

**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): June 11, 2024

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
(I.R.S. Employer
Identification No.)

**Gooimeer 2-35
Naarden
The Netherlands**
(Address of principal executive offices)

1411 DC
(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 is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communication 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-commencements 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 Symbols	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 7.01 Regulation FD Disclosure.

On June 11, 2024, NewAmsterdam Pharma Company N.V. (the “Company”) issued a press release announcing the issuance of a new patent.

The information contained in this Item 7.01, including Exhibit 99.1, is being “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 liability of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”). The information contained in this Item 7.01, including Exhibit 99.1, shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act or into any filing or other document pursuant to the Exchange Act, except as otherwise expressly stated in any such filing.

Item 8.01 Other Events.

The Company announced the issuance of a composition of matter patent for obicetrapib by the United States Patent and Trademark Office. The newly issued patent contains claims covering amorphous obicetrapib hemicalcium, the solid form that will be used in the Company’s products and will be listed in the FDA’s “Orange Book” as a drug substance patent, if any such products are approved. The issuance of the new patent is expected to provide patent protection for obicetrapib until July 2043.

Forward-Looking Statements

Certain statements included in this Item 8.01 that are not historical facts are forward-looking statements for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements generally are accompanied by words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “should,” “would,” “plan,” “predict,” “potential,” “seem,” “seek,” “future,” “outlook” and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-looking statements include, but are not limited to, statements regarding the Company’s intellectual property and its ability to enforce, and sufficiency of, its patents, business and strategic plans, the Company’s commercial opportunity, the achievement and timing of regulatory approvals, and plans for commercialization. These statements are based on various assumptions, whether or not identified in this document, and on the current expectations of the Company’s management and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as and must not be relied on as a guarantee, an assurance, a prediction, or a definitive statement of fact or probability. Actual events and circumstances are difficult or impossible to predict and may differ from assumptions. Many actual events and circumstances are beyond the control of the Company. These forward-looking statements are subject to a number of risks and uncertainties, including changes in domestic and foreign business, market, financial, political, and legal conditions; risks related to the approval of the Company’s product candidate and the timing of expected regulatory and business milestones, including potential commercialization; ability to negotiate definitive contractual arrangements with potential customers; the impact of competitive product candidates; ability to obtain sufficient supply of materials; global economic and political conditions, including the Russia-Ukraine and Israel-Hamas conflict; the effects of competition on the Company’s future business; and those factors described in the Company’s public filings with the Securities Exchange Commission. Additional risks related to the Company’s business include, but are not limited to: uncertainty regarding outcomes of the Company’s ongoing clinical trials, particularly as they relate to regulatory review and potential approval for its product candidate; risks associated with the Company’s efforts to commercialize a product candidate; the Company’s ability to negotiate and enter into definitive agreements on favorable terms, if at all; the impact of competing product candidates on the Company’s business; intellectual property related claims; the Company’s ability to attract and retain qualified personnel; ability to continue to source the raw materials for its product candidate. If any of these risks materialize or the Company’s assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. There may be additional risks that the Company does not presently know or that the Company currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. In addition, forward-looking statements reflect the Company’s expectations, plans, or forecasts of future events and views as of the date of this document and are qualified in their entirety by reference to the cautionary statements herein. The Company anticipates that subsequent events and developments may cause the Company’s assessments to change. These forward-looking statements should not be relied upon as representing the Company’s assessment as of any date subsequent to the date of this communication. Accordingly, undue reliance should not be placed upon the forward-looking statements. Neither the Company nor any of its affiliates undertakes any obligation to update these forward-looking statements, except as may be required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>EXHIBIT NUMBER</u>	<u>EXHIBIT DESCRIPTION</u>
99.1	Press Release, dated June 11, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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.

By: /s/ Michael Davidson

Michael Davidson
Chief Executive Officer

Dated: June 11, 2024

NewAmsterdam Pharma Announces Issuance of Composition of Matter Patent for Obicetrapib by the United States Patent and Trademark Office

— New patent extends patent term for obicetrapib until July 2043 —

Naarden, the Netherlands and Miami, USA; June 11, 2024 — 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, today announced that the United States Patent and Trademark Office (“USPTO”) has issued U.S. Patent No. 12,006,305, titled “Salts of Obicetrapib and Processes for their Manufacture and Intermediates Thereof.”

The newly issued patent contains claims covering amorphous obicetrapib hemicalcium, the solid form that will be used in the Company’s products and will be listed in the FDA’s “Orange Book” as a drug substance patent, if any such products are approved. The issuance of this composition of matter patent provides intellectual property (“IP”) protection for obicetrapib until July 2043. The USPTO has now issued or allowed a total of nine patents covering obicetrapib and its uses.

“We are excited to announce that obicetrapib has been granted our third-generation composition of matter patent by the USPTO, which extends obicetrapib’s IP protection and exclusivity until July 2043, more than 9 years beyond our previous second-generation patent expiration in 2034,” said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam. “There continues to be a need for a safe, efficacious, oral, and potent LDL-lowering therapy. Securing robust patent protection for obicetrapib enables us both to continue the execution of multiple ongoing pivotal Phase 3 trials, as well as reap the potential benefits of obicetrapib’s scientific innovation years beyond potential FDA approval.”

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, 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 is conducting two Phase 3 pivotal trials, BROADWAY and BROOKLYN, to evaluate obicetrapib as a monotherapy used as an adjunct to maximally tolerated lipid-lowering therapies to provide additional LDL-lowering for CVD patients and TANDEM, to evaluate obicetrapib and ezetimibe as a fixed-dose combination. The Company began enrolling patients in BROADWAY in January 2022, in BROOKLYN in July 2022, and in TANDEM in March 2024; completing enrollment of BROOKLYN in April 2023 and BROADWAY in July 2023. The Company also commenced the Phase 3 PREVAIL cardiovascular outcomes trial in March 2022, which is designed to assess the potential of obicetrapib to reduce occurrences of major adverse cardiovascular events, including cardiovascular death, non-fatal myocardial infarction, non-fatal stroke and non-elective coronary revascularization. NewAmsterdam completed enrollment of PREVAIL in April 2024 and randomized over 9,500 patients.

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 LDL-lowering therapy. In multiple phase 3 studies, 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.

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