UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 10, 2025

METAVIA INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-37809**	**47-2389984**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

545 Concord Avenue, Suite 210 Cambridge, Massachusetts	**02138**
(Address of principal executive offices)	(Zip Code)

(857) 702-9600
(Registrant's telephone number, including area code)

Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	MTVA	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On January 10, 2025, MetaVia Inc. (the “Company”) posted an updated corporate presentation to its website at https://www.metaviatx.com/events-presentations/presentations, which the Company may use from time to time in communications or conferences. A copy of the corporate presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K (this “Report”).

Information contained on or accessible through any website reference in the corporate presentation is not part of, or incorporated by reference in, this Report, and the inclusion of such website addresses in this Report by incorporation by reference of the corporate presentation is as inactive textual references only.

Exhibit 99.1 hereto contains forward-looking statements within the meaning of the federal securities laws. These forward-looking statements are based on current expectations and are not guarantees of future performance. Further, the forward-looking statements are subject to the limitations listed in Exhibit 99.1 and in the other reports of the Company filed with the Securities and Exchange Commission, including that actual events or results may differ materially from those in the forward-looking statements.

The information in this Report, including Exhibit 99.1 hereto, is furnished pursuant to Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing. The Company’s submission of this Report shall not be deemed an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Presentation dated January 2025.
104	Cover Page Interactive Data File (embedded within Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

METAVIA INC.

Date: January 10, 2025

By: /s/ Hyung Heon Kim
Hyung Heon Kim
President and Chief Executive Officer

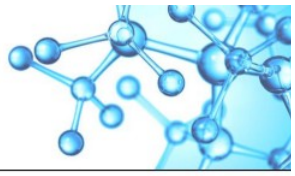
MetaVia

DA-1241 Phase 2a Topline Data MASH-TAG 2025

Jan 2025

NASDAQ: MTVA

Forward-Looking Statements



This presentation may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that do not relate solely to historical or current facts and can be identified by the use of words such as “believes”, “expects”, “anticipates”, “may”, “will”, “should”, “seeks”, “approximately”, “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). 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. These forward-looking statements include statements regarding the market size and potential growth opportunities of our current and future product candidates, capital requirements and use of proceeds, clinical development activities, the timeline for, and results of, clinical trials, regulatory submissions, and potential regulatory approval and commercialization of our current and future product candidates. Many factors could cause actual future events to differ materially from the forward-looking statements in this presentation, including, without limitation, those risks associated with our ability to execute on our commercial strategy; the timeline for regulatory submissions; ability to obtain regulatory approval through the development steps of our current and future product candidates; our 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 our contract manufacturers, clinical study partners and others involved in the development of our current and future product candidates; potential negative interactions between our product candidates and any other products with which they are combined for treatment; our ability to initiate and complete clinical trials on a timely basis; our ability to recruit subjects for our clinical trials; whether we receive results from our 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; effects of changes in applicable laws or regulations; whether we are able to maintain compliance with Nasdaq listing requirements; and effects of changes to our stock price on the terms of the license agreement and any future fundraising. These forward-looking statements are based on information currently available to us and our current plans or expectations and are subject to a number of known and unknown uncertainties, risks and other important factors that may cause our actual results, performance or achievements expressed or implied by the forward-looking statements. These and other important factors are described in detail in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2023 and our other filings with the Securities and Exchange Commission.

While we may elect to update such forward-looking statements at some point in the future, except as required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to this presentation.

This presentation also may contain estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

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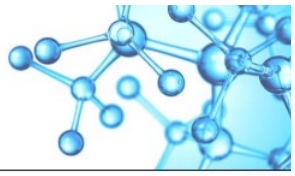
Compelling Investment Opportunity



Targeting **Obesity and MASH** with a Pipeline of **Next Generation Therapeutics**

- Aiming to increase Shareholder Value through ***Multiple, Near-Term, Value Creating Milestones***
  - **DA-1726 (GLP1R/GCGR dual agonist)**
    - ✓ Ongoing Phase 1 trial for the treatment of obesity
    - ✓ Part 1 (SAD) interim data from planned cohorts showed a strong tolerability and safety profile
    - ✓ Part 2 (MAD) interim data readout expected in Q1 2025
  - **DA-1241 (GPR-119 agonist)**
    - ✓ Phase 2a in subjects with presumed MASH top-line data met primary endpoint in ALT and showed direct hepatic effects
    - ✓ Significant improvements in the CAP score and statistically significant reduction in the FAST score at 100mg dosing at Week 16
    - ✓ Significant reductions in HbA1C from baseline 100mg dosing at Week 16 compared to the placebo group
    - ✓ Other exploratory end points including MRI-PDFF to be released at major future medical conferences
    - ✓ Plan to meet with FDA during the first half of 2025
- Backed by Strategic Partner and Major Shareholder, Dong-A ST
- Well capitalized with approximately ***$21.7 million in Cash at the end of Q3 2024***

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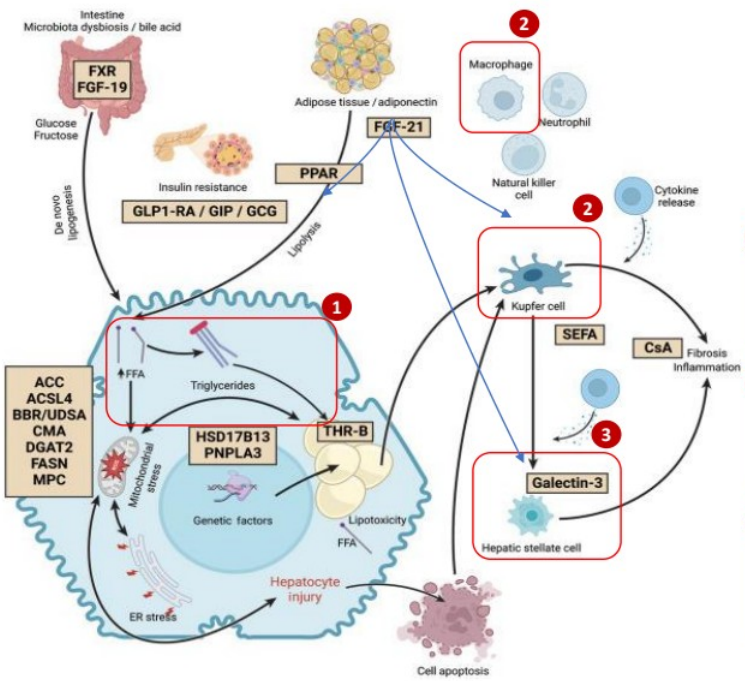
DA-1241

Orally Available, Potential
First-in-Class GPR119 Agonist for
the Treatment of **MASH**

Mode of Action



Harrison et al., Clinical Gastroenterology and Hepatology, 2023;21(8):2001-2014

- **DA-1241** is a synthetic drug that binds to GPR119 express on the cell surface of liver cells, immune cells (Kupfer cell macrophages, monocytes), and hepatic astrocytes.
- Multiple effects are expected by direct action on representative cells involved in pathogenesis.

	MOA	Potential Effe
1 Fatty Liver	• Inhibition of fatty acid biosynthesis in liver cells	• Reduced fat in li tissue
2 Inflammation	• Inhibition of Kupfer cell activation in liver tissue • Inhibition of blood monocyte and macrophage activation	• Inhibits the secr inflammatory cy • Reduces inflamm cell infiltration
3 Fibrosis	• Inhibition of hepatic astrocyte activation	• Inhibits the accumulation of protein (collagen liver tissue

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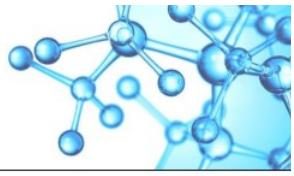

DA-1241 Phase 2a: Clinical Study Design

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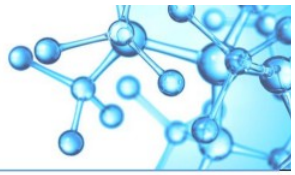
DA-1241 Phase 2a: Clinical Study



A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL, PHASE 2A CLINICAL TRIAL TO EVALUATE THE EFFICACY AND SAFETY OF DA-1241 IN SUBJECTS WITH PRESUMED NON-ALCOHOLIC STEATOHEPATITIS (NASH)

Objective	• **Part 1:** To explore the efficacy (change from baseline in ALT) of DA-1241 in subjects at risk of NASH or subjects with non-alcoholic fatty liver disease (NAFLD) after administration of oral DA-1241 at varying doses or identical placebo for 16 weeks/112 days. • **Part 2:** To explore the efficacy (change from baseline in ALT) of DA-1241 in subjects at risk of NASH or subjects with NAFLD after administration of oral DA-1241 in combination with sitagliptin versus identical placebo for 16 weeks/112 days.
NCT Number	NCT06054815
Dosing Regimen	DA-1241 50mg, 100mg, 100mg+Sitagliptin, or Matching Placebo, Oral, Once Daily
Planned # of Subjects	Total # Planned – 86 DA-1241 50mg group – 12 DA-1241 100mg group – 25 DA-1241 100mg / Sitagliptin group – 25 Combined Placebo group – 24
Duration of Study	Screening Period – up to 8 weeks prior to Randomization Treatment Period – Baseline to Week 16 Follow up – Week 20

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DA-1241 Phase 2a: Top-Line Results

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Phase 2a Top-line Results

Primary Efficacy Endpoint

LS Mean ALT Changes from Baseline (U/L)

	Placebo (N=23)	95% CI	DA-1241 50mg (N=12)	95% CI	DA-1241 100mg (N=22)	95% CI	DA-1241 100mg + Sita 100mg (N=34)	95% CI
Baseline Mean	68.4		65.8		57.2		63.2	
Week 16 LS Mean	-4.70	(-14.05, 4.65)	-16.81	(-29.72, -3.89)*	-18.09 *	(-27.67, -8.52)*	-8.24	(-15.91, -0.57)*

* Confidence interval excludes 0, suggesting a statistically meaningful differ

Proportion of Subjects with Normalized ALT <30 IU/L at Week 16

	Placebo (N=23)	DA-1241 50mg (N=12)	DA-1241 100mg (N=22)	DA-1241 100mg + Sitagliptin 100mg (N=34)
Number of Subjects, n				
< 30, n (%)	1 (4.3%)	4 (33.3%)	4 (18.2%)	3 (8.8%)
Odds Ratio (p value)		10.500* (0.0487)	5.600 (0.1402)	2.423 (0.4576)

* p < 0.05 vs. placebo
* p < 0.051 vs. placebo

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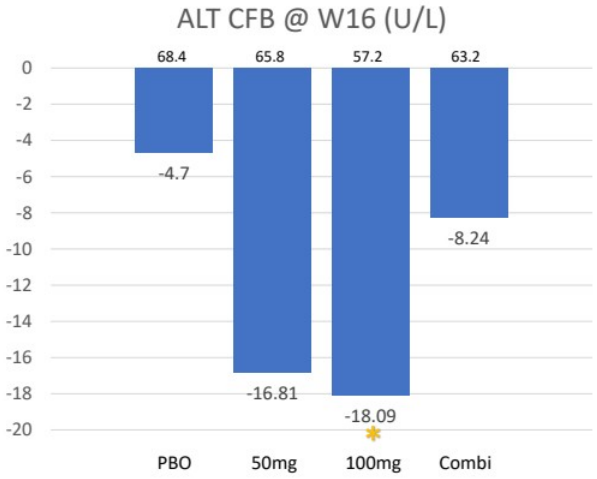
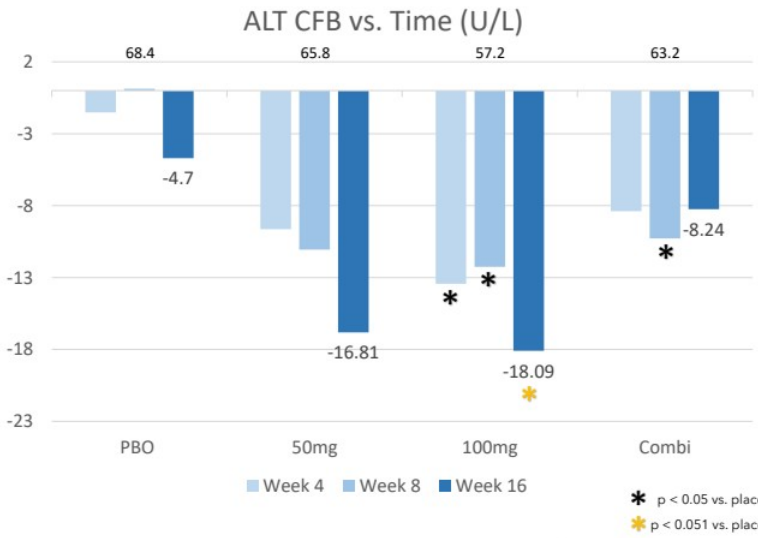
Phase 2a Top-line Results

Primary Efficacy Endpoint

LS Mean ALT Changes from Baseline (U/L)





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Phase 2a Top-line Results

Select Secondary Efficacy Endpoint

LS Mean CAP, VCTE, FAST score Changes from Baseline at Week 16

	Placebo (N=23)	95% CI	DA-1241 50mg (N=12)	95% CI	DA-1241 100mg (N=22)	95% CI	DA-1241 100mg + Sita 100mg (N=34)	95% CI
Baseline Mean (dB/m)	347.4		347.3		336.0		344.1	
Week 16 LS Mean CAP Score (dB/m)	-2.32	(-16.17, 11.52)	-8.94	(-28.08, 10.20)	-24.32*	(-38.54, -10.10)*	-20.62*	(-31.99, -9.26)*
Baseline Mean (kPa)	10.00		10.71		10.32		9.89	
Week 16 LS Mean VCTE Score (kPa)	0.29	(-1.31, 1.89)	-1.40	(-3.62, 0.83)	0.00	(-1.64, 1.64)	-1.45	(-2.77, -0.13)*
Baseline Mean	0.555		0.604		0.538		0.564	
Week 16 LS Mean FAST score	-0.09	(-0.17, -0.01)*	-0.17	(-0.28, -0.06)*	-0.19	(-0.27, -0.11)*	-0.19*	(-0.26, -0.13)*

* Confidence interval excludes 0, suggesting a statistically meaningful difference.

* $p < 0.05$ vs. placebo

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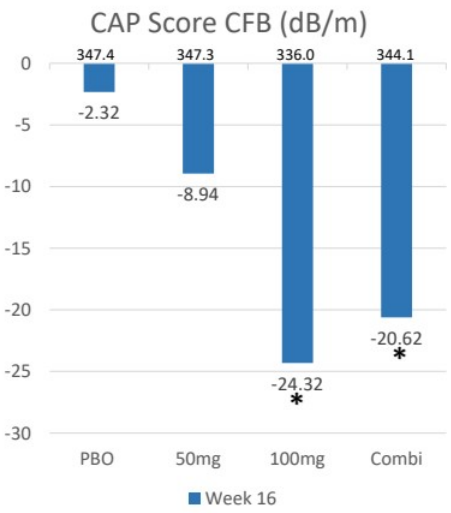
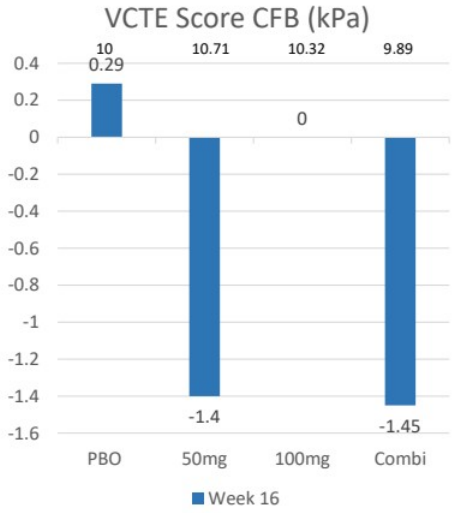
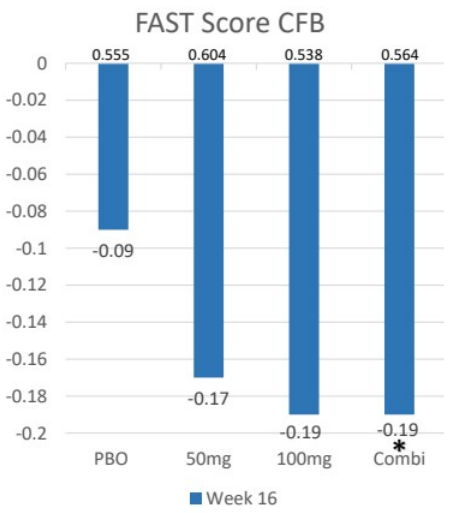
Phase 2a Top-line Results

Select Secondary Efficacy Endpoint

LS Mean CAP, VCTE, FAST score Changes from Baseline at Week 16







* p < 0.05 vs. placebo

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Select Secondary Efficacy Endpoint

LS Mean HbA1C Changes from Baseline at Week 16 (%)

	Placebo (N=23)	95% CI	DA-1241 50mg (N=12)	95% CI	DA-1241 100mg (N=22)	95% CI	DA-1241 100mg + Sita 100mg (N=34)	95% CI
Baseline Mean	6.78		6.58		7.01		6.51	
Week 16 LS Mean	-0.10	(-0.23, 0.44)	-0.24	(-0.70, 0.22)	-0.48*	(-0.82, -0.13)*	-0.52*	(-0.80, -0.25)*

* Confidence interval excludes 0, suggesting a statistically meaningful difference.

* $p < 0.05$ vs. placebo

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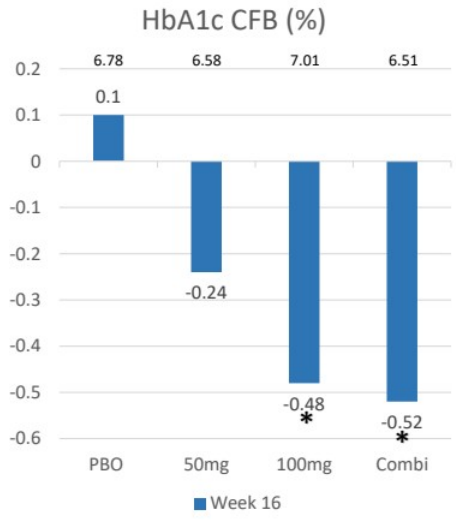
Phase 2a Top-line Results

Select Secondary Efficacy Endpoint

LS Mean HbA1C Changes from Baseline at Week 16 (%)



* p < 0.05 vs. placebo

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Safety Assessment

Overall TEAE Summary

N (%)	Placebo (N=32)	DA-1241 50mg (N=14)	DA-1241 100mg (N=26)	DA-1241 100mg + Sitagliptin 100mg (N=36)
Subjects with any Treatment Related AE	9 (28.1%)	4 (28.6%)	9 (34.6%)	10 (27.8%)
Mild	8 (25.0%)	4 (28.6%)	8 (30.8%)	9 (25.0%)
Moderate	1 (3.1%)	0	1 (3.8%)	1 (2.8%)
Severe	0	0	0	0
Subjects with any Treatment related SAE	0	0	0	0
Subjects with any TEAE leading to study discontinuation	0	0	0	1 (3.1%)
Subjects with any TEAE leading to study drug discontinuation	1 (3.1%)	0	0	0

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Thank You!

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