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): November 12, 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	**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 Disclosures.

On November 12, 2026, MetaVia Inc. (the ***"Company"***) issued a press release announcing additional positive data from the previously reported interim analysis of Part 3B of its Phase 1 clinical trial of DA-1726, a novel oxyntomodulin (OXM) analog targeting both GLP-1 (GLP1R) and glucagon (GCGR) receptors. 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.

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

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 are as inactive textual references only.

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 that the Company has 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 Number	Exhibit Description
99.1	Press Release dated November 12, 2026.
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: November 12, 2026

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

MetaVia Announces Statistically Significant Reduction in Uric Acid Levels with DA-1726 in Phase 1 Part 3B Clinical Trial

Adding to Previously Reported 68.1% Liver Fat Reduction and Strengthening Its Liver Profile for MetALD

Additional Phase 1 Part 3B Data Highlight DA-1726's 1.47 mg/dL Placebo-Adjusted Reduction in Uric Acid After 16 Weeks of Treatment (p<0.001), Despite Normal Mean Uric Acid Levels at Baseline

Normalization of Liver Fat in All Subjects with Baseline Steatosis, 13.5% Placebo-Adjusted Weight Loss and Improvements in HbA1c

MetaVia Advancing DA-1726 Toward Planned Phase 2 Study in MetALD and ALD in the Second Half of 2027

CAMBRIDGE, Mass., November 12, 2026 – MetaVia Inc. (Nasdaq: MTVA), a clinical-stage biotechnology company focused on transforming liver-related cardiometabolic diseases, today announced additional positive data from the previously reported interim analysis of Part 3B of its Phase 1 clinical trial of DA-1726, a novel oxyntomodulin (OXM) analog targeting both GLP-1 (GLP1R) and glucagon (GCGR) receptors. The results demonstrated a statistically significant 1.47 mg/dL placebo-adjusted reduction in serum uric acid from baseline (p<0.001) following 16 weeks of once-weekly DA-1726 treatment in otherwise healthy adults with obesity.

"These additional findings further strengthen the metabolic profile emerging for DA-1726 and provide another encouraging signal as we advance its development in liver-related cardiometabolic diseases," said Hyung Heon Kim, President and Chief Executive Officer of MetaVia. "The statistically significant reduction in uric acid is particularly noteworthy given that participants entered the study with mean levels already within the normal range. Elevated uric acid has been associated with liver fat accumulation, insulin resistance and alcohol consumption, making these findings particularly relevant to our focus on MetALD and ALD. Combined with the previously reported significant reductions in liver fat, body weight and HbA1c, these results reinforce our belief that DA-1726 has the potential to deliver benefits beyond weight loss alone."

At Day 109, mean serum uric acid levels in DA-1726-treated participants decreased by 1.02 mg/dL from a baseline of 5.89 mg/dL (p<0.001), compared with a 0.45 mg/dL increase from a baseline of 4.80 mg/dL in the placebo group. The resulting placebo-adjusted reduction of 1.47 mg/dL was statistically significant (95% CI: −2.0 to −0.9; p<0.001). The analysis included 15 participants treated with DA-1726 and four receiving placebo. The findings complement previously reported Part 3B interim results demonstrating a statistically significant 68.1% placebo-adjusted reduction in liver fat (p<0.001), 13.5% placebo-adjusted weight loss (p<0.001) and a 0.44 absolute percentage-point reduction in HbA1c (p=0.006). In addition, all five DA-1726-treated participants with liver steatosis at baseline achieved MRI-PDFF below 5% by Day 109.

Mr. Kim concluded, "We believe the dual GLP-1 and glucagon receptor agonism of DA-1726, together with the robust effects observed across multiple metabolic parameters, provides a compelling foundation for further clinical development. We expect to report full data from Part 3A and Part 3B in the first quarter of

2027 and are planning a 48-week, non-biopsy Phase 2 study in up to 150 subjects with MetALD and ALD, targeted to begin in the second half of 2027."

About the DA-1726 Phase 1 Part 3B Study

Part 3B of the Phase 1 trial of DA-1726 is a 16-week, randomized, placebo-controlled study in otherwise healthy adults with obesity. Participants receiving DA-1726 were titrated from 16 mg for 4 weeks, to 32 mg for 4 weeks, to the target dose of 64 mg, administered once weekly by subcutaneous injection. The interim analysis includes 15 participants treated with DA-1726 and four treated with placebo; an MRI substudy of 12 DA-1726-treated and four placebo participants assessed liver fat by MRI-PDFF and body composition.

About DA-1726

DA-1726 is a novel GLP1R/GCGR dual agonist being developed to address various cardiometabolic indications, with potential in both Metabolic and Alcohol-Associated Liver Disease (MetALD) and Alcohol-Associated Liver Disease (ALD), which is designed for once weekly, subcutaneous administration. 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. It is engineered with a 3:1 GLP1R:GCGR potency ratio intended to balance the complementary effects of GLP1R activation on appetite and glucose control with GCGR activation on energy expenditure and fat breakdown. DA-1726 has a well understood mechanism and preclinical tissue-distribution studies have shown that it concentrates most heavily in adipose tissue and in the liver. In a Phase 1 Part 3B interim analysis at Day 109, DA-1726 demonstrated a 13.5% placebo-adjusted reduction in body weight, a 68.1% placebo-adjusted reduction in liver fat and a 0.24 percentage-point placebo-adjusted reduction in HbA1c, along with reductions in visceral and subcutaneous adipose tissue and relatively preserved lean mass. MetaVia is planning a Phase 2, 48-week, non-biopsy study of DA-1726 in MetALD and ALD, targeted to begin in the second half of 2027.

About MetaVia

MetaVia Inc. is a clinical-stage biotechnology company focused on transforming liver-related cardiometabolic diseases. The company is currently developing DA-1726 for the treatment of various cardiometabolic conditions, with potential in both Metabolic and Alcohol-Associated Liver Disease (MetALD) and Alcohol-Associated Liver Disease (ALD), and is advancing vanoglipel (DA-1241) in combination with resmetirom 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, engineered with a 3:1 GLP1R:GCGR potency ratio. OXM is a naturally-occurring gut hormone that activates GLP1R and GCGR, thereby decreasing food intake while increasing energy expenditure. In a Phase 1 Part 3B interim analysis at Day 109, DA-1726 demonstrated placebo-adjusted reductions of 13.5% in body weight, 68.1% in liver fat and 0.24 percentage points in HbA1c, along with reductions in visceral and subcutaneous adipose tissue and relatively preserved lean mass. A Phase 2, 48-week, non-biopsy study of DA-1726 in MetALD and ALD, is targeted to begin in the second half of 2027. Vanoglipel is a potential first-in-class drug candidate targeting G-protein-coupled receptor 119 (GPR119). It acts directly in the liver on pathways involved in steatosis, inflammation and fibrosis, while GPR119 activation in the pancreas and gut also supports glucose and metabolic regulation. In a Phase 2a clinical study, vanoglipel demonstrated direct hepatic action in addition to its glucose lowering effects. MetaVia is advancing vanoglipel in combination with resmetirom as a once-daily oral combination therapy for MASH, with a Phase 2a proof-of-concept study targeted to begin in the first half of 2027.

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 history of net losses, the sufficiency of its existing cash on hand to fund operations and raising additional capital; adverse global economic conditions; MetaVia’s ability to execute on its commercial strategy; 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 obtain, maintain, protect and/or enforce sufficient intellectual property rights to execute its commercial strategy; 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 preclinical 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, regulations or Nasdaq listing rules; the effects of changes to MetaVia's stock price; 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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