

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 21, 2026

NewAmsterdam Pharma Company N.V.

(Exact name of Registrant as Specified in Its Charter)

The Netherlands
(State or Other Jurisdiction
of Incorporation)

001-41562
(Commission File Number)

N/A
(IRS Employer
Identification No.)

Goomieer 2-35
Naarden
The Netherlands
(Address of Principal Executive Offices)

+31 (0) 35 206 2971
(Registrant's Telephone Number, Including Area Code)

1411 DC
(Zip 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
Ordinary shares, nominal value €0.12 per share	NAMS	The Nasdaq Stock Market LLC
Warrants to purchase ordinary shares	NAMSW	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).
- ☐ 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 8.01 Other Events.

On September 21, 2026, NewAmsterdam Pharma Company N.V. (the “Company”) along with its partner Menarini Group (“Menarini”) announced that the European Commission (“EC”) has granted marketing authorization for Ubeslo[®] (obicetrapib 10 mg monotherapy) and Evlarco[®] (10 mg obicetrapib plus 10 mg ezetimibe fixed-dose combination, or “FDC”) for patients with primary hypercholesterolaemia (heterozygous familial (“HeFH”) and non-familial) or mixed dyslipidaemia, marking the first regulatory approval of obicetrapib worldwide. The authorizations apply across all EU Member States, as well as Iceland, Liechtenstein and Norway. The authorizations require customary post-approval safety monitoring, pharmacovigilance activities, and risk-minimization measures, as well as, among other things, a post-authorization efficacy study, for which the EC has specified that the Company must submit the final results from the Company’s PREVAIL cardiovascular outcomes trial, a placebo-controlled, double-blind, randomized trial evaluating obicetrapib as a monotherapy used as an adjunct to maximally tolerated lipid-lowering therapies to potentially enhance low-density lipoprotein cholesterol lowering in patients with atherosclerotic cardiovascular disease and/or HeFH.

The Company and Menarini are party to a licensing agreement pursuant to which Menarini holds exclusive commercialization rights for obicetrapib in Europe and is responsible for regulatory interactions and commercialization activities throughout the region. The Company is entitled to tiered double-digit percentage royalties ranging from the low double-digits to mid-twenties on net sales in the Menarini Territory (as defined in the Menarini licensing agreement) and up to an additional €833 million upon the achievement of various clinical, regulatory and commercial milestones, of which milestone payments in the mid-teens of millions of euros are triggered by the EC’s marketing authorizations for obicetrapib and the FDC.

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.

NewAmsterdam Pharma Company N.V.

Date: September 21, 2026

By: /s/ Mike Marino

Name: Mike Marino

Title: Chief Legal Officer
