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 5, 2026

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** (Address of principal executive offices)	**02138** (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 Disclosures.

On January 5, 2026, MetaVia Inc. (the "Company") issued a press release announcing positive statistically significant results from the eight-week (extended from four weeks) non-titrated 48 mg, multiple ascending dose (MAD) cohort of its 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. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K (this "Report") and is incorporated herein by reference.

Information contained on or accessible through any website reference in the press release 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 press release is as inactive textual references only.

The information in Item 7.01 of this Report, including Exhibit 99.1 attached 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.

Forward-Looking Statements

This Report, including Exhibit 99.1 attached 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.

Item 9.01.Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release, dated January 5, 2026
104	Cover Page Interactive Data File (embedded within the 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 5, 2026

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

Exhibit 99.1

MetaVia Reports Positive Statistically Significant Results from Its Phase 1b Clinical Trial of DA-1726 In Metabolic Disease - Demonstrating Strong Glycemic Response, Significant Direct Hepatic Effects, Robust Weight Loss, and Favorable Safety Profile

Statistically Significant (p=0.006) Waist Circumference Reduction of 9.8 cm at Day 54

Significant Direct Hepatic Activity with a 23.7% Reduction in Liver Stiffness (VCTE) by Day 54

Strong Glycemic Response with a 12.3 mg/dL Fasted Glucose Reduction by Day 54

Robust Weight Loss with 9.1% Reduction (21.2 lbs) by Day 54

CAMBRIDGE, Mass., January 5, 2026 – MetaVia Inc. (Nasdaq: MTVA), a clinical-stage biotechnology company focused on transforming cardiometabolic diseases, today announced positive statistically significant results from the 8-week (extended from four weeks) non-titrated 48 mg, multiple ascending dose (MAD) cohort of its 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. The results show robust early weight loss, statistically significant reductions in waist circumference, strong improvements in glucose control, and meaningful reductions in liver stiffness, alongside a favorable safety and tolerability profile.

In the non-titrated 48 mg cohort, patients experienced no treatment-related discontinuations, and gastrointestinal events were mild to moderate in severity. By Day 26, patients receiving DA-1726 achieved a statistically significant average weight reduction of 6.1% (14.6 lbs.) (p=0.003) and a statistically significant decrease in waist circumference of 5.8 cm (2.3 inches) (p=0.006). These improvements deepened through Day 54, with an average weight loss of 9.1% (21.2 lbs.) and a statistically significant 9.8 cm (3.8 inch) (p=0.022) reduction in waist circumference. Patients also demonstrated a 12.3 mg/dL improvement in fasted glucose from a baseline of 105.3 mg/dL by Day 54. In addition, vibration-controlled transient elastography (VCTE) indicated a 23.7% reduction in liver stiffness from a baseline of 5.9 kPa, suggesting a significant direct hepatic effect from DA-1726.

“Extending DA-1726 administration to a full eight weeks at the non-titrated 48 mg dose has provided us with extremely encouraging insights,” said Hyung Heon Kim, president and chief executive officer of MetaVia. “Patients in this cohort achieved a statistically significant 6.1% weight loss by Day 26 and 9.1% by Day 54, along with reductions in waist circumference of 5.8 cm and 9.8 cm at those same time points. We believe the statistically significant waist reductions reflect the glucagon component of DA-1726, which may contribute to deeper visceral fat loss than GLP-1 agonists alone. Combined with a favorable tolerability profile with no treatment-related discontinuations, these results highlight DA-1726’s differentiated potential to be a best-in-class treatment option.”

“We also observed meaningful metabolic improvements, including a 12.3 mg/dL reduction in fasted glucose and early HbA1c benefits, such as a drop from 6.0% to 5.5% by day 54, in a prediabetic subject. These findings are especially important because the vast majority of people with obesity—ranging from 70% to 80%—have diabetes or prediabetes, and diabetic patients typically receive broader insurance coverage for anti-obesity therapies. DA-1726 has the potential to be the most effective GLP-1/glucagon dual agonist in development that has demonstrated glucose lowering without elevations, which may offer both clinical and reimbursement advantages. Because VCTE is the leading noninvasive tool for liver stiffness assessment and is recognized by the FDA as a biomarker in MASH development, seeing a 23.7% reduction in only eight weeks underscores the hepatic potential of DA-1726. Taken together, the data reinforce our view that DA-1726 has best-in-class potential, delivering a compelling balance of weight loss, metabolic improvement, direct hepatic benefit, and tolerability as we advance toward later-stage development.”

Mr. Kim added, “Looking ahead, our planned 16-week titration studies—to 48 mg in a single step and to 64 mg using a two-step regimen—reflect our confidence in DA-1726’s tolerability and our expectation that it will compare favorably to the slower, more restrictive titration schedules required by today’s GLP-1 drugs. We believe this represents a key competitive advantage. With results expected in the fourth quarter of 2026, we are well positioned to unlock further value creation as we continue advancing DA-1726 toward later-stage development.”

The Phase 1 trial was a randomized, double-blind, placebo-controlled study designed to evaluate the safety, tolerability, PK, and pharmacodynamics (PD) of single and multiple ascending doses of DA-1726 in obese but otherwise healthy adults with a body mass index (BMI) of 30–45 kg/m². Nine subjects in each cohort were randomized in a 6:3 ratio, with each subject receiving either 4 weekly administrations of DA-1726 or placebo. The extended dosing cohort added 4 weekly administrations of DA-1726 or placebo for a total of 8 weeks of exposure. The primary objective was to assess safety and tolerability based on adverse events (AEs), serious adverse events (SAEs), treatment-emergent events (TAEs), and discontinuations. Secondary endpoints included the PK of DA-1726, assessed via serum concentrations over time and metabolite profiling at the highest doses of DA-1726. Exploratory endpoints included the effect of DA-1726 on metabolic parameters, cardiac parameters, fasting lipid levels, body weight, waist circumference and body mass index (BMI), among others.

For more information on this clinical trial, please visit: www.clinicaltrials.gov NCT06252220.

About DA-1726

DA-1726 is a novel oxyntomodulin (OXM) analogue functioning as a GLP1R/GCGR dual agonist for the treatment of obesity and Metabolic Dysfunction-Associated Steatohepatitis (MASH) that is to be administered once weekly subcutaneously. DA-1726 acts as a dual agonist of GLP-1 receptors (GLP1R) and glucagon receptors (GCGR), leading to weight loss through reduced appetite and increased energy expenditure. DA-1726 has a well understood mechanism and, in pre-clinical mice models, resulted in improved weight loss compared to semaglutide (Wegovy®). Additionally, in pre-clinical mouse models, DA-1726 elicited similar weight reduction, while consuming more food, compared to tirzepatide (Zepbound®) and survodutide (a drug with the same MOA), while also preserving lean body mass and demonstrating improved lipid-lowering effects compared to survodutide. In the Phase 1 multiple ascending dose (MAD) trial in obesity, the 32 mg dose of DA-1726 demonstrated best-in-class potential for weight loss, glucose control, and waist circumference reduction.

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 vanoglipel (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. Vanoglipel 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, vanoglipel 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, vanoglipel 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, which include, among other statements, statements regarding the timing and release of data related to the company’s planned 16-week titration studies. 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; MetaVia's expectations regarding the sufficiency of its existing cash on hand to fund MetaVia's 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 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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