before deducting the placement agent's fees and related offering expenses. The offering was 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 all outstanding pre-funded warrants issued in June 2024 were exercised for 1,430,000 shares of the Company's common stock.
- 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).

Anticipated Clinical Milestones

- **DA-1726 in Obesity:**
  - Data from the 8-week 48 mg MAD cohort to explore the maximum tolerated dose is expected in the fourth quarter of 2025.
- **DA-1241 in MASH:**
  - The Company is currently working to schedule an end-of-Phase 2 meeting with the FDA.

Second Quarter Financial and Operating Results

- **Research and Development (R&D) Expenses** were approximately $2.3 million for the second quarter ended June 30, 2025, as compared to approximately $8.1 million for the second quarter ended June 30, 2024. The decrease of approximately $5.8 million was primarily attributable to (i) $2.4 million in lower direct R&D expenses related to DA-1241 product development, (ii) $3.4 million in lower direct R&D expenses related to DA-1726 product development, and (iii) $0.1 million in lower direct other R&D costs. These decreases were partially offset by an aggregate $0.1 million increase in indirect R&D expenses related to employee compensation and benefits and consulting. Included in direct R&D costs were expenses totaling $1.3 million and $3.4 million for the three months ended June 30, 2025 and 2024, respectively, related to investigational drug manufacturing, non-clinical and preclinical costs incurred under the Shared Services Agreement with Dong-A ST (related party).

  R&D expenses were approximately $4.6 million for the six months ended June 30, 2025, as compared to approximately $13.0 million for the six months ended June 30, 2024. The approximately $8.3 million decrease was primarily attributable to (i) $5.3 million in lower direct R&D expenses related to DA-1241 product development, (ii) $2.9 million in lower direct R&D expenses related to DA-1726 product development, and (iii) $0.3 million in lower direct other R&D costs. These decreases were partially offset by $0.2 million in higher indirect R&D expenses related to employee compensation and benefits. Included in direct R&D costs were expenses totaling $2.4 million and $3.6 million for the six months ended June 30, 2025 and 2024, respectively, related to investigational drug manufacturing, non-clinical and preclinical costs incurred under the Shared Services Agreement with Dong-A ST (related party).

- **General and Administrative Expenses** were approximately $2.0 million for the second quarter ended June 30, 2025 and 2024.

  G&A expenses were approximately $3.5 million for the six months ended June 30, 2025, as compared to approximately $4.0 million for the six months ended June 30, 2024. The approximately $0.4 million decrease was primarily attributable to

(i) $0.7 million in lower consulting expenditures and (ii) $0.2 million in lower other G&A expenses. These decreases were partially offset by (i) $0.3 million in higher legal and professional fees and (ii) $0.2 million in higher employee compensation and benefits.

- **Total Operating Expenses** were approximately $4.3 million for the second quarter ended June 30, 2025, compared to approximately $10.1 million for the second quarter ended June 30, 2024. The approximately $5.8 million decrease was primarily attributable to lower R&D expenses.

  Total Operating expenses were approximately $8.2 million for the six months ended June 30, 2025, compared to approximately $17.0 million for the six months ended June 30, 2024. The approximately $8.8 million decrease was primarily attributable to lower R&D and general and administrative expenses for the six months ended June 30, 2025.

- **Total Other Income** was approximately $0.3 million for the second quarter ended June 30, 2025, compared to approximately $31 thousand for the second quarter ended June 30, 2024. The approximately $0.3 million increase was mainly attributable to the $0.3 million increase in the change in fair value of warrant liabilities. The Company recorded a gain of $0.2 million from the change in fair value of warrant liabilities during the three months ended June 30, 2025 compared to a loss of $0.1 million from the change in fair value of warrant liabilities during the three months ended June 30, 2024.

  Total other income was approximately $0.5 million for the six months ended June 30, 2025, as compared to approximately $0.2 million for the six months ended June 30, 2024. The approximately $0.3 million increase was primarily attributable to the $0.5 million increase in the change in fair value of warrant liabilities, partially offset by $0.1 million in lower interest income. The Company recorded a gain of $0.2 million from the change in fair value of warrant liabilities during the six months ended June 30, 2025 compared to a loss of $0.2 million from the change in fair value of warrant liabilities during the six months ended June 30, 2024. The decrease in interest was due to a lower average invested amount during the six months ended June 30, 2025 and lower interest rates.

- **Net Loss** for the second quarter ended June 30, 2025, was $4.0 million, or $0.26 per basic and diluted share, based on 15,287,278 weighted average shares of common stock outstanding, compared with a net loss of $10.1 million, or $1.85 per basic and diluted share, based on 5,428,906 weighted average shares of common stock outstanding for the second quarter ended June 30, 2025.

  Net loss for the six months ended June 30, 2025, was approximately $7.7 million, or $0.60 per basic and diluted share, based on 12,789,616 weighted average shares of common stock, basic and diluted, compared with a net loss of approximately $16.8 million, or $3.19 per basic and diluted share, based on 5,259,939 weighted average shares of common stock, basic and diluted, for the six months ended June 30, 2024.

- **Cash** was $17.6 million as of June 30, 2025, compared with $16.0 million as of December 31, 2024. The company expects its cash position 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	
	June 30, 2025 (Unaudited)	December 31, 2024
Assets		
Current assets		
Cash	$ 17,589	$ 16,017
Prepaid expenses and other current assets	726	55
Total current assets	18,315	16,072
Property and equipment, net	27	34
Right-of-use asset	96	133
Other assets	21	21
Total assets	$ 18,459	$ 16,260
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 2,875	$ 3,879
Clinical trial accrued liabilities	1,463	1,696
Accrued expenses and other current liabilities	610	785
Warrant liabilities	114	361
Related party payable	3,675	1,472
Lease liability, short-term	83	78
Total current liabilities	8,820	8,271
Lease liability, long-term	15	58
Total liabilities	8,835	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 June 30, 2025 and December 31, 2024	—	—
Common stock, $0.001 par value per share, 100,000 shares authorized as of June 30, 2025 and December 31, 2024; 24,194 and 8,637 shares issued and outstanding as June 30, 2025 and December 31, 2024,	24	9

respectively		
Additional paid–in capital	153,123	143,779
Accumulated deficit	(143,523)	(135,857)
Total stockholders' equity	9,624	7,931
Total liabilities and stockholders' equity	$ 18,459	$ 16,260

MetaVia Inc.

Consolidated Statements of Operations

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses				
Research and development	$ 2,320	$ 8,074	$ 4,647	$ 12,978
General and administrative	1,981	2,010	3,540	3,987
Total operating expenses	4,301	10,084	8,187	16,965
Loss from operations	(4,301)	(10,084)	(8,187)	(16,965)
Other income (expense)				
Gain (loss) from change in fair value of warrant liabilities	160	(133)	247	(203)
Interest income	146	164	274	401
Total other income	306	31	521	198
Loss before income taxes	(3,995)	(10,053)	(7,666)	(16,767)
Provision for income taxes	—	—	—	—
Net loss and comprehensive net loss	$ (3,995)	$ (10,053)	$ (7,666)	$ (16,767)
Loss per share of common stock, basic and diluted	$ (0.26)	$ (1.85)	$ (0.60)	$ (3.19)
Weighted average shares of common stock, basic and diluted	15,287,278	5,428,906	12,789,616	5,259,939

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