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): July 24, 2026

NewAmsterdam Pharma Company N.V.

(Exact name of Registrant as Specified in Its Charter)

The Netherlands	**001-41562**	**N/A**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

Goomieer 2-35 **Naarden** **The Netherlands**	**1411 DC**
(Address of Principal Executive Offices)	**(Zip Code)**

+31 (0) 35 206 2971
(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
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 July 24, 2026, NewAmsterdam Pharma Company N.V. (the "Company") issued a press release announcing that the Company and the Menarini Group have received a positive opinion from the Committee for Medicinal Products for Human Use of the European Medicines Agency recommending marketing authorization for Ubeslo® (obicetrapib monotherapy) and Evlarco® (obicetrapib plus ezetimibe fixed-dose combination). A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 8.01 by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press Release issued by the Company on July 24, 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.

NewAmsterdam Pharma Company N.V.

Date: July 24, 2026

By: /s/ Mike Marino
Name: Mike Marino
Title: Chief Legal Officer

Exhibit 99.1

NewAmsterdam Pharma and Menarini Group Receive Positive CHMP Opinion Recommending Marketing Authorization for Ubeslo® (Obicetrapib Monotherapy) and Evlarco® (Obicetrapib Plus Ezetimibe Fixed-Dose Combination)

- Positive CHMP opinion supports potential commercialization of obicetrapib monotherapy and obicetrapib/ezetimibe fixed-dose combination in Europe -

- Recommendation based on positive Phase 3 BROADWAY, BROOKLYN, and TANDEM data -

- European Commission decision expected in 2H26 -

Naarden, the Netherlands, Miami, USA, and Florence, Italy; July 24, 2026 – NewAmsterdam Pharma Company N.V. (Nasdaq: NAMS or "NewAmsterdam" or the "Company"), a late-stage, clinical biopharmaceutical company developing oral, non-statin medicines for patients at risk of cardiovascular disease ("CVD") with elevated low-density lipoprotein cholesterol ("LDL-C"), for whom existing therapies are not sufficiently effective or well-tolerated, along with partner Menarini Group ("Menarini"), today announced that the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") has adopted a positive opinion recommending marketing authorization for Ubeslo® (obicetrapib 10 mg monotherapy) and Evlarco® (10 mg obicetrapib plus 10 mg ezetimibe fixed-dose combination ("FDC")) for patients with primary hypercholesterolemia, both heterozygous familial ("HeFH") and non-familial or mixed dyslipidemia.

"Today's positive CHMP opinion is a significant milestone—not just for NewAmsterdam but for a novel therapy, addressing LDL-C and other drivers of residual cardiovascular risk," said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam. "With its compelling clinical profile, and the convenience of oral, once daily dosing with or without food, obicetrapib, if approved, has the potential to address a major unmet need for those not reaching LDL-C goals on existing therapies. We are thankful for the continued collaboration with Menarini and look forward to the European Commission's final decision later this year."

The positive CHMP recommendation is supported by data from NewAmsterdam's comprehensive clinical development program evaluating obicetrapib, including the Phase 3 BROADWAY, BROOKLYN and TANDEM trials, which demonstrated statistically significant LDL-C reductions up to 40% with obicetrapib monotherapy versus placebo and approximately 50% with obicetrapib combined with ezetimibe versus placebo, with a tolerability profile comparable to placebo. NewAmsterdam and Menarini continue to advance the clinical development of obicetrapib through multiple ongoing Phase 3 trials, including PREVAIL, a cardiovascular outcomes trial, as well as REMBRANDT and RUBENS.

The CHMP's positive opinion will now be reviewed by the European Commission ("EC"), which is expected to adopt a final decision on marketing authorization and has authority to grant centralized marketing authorization applicable across all European Union member states, as well as Iceland, Liechtenstein and Norway.

"We are very pleased to have reached this important regulatory milestone in Europe and appreciate the continued collaboration with NewAmsterdam," said Elcin Barker Ergun, Chief Executive Officer of Menarini. "Pending a positive European Commission decision, we look forward to helping bring obicetrapib, an oral pill with a unique mechanism of action, to patients across Europe to help reach their LDL-C targets that they could not reach with existing treatments."

Under the parties' licensing agreement, Menarini holds exclusive commercialization rights for obicetrapib in Europe and is responsible for regulatory interactions and commercialization activities throughout the region.

NewAmsterdam is entitled to tiered double-digit percentage royalties ranging from the low double-digits to mid-twenties on net sales in the Menarini Territory and up to an additional €833 million upon the achievement of various clinical, regulatory and commercial milestones.

About Obicetrapib

Obicetrapib is a novel, oral, low-dose CETP inhibitor that NewAmsterdam is developing to overcome the limitations of current LDL-lowering treatments. In each of the Company's Phase 2 trials, ROSE2, TULIP, ROSE, and OCEAN, as well as the Company's Phase 3 BROOKLYN, BROADWAY and TANDEM trials, evaluating obicetrapib as monotherapy or combination therapy, the Company observed statistically significant LDL-lowering combined with a side effect profile similar to that of placebo. The Company commenced the Phase 3 PREVAIL cardiovascular outcomes trial in March 2022, which is designed to assess the potential of obicetrapib to reduce occurrences of MACE. The Company completed enrollment of PREVAIL in April 2024 and randomized over 9,500 patients. Commercialization rights of obicetrapib in Europe, either as a monotherapy or as part of a fixed-dose combination with ezetimibe, have been exclusively granted to the Menarini Group, an Italy-based, leading international pharmaceutical and diagnostics company.

About Cardiovascular Disease

Cardiovascular disease remains the leading cause of death globally, despite the availability of lipid-lowering therapies ("LLTs"). By 2050 more than 184 million U.S. adults are expected to be affected by CVD and hypertension, including 27 million with coronary heart disease and 19 million with stroke. In the United States from 2019 through 2022, CVD age-adjusted mortality rates increased by 9%, reversing the trend observed since 2010 and undoing nearly a decade of progress. Despite the availability of high-intensity statins and non-statin LLTs, LDL-C target level attainment remains low, contributing to residual cardiovascular risk, and underscoring a significant clinical need for improved therapeutic regimens. Even with 269 million LLT prescriptions written over the last 12 months, 30 million under-treated US adults are not at their risk-based LDL-C goal, of which 13 million have ASCVD. Less than 1 in 4 patients with ASCVD achieve an LDL-C goal of less than 70 mg/dL and only 10% of very high risk ASCVD patients achieve the goal below 55 mg/dL. In addition to the 30 million under-treated U.S. adults, there are 10 million patients diagnosed with elevated LDL-C who are not taking any LLTs including statins. Beyond LDL-C, additional factors are at play, such as lifestyle choices, tobacco use, and obesity, as well as inflammation, thrombosis, triglyceride levels, elevated Lp(a) levels, and type 2 diabetes.

About NewAmsterdam

NewAmsterdam Pharma (Nasdaq: NAMS) is a late-stage biopharmaceutical company whose mission is to improve patient care in populations with metabolic diseases where currently approved therapies have not been adequate or well tolerated. We seek to fill a significant unmet need for a safe, well-tolerated and convenient therapy that lowers LDL-C while advancing innovation beyond a single marker to better address cardiovascular risk. In multiple phase 3 trials, NewAmsterdam is investigating obicetrapib, an oral, low-dose and once-daily CETP inhibitor, alone or as a fixed-dose combination with ezetimibe, as LDL-C lowering therapies to be used as an adjunct to statin therapy for patients at risk of CVD with elevated LDL-C, for whom existing therapies are not sufficiently effective or well tolerated.

About Menarini Group
The Menarini Group, with headquarters in Florence, is present in 140 countries worldwide to date, with $5.5 billion in consolidated turnover and more than 17,000 employees. Menarini's products are present in the most important treatment areas, including those of cardiometabolic, oncology, gastroenterology, diabetology, pneumology, and anti-inflammatory/analgesic products. Through its commitment in R&D and high quality manufacturing activities, Menarini continuously contributes to patients' health worldwide, maintaining the highest quality standards.

Forward-Looking Statements
This press release contains "forward-looking" statements within the meaning of the United States Private Securities Litigation Reform Act of 1995 and are subject to the "safe harbor" provisions created thereunder. All statements that are not historical facts are hereby identified as forwarding-looking statements for this purposes and include, among others, statements relating to: the therapeutic potential of the Company's product candidates; the Company's expectations surrounding potential regulatory progress or approvals and timing thereof for any of its product candidates, including a potential marketing authorization in the European Union; the timing of review and final decision by the EC with respect to marketing authorization of obicetrapib 10 mg monotherapy and 10 mg obicetrapib plus 10 mg ezetimibe FDC for patients with primary hypercholesterolemia, both HeFH and non-familial or mixed dyslipidemia; the Company's licensing agreement with Menarini and entitlement to potential future payments thereunder; and other statements regarding the Company's future operations, prospects, objectives, strategies and other future events. The Company may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements,

and you should not place undue reliance on these forward-looking statements. These forward-looking statements are based upon management's current expectations and assumptions. Actual results or events could differ materially and adversely from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various risks, uncertainties and other factors, including, among others: uncertainties regarding whether the outcomes of the Company's clinical trials will be adequate to support regulatory review and approval of its product candidates; the risk that the EC may not grant marketing authorization for obicetrapib 10 mg monotherapy or 10 mg obicetrapib plus 10 mg ezetimibe FDC for patients with primary hypercholesterolemia, both HeFH and non-familial or mixed dyslipidemia; whether projections regarding clinical outcomes will reflect actual results in clinical use of the Company's product candidates; the potential for varying interpretation of the results of clinical trials and analyses; risks related to the Company's ability to achieve its business plans, objectives and milestones, including approval of the Company's product candidates and potential commercialization; challenges inherent to the launch of new drug products, if approved; risks related to the Company's reliance on third parties; and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, that are described in greater detail in the sections entitled "Risk Factors" in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on February 18, 2026 and in its Quarterly Report on Form 10-Q filed with the SEC on May 7, 2026, as well as in other filings the Company may make with the SEC in the future, which are available at www.sec.gov. Any forward-looking statements contained in this press release speak only as of the date of this press release, and the Company expressly disclaims any obligation to update any forward-looking statements contained herein, whether because of new information, future events, changed circumstances or otherwise, except as otherwise required by law.

BROADWAY (NCT05142722)
BROOKLYN (NCT05425745)
PREVAIL (NCT05202509)
REMBRANDT (NCT06305559)
RUBENS (NCT07219602)
TANDEM (NCT06005597)

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