# 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 May 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 May 8, 2023, NewAmsterdam Pharma Company N.V. (the "Company") issued a press release announcing a corporate update and its first quarter financial highlights. A copy of the press release is furnished as Exhibit 99.1 to this Report on Form 6-K.

This Report on Form 6-K (including Exhibit 99.1) shall be deemed to be incorporated by reference into the registration statements on Form S-8 (File No. 333-271019).

## EXHIBIT INDEX

Exhibit No.Description99.1Press Release, dated May 8, 2023.

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.

May 8, 2023

#### NewAmsterdam Pharma Company N.V.

By: /s/ Michael Davidson

Name: Michael Davidson Title: Chief Executive Officer

#### NewAmsterdam Pharma Provides Corporate Update and Reports First Quarter Financial Highlights

- Completed enrollment in BROOKLYN Phase 3 clinical trial evaluating obicetrapib in patients with heterozygous familial hypercholesterolemia ("HeFH") ahead of schedule; topline results expected in 2H 2024 —

— Announced positive topline results in January 2023 and scheduled to present full data from ROSE2 Phase 2 clinical trial evaluating combination of obicetrapib and ezetimibe at the National Lipid Association ("NLA") Scientific Sessions in June 2023 —

- Expect to report topline results from Phase 2 dose-finding trial of obicetrapib in Japanese patients with dyslipidemia and from Phase 2a trial evaluating obicetrapib in patients with early Alzheimer's disease in 2H 2023 -

- Topline data from pivotal Phase 3 BROADWAY and PREVAIL trials on-track to be announced in 2H 2024 and 2026, respectively -

Naarden, the Netherlands and Miami, USA; May 8, 2023 – NewAmsterdam Pharma Company N.V. (Nasdaq: NAMS or "NewAmsterdam" or the "Company"), a clinical-stage company focused on the research and development of transformative oral therapies for major cardiometabolic diseases, today provided a corporate update and announced financial highlights for the first quarter ended March 31, 2023.

"We are pleased to report an exceptional start to the year, marked by key accomplishments across our business," said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam. "We recently announced the early completion of enrollment in our Phase 3 BROOKLYN trial evaluating obicetrapib in patients with HeFH. Likewise, enrollment in our Phase 3 BROADWAY trial and Phase 3 cardiovascular outcomes ("CVOT") PREVAIL trial continues to be strong. We have over 1,700 patients randomized in BROADWAY and over 3,400 patients randomized in PREVAIL and expect to complete enrollment in the middle of 2023 and the first quarter of 2024, respectively. We believe that the strong enrollment we have seen in each clinical trial, at a time when patients and investigators have the option of similar clinical trials using injectable drugs, reflects the significant unmet need for a potent oral therapy that can be used as an adjunct to maximally tolerated statin therapy to help patients achieve target low-density lipoprotein cholesterol ("LDL-C") levels."

Dr. Davidson continued, "In addition, we plan to announce data from multiple Phase 2 trials in the coming months. We are eager to share full data from the Phase 2 ROSE2 trial at the NLA Scientific Sessions in June, as well as topline results from the Phase 2 dose-finding trial in Japanese patients with dyslipidemia and from the Phase 2a trial in patients with early Alzheimer's disease, which we expect in the second half of 2023. We believe that, taken together, these datasets can provide important information on the potential of obicetrapib as a next-generation, oral, low-dose CETP inhibitor with the potential to deliver a safe, convenient and effective solution to patients living with some of the world's most prevalent and debilitating diseases."

#### **Clinical Development Updates:**

NewAmsterdam is developing 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. 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 HeFH as an adjunct to maximally tolerated lipid-lowering therapy; 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"); and PREVAIL, a CVOT in patients with a history of ASCVD with inadequately controlled LDL-C despite treatment with maximally tolerated lipid-modifying therapies.

In April 2023, NewAmsterdam announced the early completion of enrollment of over 350 patients in the pivotal Phase 3 BROOKLYN trial.

NewAmsterdam is also evaluating obicetrapib in a Phase 2a clinical trial in patients with early Alzheimer's disease and at least one copy of the apolipoprotein E4 mutation. This study is designed to assess pharmacodynamic and pharmacokinetic effects, safety and tolerability, including whether CETP inhibition results in increased ApoA1 levels in patient cerebrospinal fluid. There is abundant pre-clinical data that suggests patients with the E4 variant of the ApoE protein are worse at transporting amyloid-beta peptides out of the brain, and increasing ApoA1 levels in the brain may rescue this loss-of-function by restoring appropriate cholesterol clearance. Pre-clinical data suggests that cholesterol accumulation in the brain may be a precursor to Alzheimer's disease; in pre-clinical animal studies, the Company observed a statistically significant reduction in a biomarker of Alzheimer's disease.

#### **Corporate Updates**

- In April 2023, NewAmsterdam appointed Janneke van der Kamp to its Board of Directors.
- In February 2023, NewAmsterdam appointed John W. Smither to its Board of Directors. Mr. Smither also serves as chair of the Company's Audit Committee.

# **Upcoming Potential Milestones**

NewAmsterdam currently expects to achieve the following upcoming milestones:

- Present full data from the Phase 2 ROSE2 clinical trial testing the combination of obicetrapib and ezetimibe at the NLA Scientific Sessions, June 1-4, 2023 in Atlanta, GA.
- Complete enrollment of the Phase 3 BROADWAY trial for obicetrapib monotherapy in mid-2023 and announce topline data in the second half of 2024.
- Announce topline data from the Phase 2a trial evaluating obicetrapib in ApoE4-carrying patients with early Alzheimer's disease in the second half of 2023.
- Announce topline results from the Phase 2 obicetrapib monotherapy dose-finding trial in Japanese patients in the second half of 2023.
- Select formulation for Phase 3 fixed-dose combination of obicetrapib and ezetimibe in the second half of 2023.
- Complete enrollment in the Phase 3 PREVAIL trial for obicetrapib monotherapy in the first quarter of 2024 and announce topline data in the second half of 2026.
- Announce topline data from Phase 3 BROOKLYN trial for obicetrapib monotherapy in the second half of 2024.

# **Financial Highlights**

- Cash Position: As of March 31, 2023, NewAmsterdam recorded cash of \$441 million, compared to \$468 million as of December 31, 2022 (equivalent to €439 million as was reported in the company's Full Year 2022 Financial Results). The decrease reflects cash used to fund operating activities, partially offset by the receipt of a milestone payment from Menarini pursuant to the Company's license agreement with Menarini.
- Financial Guidance: Based on its current operating and development plans, NewAmsterdam believes that its existing cash and cash equivalents 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 NewAmsterdam

NewAmsterdam Pharma (Nasdaq: NAMS) is a clinical-stage biopharmaceutical company whose mission is to improve patient care in populations with cardiometabolic diseases where currently approved therapies have not been sufficiently successful or well tolerated. 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 ("CVD") patients. Results from NewAmsterdam Pharma's ROSE Phase 2b trial (presented at AHA Scientific Sessions in 2021) included observations that patients receiving obicetrapib 10 mg experienced a median reduction in LDL-C of 51% versus baseline in patients on high-intensity

statin therapy (vs. a 7% reduction in the placebo arm). In addition, topline results from NewAmsterdam Pharma's ROSE2 trial evaluating the combination of 10 mg obicetrapib and 10 mg ezetimibe demonstrated a median reduction in LDL-C levels of 59% versus baseline in patients on high-intensity statin therapy (vs. a 6% reduction in the placebo arm). Based in the Netherlands, NewAmsterdam recently completed a business combination with FLAC, a special purpose acquisition company sponsored by an affiliate of Frazier Healthcare Partners. Proceeds from this transaction were approximately \$328 million, prior to deducting transaction expenses. In June 2022, NewAmsterdam Pharma entered into an exclusive licensing agreement with the Menarini Group for the commercialization of obicetrapib in Europe, while retaining all rights to commercialize obicetrapib, if approved, in the rest of the world, as well as rights to develop certain forms of obicetrapib for other diseases such as Alzheimer's disease. For more information, please visit: www.newamsterdampharma.com.

#### **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 and the achievement and timing of regulatory approvals. 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 related to the approval of the Company's product candidate and the timing of expected regulatory and business milestones; ability to negotiate definitive contractual arrangements with potential customers; the impact of competitive product candidates; ability to obtain sufficient supply of materials; the impact of COVID-19; 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 forwardlooking 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.

#### **Company Contact**

Matthew Philippe P: 917-882-7512 matthew.philippe@newamsterdampharma.com

## Media Contact

Spectrum Science on behalf of NewAmsterdam Bryan Blatstein P: 917-714-2609 bblatstein@spectrumscience.com

## **Investor Contact**

Stern Investor Relations on behalf of NewAmsterdam Hannah Deresiewicz P: 1 212-362-1200 <u>hannah.deresiewicz@sternir.com</u>