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 17, 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 17, 2026, MetaVia Inc. (the "Company") issued a press release announcing that the last patient has completed the final study visit for its Phase 1 clinical trial evaluating DA-1726, a novel GLP-1 (GLP1R)/glucagon (GCGR) dual-receptor agonist. A copy of the press release is attached 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 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 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 17, 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 17, 2026

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

MetaVia Announces Completion of Last Patient Visit in Extended 24-Week Phase 1 Part 3A Study of DA-1726

Encouraging Preliminary Safety and Tolerability Observations in Part 3A Supported Decision to Extend Treatment from 16 to 24 Weeks

Positive Part 3B Interim Data Presented at Precision Liver Symposium Demonstrated Statistically Significant 68.1% Placebo-Adjusted Reduction in Liver Fat

Full Data from Parts 3A and 3B Expected in First Quarter of 2027; Phase 2 Study in MetALD and ALD Planned for Second Half of 2027

CAMBRIDGE, Mass., November 17, 2026 – MetaVia Inc. (Nasdaq: MTVA), a clinical-stage biotechnology company focused on transforming liver-related cardiometabolic diseases, today announced that the last patient has completed the final study visit for its Phase 1 clinical trial evaluating DA-1726, a novel GLP-1 (GLP1R)/glucagon (GCGR) dual-receptor agonist. MetaVia elected to extend the treatment period from 16 to 24 weeks, with patients receiving 48 mg of DA-1726 weekly for an additional eight weeks. In parallel, the company analyzed and previously released the data from part 3B, in which patients were titrated from 16 mg to 32 mg and ultimately to 64 mg of DA-1726 weekly during the 16-week regimen, accelerating towards Phase 2 readiness.

“The encouraging preliminary safety and tolerability observations in Part 3A supported our decision to extend treatment for an additional eight weeks at the 48 mg dose, providing an opportunity to further assess the durability of treatment effects and longer-term safety of DA-1726.” stated Hyung Heon Kim, President and Chief Executive Officer of MetaVia. “Simultaneously, we were finalizing the Part 3B interim data for presentation at the Precision Liver Symposium 2026 and advancing preparations for Phase 2 development. The recently reported Part 3B interim results demonstrated a statistically significant 68.1% placebo-adjusted reduction in liver fat, accompanied by 13.5% placebo-adjusted weight loss and improvements in glycemic control. These findings further strengthen our confidence in the potential of DA-1726 to address multiple aspects of liver-related cardiometabolic disease.”

Mr. Kim continued, “We look forward to reporting the full data from Parts 3A and 3B in the first quarter of 2027, which we expect will provide additional insight into the safety, tolerability and metabolic effects of DA-1726. Building on these encouraging findings, we are preparing to initiate a 48-week, non-biopsy Phase 2 study in up to 150 patients with metabolic dysfunction and alcohol-associated liver disease (MetALD) and alcohol-associated liver disease (ALD), targeted to begin in the second half of 2027.”

In the previously reported Phase 1 Part 3B interim analysis, DA-1726 demonstrated a statistically significant 68.1% placebo-adjusted reduction in liver fat, as measured by MRI-PDFF, following 16 weeks of treatment. All five DA-1726-treated participants with liver steatosis at baseline achieved MRI-PDFF below 5% by Day 109. These findings, together with significant reductions in body weight, HbA1c and adipose tissue, and preservation of lean mass, support the potential of DA-1726 as a differentiated treatment for liver-related cardiometabolic diseases.

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 and a 68.1% placebo-adjusted reduction in liver fat, 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 and 68.1% in liver fat, 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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