
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the month of November 2023

Commission File Number: 001-41562

NewAmsterdam Pharma Company N.V.
(Exact name of registrant as specified in its charter)

**Gooimeer 2-35
1411 DC Naarden
The Netherlands**
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

On November 13, 2023, NewAmsterdam Pharma Company N.V. (“NewAmsterdam” or the “Company”) issued a press release announcing corporate updates and its financial highlights for the nine months ended September 30, 2023.

The Company’s financial highlights as of and for the nine months ended September 30, 2023 are set out below.

Cash Position: As of September 30, 2023, NewAmsterdam recorded cash of \$368.3 million (€347.7 million), compared to \$467.7 million (€438.5 million) as of December 31, 2022. The decrease reflects cash used to fund operating activities, partially offset by the receipt of a milestone payment from Menarini pursuant to its license agreement with the Company and the proceeds from exercise of warrants in the first three quarters of 2023.

Revenue: Revenues were \$13.3 million (€12.3 million) for the nine months ended September 30, 2023, as compared to \$100.6 million (€95.5 million) for the nine months ended September 30, 2022. This decrease was primarily due to recognition of revenues related to the upfront payment by Menarini in the prior year.

Research and Development (“R&D”) Expenses: R&D expenses were \$118.5 million (€109.2 million) for the nine months ended September 30, 2023, as compared to \$56.4 million (€52.7 million) for the nine months ended September 30, 2022. This increase was primarily due to an increase in clinical expenses and manufacturing costs largely due to the administration and enrollment of three Phase 3 trials, as well as an increase in personnel costs driven by an increase in staff headcount as well as share-based compensation expense.

Selling, General and Administrative (“SG&A”) Expenses: SG&A expenses were \$27.2 million (€25.4 million) for the nine months ended September 30, 2023, as compared to \$15.0 million (€14.3 million) for the nine months ended September 30, 2022. This increase was primarily due to an increase in personnel costs driven by an increase in staff headcount and share-based compensation expense.

Net loss: Net loss was \$128.0 million (€118.0 million) for the nine months ended September 30, 2023, or a net loss per basic and fully diluted share of \$1.55 (€1.43), as compared to a net profit of \$30.8 million (€30.0 million) or of \$0.85 and \$0.76 (€0.83 and €0.74) per basic and fully diluted share, respectively, for the nine months ended September 30, 2022.

A copy of the press release is furnished as Exhibit 99.1 hereto. This Report on Form 6-K (excluding Exhibit 99.1) shall be deemed to be incorporated by reference into the Company’s registration statement on Form S-8 (File No. 333-271019).

EXHIBIT INDEX

Exhibit No.	Description
99.1	<u>Press Release, dated November 13, 2023.</u>

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, thereunto duly authorized.

November 13, 2023

NewAmsterdam Pharma Company N.V.

By: /s/ Michael Davidson

Name: Michael Davidson

Title: Chief Executive Officer

NewAmsterdam Pharma Provides Corporate Update and Reports Third Quarter 2023 Financial Highlights

— BROADWAY Phase 3 trial enrollment completed; on-track to report topline data for Phase 3 BROOKLYN and BROADWAY trials in 2H 2024 —

— Announced initial data from Phase 2a clinical trial evaluating obicetrapib in patients with early Alzheimer’s Disease (“AD”) who carry an apolipoprotein E4 (“ApoE4”) mutation; biomarker data suggest improvements in brain cholesterol metabolism and disease pathology —

— Expanded leadership team with key senior hires, appointing William “BJ” Jones as Chief Commercial Officer and Ian Somaiya as Chief Financial Officer —

Naarden, the Netherlands and Miami, USA; November 13, 2023 – 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 with residual elevation of low-density lipoprotein cholesterol (“LDL-C”), for whom existing therapies are not sufficiently effective or well-tolerated, today provided a corporate update and announced financial highlights for the quarter ended September 30, 2023.

“We experienced strong momentum in the third quarter, continuing the foundational work required to scale NewAmsterdam into a robust clinical and commercial organization,” said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam. “We recently expanded our leadership team with appointments of BJ Jones as Chief Commercial Officer and Ian Somaiya as Chief Financial Officer. Together, they bring tremendous expertise and functional knowledge, which will enable us to invest in the continued development of obicetrapib, while building a strategic go-to-market approach to support a potential launch. We look forward to their many contributions as we continue toward our goal of establishing NewAmsterdam as a global leader in cardiometabolic disease.”

Dr. Davidson continued, “We recently announced initial data from our Phase 2a trial evaluating obicetrapib in patients with early AD who carry the ApoE4 mutation. We are encouraged by these data, which suggest CETP inhibition may offer a novel approach to reducing the risk of AD in this targeted patient population. We continue to make meaningful progress across our pivotal Phase 3 clinical trials, with topline data from BROOKLYN and BROADWAY expected in the second half of 2024 and enrollment on track in PREVAIL. With our strong clinical expertise, growing leadership team and robust financial position, we believe we are well-positioned to execute on our mission of delivering safe, convenient and effective treatment options for patients with metabolic diseases.”

Third Quarter 2023 Highlights and Recent Progress

Clinical Development Updates:

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 cardiovascular disease patients. The Company is currently conducting three pivotal Phase 3 clinical trials of obicetrapib: BROOKLYN, evaluating the effect of obicetrapib on LDL-C levels in patients with heterozygous familial hypercholesterolemia (“HeFH”) as an adjunct to maximally tolerated lipid-lowering therapy, which completed enrollment in April 2023; BROADWAY, evaluating the effect of obicetrapib on top of maximally tolerated lipid-lowering therapy in patients with HeFH and/or established atherosclerotic cardiovascular disease (“ASCVD”), which completed enrollment in July 2023; and PREVAIL, a CVOT (“cardiovascular outcomes trial”) in patients with a history of ASCVD with inadequately controlled LDL-C despite treatment with maximally tolerated lipid-modifying therapies, expected to complete enrollment in the first quarter of 2024.

- At the American Heart Association (AHA) Scientific Sessions in November 2023, NewAmsterdam presented previously reported data from its Phase 2b dose-finding trial evaluating obicetrapib as an adjunct to stable statin therapy in Japanese patients with dyslipidemia. As previously disclosed, patients treated with obicetrapib 2.5 mg, 5 mg or 10 mg achieved a median reduction in LDL-C of 24.8%, 31.9%, and 45.8%, respectively, as compared to patients treated with placebo, who achieved a median reduction in LDL-C of 0.9%. In addition, patients treated with obicetrapib 10 mg achieved a median reduction in ApoB of 29.7%, compared to a 0.4% reduction in patients treated with placebo, and a median reduction in non-HDL-C of 37.0%, as compared to a 0.4% reduction in patients treated with placebo. The p-value for each endpoint in the obicetrapib arms of the trial compared to placebo was <0.0001.
- In October 2023, NewAmsterdam and other scientists published an article in *21st Century Cardiology*, “Recent Advances and Emerging Therapies in the Management of Dyslipidemia.” The publication details the significant need for novel therapeutic agents for the treatment of dyslipidemia and highlights the potential for obicetrapib as 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 cardiovascular disease patient.

NewAmsterdam is also advancing obicetrapib as a potential therapy for patients with early AD and at least one copy of the ApoE4 mutation.

- In October 2023, NewAmsterdam and other scientists published an article in *Pharmacological Research*, “The evolving role of cholesteryl ester transfer protein inhibition beyond cardiovascular disease.” This review describes biological evidence regarding the relationship between high-density lipoprotein and CETP inhibition for AD, as well as other diseases beyond cardiovascular disease.
- In September 2023, NewAmsterdam announced initial data from a Phase 2a clinical trial in patients with early AD, which was designed to assess the pharmacodynamics, pharmacokinetics, safety and tolerability of obicetrapib in the brains of ApoE4 carriers. Data showed reductions of 11% and 12% in levels of 24- and 27- hydroxycholesterol, two key biomarkers of degenerative changes in the brain, respectively, as well as an increase of 8% in the A β 42/40 ratio, a key biomarker of AD risk. NewAmsterdam anticipates sharing the full results of this Phase 2a clinical trial in a forthcoming publication or in a presentation at an upcoming medical meeting.

Corporate Updates

- In October 2023, NewAmsterdam appointed Ian Somaiya as Chief Financial Officer. Mr. Somaiya is an established healthcare executive with extensive financial, business development, and operational expertise, including experience as a senior leader within emerging biopharmaceutical companies and as a prominent biotechnology research analyst.
- In August 2023, NewAmsterdam appointed William “BJ” Jones as Chief Commercial Officer. Mr. Jones brings 30 years of commercial and launch experience in the U.S. and globally, with particular experience in driving mass market product launch strategies for industry-leading brands.

Upcoming Potential Milestones

NewAmsterdam currently expects to achieve the following upcoming milestones:

- Initiate a Phase 3 clinical trial evaluating a fixed-dose combination tablet of obicetrapib and ezetimibe in the first quarter of 2024.
- Complete enrollment in the Phase 3 PREVAIL trial for obicetrapib monotherapy in the first quarter of 2024 and announce topline data in 2026.
- Announce topline data from the Phase 3 BROOKLYN trial for obicetrapib monotherapy in the second half of 2024.
- Announce topline data from the Phase 3 BROADWAY trial for obicetrapib monotherapy in the second half of 2024.

Financial Highlights

- **Cash Position:** As of September 30, 2023, NewAmsterdam recorded cash of \$368.3 million (€347.7 million), compared to \$467.7 million (€438.5 million) as of December 31, 2022. The decrease reflects cash used to fund operating activities, partially offset by the receipt of a milestone payment from Menarini pursuant to its license agreement with the Company and the proceeds from exercise of warrants in the first three quarters of 2023.
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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.

Upcoming Investor Conferences

NewAmsterdam management will participate in fireside chats at the following upcoming conferences:

- **Jefferies London Healthcare Conference 2023** on Thursday, November 16 at 10:30 a.m. GMT (5:30 a.m. ET) in London.
- **Piper Sandler 35th Annual Healthcare Conference** on Tuesday, November 28 at 3:30 p.m. ET in New York.

Live webcasts of both fireside chats will be available through the investor relations section of the NewAmsterdam Pharma website at ir.newamsterdampharma.com. Following the live webcasts, archived replays will be available on the Company’s website.

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 (“dyslipidemia”) 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 cardiovascular disease (“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 cardiovascular disease 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,” “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, including the Russia-Ukraine conflict; 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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