
**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): September 9, 2026



(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37809
(Commission
File Number)

47-2389984
(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 September 9, 2026, MetaVia Inc. (the “**Company**”) issued a press release announcing results from a preclinical tissue distribution study (the “**DA-1726 Study**”) demonstrating that DA-1726-derived radioactivity is slowly absorbed and extensively distributed throughout the body following subcutaneous administration, with broad tissue distribution and the highest tissue exposure observed in adipose (fat) tissue. 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.

Item 8.01. Other Events.

On September 9, 2026, the Company announced results from its DA-1726 Study, demonstrating that DA-1726-derived radioactivity is slowly absorbed and extensively distributed throughout the body following subcutaneous administration, with broad tissue distribution and the highest tissue exposure observed in adipose (fat) tissue. The DA-1726 Study showed that tissue-to-plasma ratios increased over time, indicating prolonged retention of DA-1726-derived radioactivity in tissues relative to plasma. Consistent with this finding, the DA-1726 Study also showed that the greatest exposure outside of the injection site occurred in abdominal, subcutaneous and brown fat, as well as the liver. The DA-1726 Study also demonstrated prolonged retention of DA-1726-derived radioactivity in tissues through the final 144-hour assessment, consistent with the prolonged pharmacokinetic profile supporting once-weekly dosing of DA-1726. In addition, the DA-1726 Study demonstrated that only minimal radioactivity was detected in the central nervous system, consistent with the limited brain penetration typically observed with peptide-based therapies.

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 results from preclinical studies are not necessarily predictive of future clinical results.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits**

Exhibit Number	Exhibit Description
99.1	Press Release dated September 9, 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: September 9, 2026

By: /s/ Hyung Heon Kim

Hyung Heon Kim

President and Chief Executive Officer



MetaVia Announces Preclinical Findings Supporting Biological Rationale for DA-1726's Waist Circumference Reduction

Tissue Distribution Study Shows Highest Exposure in Adipose Tissue and Prolonged Retention Consistent with Once-Weekly Dosing Findings Provide Mechanistic Support for the Differentiated Profile of DA-1726

CAMBRIDGE, Mass., September 9, 2026 – MetaVia Inc. (Nasdaq: MTVA), a clinical-stage biotechnology company focused on transforming cardiometabolic diseases, today announced results from a preclinical tissue distribution study demonstrating that DA-1726-derived radioactivity is slowly absorbed and extensively distributed throughout the body following subcutaneous administration, with broad tissue distribution and the highest tissue exposure observed in adipose (fat) tissue.

Data from the study showed that tissue-to-plasma ratios increased over time, indicating prolonged retention of DA-1726-derived radioactivity in tissues relative to plasma. Consistent with this finding, the greatest exposure outside of the injection site occurred in abdominal, subcutaneous and brown fat, as well as the liver.

"We believe these findings provide important mechanistic support for the differentiated profile we continue to observe with DA-1726," stated Hyung Heon Kim, President and Chief Executive Officer of MetaVia. "In our previously reported Phase 1 study, patients receiving the 48 mg dose of DA-1726 achieved a mean reduction in waist circumference of 9.8 cm after only eight weeks of treatment (Day 54). We believe the preferential distribution of DA-1726-derived radioactivity to adipose tissue observed in this preclinical study provides an important biological rationale that is consistent with these encouraging clinical findings. In addition, the prolonged retention of DA-1726-derived radioactivity in tissues observed throughout the study may contribute to the sustained pharmacokinetic exposure of DA-1726 and may also help explain the excellent tolerability profile observed across our clinical studies, to date. Together, these findings further reinforce our confidence in the unique potential of DA-1726 as a next-generation obesity therapy. As patients in our ongoing 24-week dose-titration study continue to receive extended treatment at their highest achieved dose levels, we look forward to evaluating whether longer treatment can further enhance reductions in waist circumference, weight loss and other important cardiometabolic measures. We anticipate reporting 16-week topline data in the fourth quarter of this year, followed by 24-week topline results in the first quarter of 2027."

The preclinical study data also demonstrated prolonged retention of DA-1726-derived radioactivity in tissues through the final 144-hour assessment, consistent with the prolonged pharmacokinetic profile supporting once-weekly dosing of DA-1726. In addition, only minimal radioactivity was detected in the central nervous system, consistent with the limited brain penetration typically observed with peptide-based therapies.

About DA-1726

DA-1726 is a novel 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 preclinical mouse models, resulted in improved weight loss compared to semaglutide (Wegovy®),

a leading GLP-1 receptor agonist. Additionally, in preclinical 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 GLP-1 receptor agonists such as semaglutide. 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 potential first-in-class drug candidate targeting G-protein-coupled receptor 119 (GPR119). In preclinical studies, vanoglipel demonstrated a positive metabolic effect on glucose and lipid control, and also proved differentiated hepatic benefits reducing hepatic steatosis, hepatic inflammation, and liver fibrosis regardless independent of metabolic improvement. 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. 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 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.

Contacts:

MetaVia

Marshall H. Woodworth
Chief Financial Officer
+1-857-299-1033
marshall.woodworth@metaviatx.com

Rx Communications Group

Michael Miller
+1-917-633-6086
mmiller@rxir.com
