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): January 4, 2024

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

Gooimeer 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 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 January 4, 2024, NewAmsterdam Pharma Company N.V. issued a press release highlighting its strategic priorities and anticipated milestones for 2024. A copy of the press release is furnished as Exhibit 99.1 hereto.

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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

EXHIBIT NUMBER	EXHIBIT DESCRIPTION
99.1	Press Release, dated January 4, 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: January 4, 2024

Exhibit 99.1

NewAmsterdam Pharma Announces 2024 Strategic Priorities

— Positioned for three Phase 3 trial readouts over the next 18 months —

— Topline data expected from Phase 3 BROOKLYN trial in HeFH in 3Q 2024 and BROADWAY trial in ASCVD in 4Q 2024 —

— Plan to initiate TANDEM, a pivotal Phase 3 trial evaluating obicetrapib and ezetimibe fixed-dose combination, in 1Q 2024; topline data expected in 1Q 2025 —

— On-track to complete enrollment in Phase 3 PREVAIL CVOT in 1Q 2024; topline data expected in 2026 —

— Well-capitalized with cash to support operations through BROADWAY, BROOKLYN, and PREVAIL readouts —

Naarden, the Netherlands and Miami, USA; January 4, 2024 – NewAmsterdam Pharma Company N.V. (Nasdaq: NAMS or "NewAmsterdam" or the "Company"), a clinical-stage biopharmaceutical company developing oral, non-statin medicines for patients at high risk of cardiovascular disease ("CVD") with residual elevation of low-density lipoprotein cholesterol ("LDL-C"), for whom existing therapies are not sufficiently effective or well-tolerated, today provided an update on its clinical development programs and outlined its strategic priorities for 2024.

"NewAmsterdam is entering 2024 on the precipice of a major transformation, with the potential to deliver significant benefit to patients globally and create value for our shareholders," said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam. "In the year ahead, we are on track to report topline results from our first two pivotal Phase 3 trials of obicetrapib, BROOKLYN and BROADWAY. We are optimistic that these data will build on our prior Phase 2 trials, where we observed a robust impact on lipid and lipoprotein parameters believed to be predictive of CVD risk. We continue to believe that our oral small molecule, low-dose, once-daily CETP inhibitor, if approved, has the potential to become the preferred LDL-C lowering therapy for the millions of dyslipidemia patients who are underserved by existing therapies."

Dr. Davidson continued, "In addition, in the first quarter, we expect to complete enrollment in PREVAIL, our cardiovascular outcomes trial, and initiate a fourth pivotal Phase 3 trial evaluating a fixed-dose combination of obicetrapib and ezetimibe, which was observed in our Phase 2 trial to reduce LDL-C by 63%. Taken together, we believe our comprehensive Phase 3 program will showcase obicetrapib's potential to help many more patients reach guideline-mandated LDL-C goals and, as a result, reduce suffering from major adverse cardiac events, while also providing physicians with multiple treatment options to optimize the care of each patient. We look forward to advancing our clinical program, while investing in our commercial organization and laying the groundwork for a successful global launch if obicetrapib receives the necessary marketing approvals."

Program Updates and Upcoming Milestones:

NewAmsterdam is developing obicetrapib, an oral, low-dose and once-daily cholesteryl ester transfer protein ("CETP") inhibitor, as the preferred LDL-C lowering therapy to be used as an adjunct to maximally tolerated statin therapy for high-risk CVD patients. In 2023, NewAmsterdam reported positive, statistically significant and clinically meaningful data from two Phase 2 clinical trials of obicetrapib: the Phase 2 ROSE2 trial, which evaluated obicetrapib in combination with ezetimibe, and a Phase 2b dose-finding trial, which evaluated obicetrapib in Japanese patients. In total, the Company has completed six Phase 1 or 2 clinical trials and tested obicetrapib in over 800 patients. Statistically significant LDL-lowering was observed in each of the Company's completed Phase 2 clinical trials, combined with generally moderate side effects and no drug-related, treatment-emergent serious adverse events.

The Company is currently conducting three pivotal Phase 3 clinical trials of obicetrapib: BROOKLYN, BROADWAY and PREVAIL. In addition, the Company plans to initiate a fourth Phase 3 trial, TANDEM, evaluating a fixed-dose combination ("FDC") of obicetrapib and ezetimibe.

- BROOKLYN is evaluating obicetrapib in patients with heterozygous familial hypercholesterolemia ("HeFH"), whose LDL-C is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy. The primary objective is to evaluate the effect of obicetrapib on LDL-C levels. Secondary objectives include evaluating the effect of obicetrapib on non-high-density lipoprotein cholesterol ("non-HDL-C"), apolipoprotein B ("ApoB"), and lipoprotein(a) ("Lp(a)"). The trial is also evaluating the safety and tolerability profile of obicetrapib. NewAmsterdam completed enrollment of approximately 350 patients in April 2023 and expects to report topline data in the third quarter of 2024.
- BROADWAY is evaluating obicetrapib in adult patients with HeFH and/or established atherosclerotic cardiovascular disease ("ASCVD"), whose LDL-C is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy. The primary objective is to evaluate the effect of obicetrapib on LDL-C levels at day 84. Secondary objectives include evaluating the effect of obicetrapib on ApoB, Lp(a), HDL-C, and non-HDL-C, at day 84, and on LDL-C levels at days 180 and 365. The trial is also evaluating the safety and tolerability of obicetrapib. NewAmsterdam completed enrollment of over 2,500 patients in July 2023 and expects to report topline data in the fourth quarter of 2024.
- PREVAIL is a cardiovascular outcomes trial ("CVOT") evaluating obicetrapib in patients with a history of ASCVD, whose LDL-C is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy. The primarily objective is to evaluate the effect of obicetrapib on the risk of major adverse cardiovascular events, including cardiovascular death, non-fatal myocardial infraction, non-fatal stroke, or non-elective coronary revascularization. Secondary objectives include evaluating the effect of obicetrapib on all-cause mortality, total cardiovascular events, new-onset diabetes mellitus, and change in LDL-C, non-HDL-C, and ApoB levels. NewAmsterdam expects to complete patient enrollment in PREVAIL in the first quarter of 2024 and to report topline data in 2026.
- TANDEM is designed as a pivotal Phase 3 clinical trial to evaluate obicetrapib as part of a FDC tablet with ezetimibe, a non-statin oral LDL-lowering therapy. The Company expects to initiate TANDEM in the first quarter of 2024 and to report topline data in the first quarter of 2025.

Also in 2023, NewAmsterdam reported positive initial data from a Phase 2a clinical trial evaluating obicetrapib in patients with early Alzheimer's disease who carry at least one copy of the apolipoprotein E4 mutation. NewAmsterdam anticipates sharing the full results from this Phase 2a clinical trial in a forthcoming publication or in a presentation at a medical meeting.

Financial Guidance: Based on its current operating and development plans, NewAmsterdam believes that its existing cash will be sufficient to fund the Company's operations through 2026, beyond the anticipated readout of its three ongoing Phase 3 trials: BROADWAY, BROOKLYN and PREVAIL.

About Obicetrapib

Obicetrapib is a novel, oral, low-dose CETP inhibitor that NewAmsterdam is developing to overcome the limitations of current LDL-lowering treatments. The Company believes that obicetrapib has the potential to be a once-daily oral CETP inhibitor for lowering LDL-C, if approved. In the Company's Phase 2b ROSE trial, obicetrapib demonstrated a 51% lowering of LDL-C from baseline at a 10 mg dose level on top of high-intensity statins and, in the Company's Phase 2 ROSE2 trial, the combination of a 10 mg dose of obicetrapib and a 10 mg dose of ezetimibe demonstrated a 63% lowering of LDL-C from baseline. In all five of the Company's Phase 2 trials, ROSE2, TULIP, ROSE, OCEAN, and TA-8995-203, 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, including no increase in blood pressure or muscle related side effects. Obicetrapib has demonstrated strong tolerability in more than 800 patients with elevated lipid levels in NewAmsterdam's clinical trials to date. 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 high-risk CVD patients. The Company began enrolling patients in BROADWAY in January 2022 and in BROOKLYN in July 2022 and completed 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.

About NewAmsterdam

Based in the Netherlands, NewAmsterdam (Nasdaq: NAMS) is a clinical-stage biopharmaceutical company whose mission is to improve patient care in populations with metabolic diseases where currently approved therapies have not been sufficiently adequate or well tolerated. We seek to fill a significant unmet need for a safe, cost-effective and convenient LDL-lowering therapy as an adjunct to statins, a class of lipid-lowering medications that are the current standard of care for high-risk CVD patients with high cholesterol. NewAmsterdam is investigating obicetrapib, an oral, low-dose and once-daily CETP inhibitor, as the preferred LDL-C lowering therapy to be used as an adjunct to maximally tolerated statin therapy for high-risk CVD patients.

Forward-Looking Statements

Certain statements included in this document 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,” “position,” “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 business and strategic plans, cash runway, the therapeutic and curative potential of the Company’s product candidate, the Company’s clinical trials and the timing for enrolling patients, the timing and forums for announcing data, 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 relating to the uncertainty of the projected financial information with respect to the Company; risks relating to the uncertainty of the projected financial information with respect to the Company; 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; the effects of competition on the Company’s future business; and those factors described in the Company’s public filings with the U.S. Securities and 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.

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