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): November 18, 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 November 18, 2024, NewAmsterdam Pharma Company N.V. (the "Company") issued a press release announcing additional safety and efficacy data from its Phase 3 BROOKLYN clinical trial evaluating obicetrapib in adult patients with heterozygous familial hypercholesterolemia ("HeFH") and whose low-density lipoprotein cholesterol ("LDL-C") is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy. The additional data will be presented at the 2024 AHA Scientific Sessions conference. Details of the conference are below.

2024 AHA Scientific Sessions

Presentation Title: Safety and Efficacy of Obicetrapib in Patients with Heterozygous Familial Hypercholesterolemia (BROOKLYN)

Session Title: Late-Breaking Science 8: New Targets and New Treatments: Advances in Lipid Therapeutics

Presentation Date and Time: Monday, November 18, 2024, 2:14 p.m. - 2:26 p.m. CST (3:14 p.m. - 3:26 p.m. ET)

Presenter: Stephen Nicholls, M.B.B.S., Ph.D., Director, Monash Victorian Heart Institute and Professor of Cardiology, Monash University

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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.

On November 18, 2024, the Company announced additional data from its Phase 3 BROOKLYN clinical trial, a 52-week, global, pivotal, Phase 3, randomized, double-blind, placebo-controlled multicenter trial to evaluate the efficacy and safety of 10 mg obicetrapib compared to placebo as an adjunct to maximally tolerated lipid-lowering therapies in patients with HeFH whose LDL-C is not adequately controlled. As previously reported, the trial met its primary endpoint of percent change from baseline in LDL-C of obicetrapib 10 mg compared to placebo after 84 days.

The trial also met several of its prespecified secondary endpoints with statistical significance and observed results consistent with the Company's prior clinical trials. Key secondary endpoints included percent changes from baseline of obicetrapib 10 mg compared to placebo after 84 days in lipoprotein(a) ("Lp(a)"), apolipoprotein B ("ApoB"), high-density lipoprotein cholesterol ("HDL-C") and non-HDL-C, all as shown in the table below. The p-value for the LS mean for all secondary endpoints compared to placebo was <0.0001 following 84 days of treatment with obicetrapib.

	% LS mean change from baseline		Obicetrapib LS mean % change compared to placebo	p-value
	Placebo (n=118)	Obicetrapib (n=236)		
LDL-C	0.3%	-36.1%	-36.3%	<0.0001
Lp(a)	10.5%	-35.4%	-45.9%	<0.0001
Non-HDL-C	2.8%	-31.6%	-34.5%	<0.0001
ApoB	2.9%	-21.5%	-24.4%	<0.0001
Total LDL particles	10.7%	-41.8%	-52.5%	<0.0001
Small LDL particles	32.4%	-70.0%	-102.4%	<0.0001
HDL-C	1.3%	140.0%	138.7%	<0.0001

Note: As of day 84, except for particle data as of day 180

Obicetrapib was also observed to be well tolerated, with safety results in the treatment arm comparable to placebo and no observed increase in blood pressure. The treatment discontinuation rate for the obicetrapib arm was 7.6% versus 14.4% for placebo. Adverse events of special interest are summarized in the table below.

	Placebo N=118 n (%)	Obicetrapib 10 mg N=236 n (%)
New diabetes or worsening glycemic control (%)	26 (22.0)	48 (20.5)
HbA1c[(1)] increase >0.5% from baseline	6 (5.1)	8 (3.4)
Cardiovascular events	5 (4.2)	6 (2.6)

(1) Hemoglobin A1c

The BROOLYN trial was conducted at sites in North America, Europe and Africa. A total of 354 patients were randomized 2:1 to receive 10 mg obicetrapib or placebo dosed as a once-daily oral treatment, with or without food. The mean baseline LDL-C for enrolled patients in the obicetrapib arm was 123 mg/dL despite high intensity statin use reported by approximately 79% of patients during screening, with 54% on ezetimibe and 14% on PCSK9 inhibitors. Females comprised approximately 53% of the study population and the median age of participants at baseline was 57 years.

Forward-Looking Statements

Certain statements included in this Current Report on Form 8-K 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, the Company’s commercial opportunity, 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 Current Report on Form 8-K, 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 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 Current Report on Form 8-K 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.

EXHIBIT NUMBER	EXHIBIT DESCRIPTION
99.1	Press Release, dated November 18, 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: November 18, 2024

NewAmsterdam Pharma Presents Additional Data from Pivotal Phase 3 BROOKLYN Clinical Trial Evaluating Obicetrapib in Patients with Heterozygous Familial Hypercholesterolemia at AHA Scientific Sessions 2024

– Met primary endpoint with LDL-C mean reduction versus placebo of 36.3% at day 84 and 41.5% at day 365 –

– Lp(a) mean reduction versus placebo of 45.9% at day 84 and 54.3% at day 365 –

– Total LDL-P mean reduction versus placebo of 52.5% at day 180, with small LDL-P reduction of 102.4% –

– Safety results comparable to placebo –

Naarden, the Netherlands and Miami, USA; November 18, 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 additional results from the Company's Phase 3 BROOKLYN clinical trial (NCT05425745) evaluating obicetrapib in adult patients with heterozygous familial hypercholesterolemia ("HeFH"), whose LDL-C is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy. The data were presented today in an oral late-breaker presentation at the American Heart Association (AHA) Scientific Sessions.

"We believe the additional data presented today underscore obicetrapib's potential to significantly reduce not only LDL-C but also Lp(a), LDL particles, both total and small, along with several other biomarkers in HeFH patients when compared to treatment with placebo. Within the HeFH patient community, it is common for patients to be on multiple lipid-lowering therapies, and given the efficacy and safety profile observed to date, we believe obicetrapib has the potential, if approved, to provide physicians with a new tool to address unmet need in these patients." said Stephen Nicholls, M.B.B.S., Ph.D., Director, Monash Victorian Heart Institute and Professor of Cardiology, Monash University.

"Despite the availability of lipid lowering therapies, CVD risk remains high and many people suffering from HeFH fail to meet their target cholesterol levels. We believe these additional results from the BROOKLYN pivotal trial further highlight obicetrapib's potential to meaningfully reduce LDL-C, while also significantly improving additional CVD risk parameters including Lp(a), non- HDL-C, ApoB, and HDL-C," said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam. "Together with the supportive data generated to date, these results reinforce our belief that, if approved, obicetrapib has the potential to meaningfully improve treatment for CVD patients worldwide. We look forward to building on these results with topline data from our TANDEM and BROADWAY studies expected in the fourth quarter of 2024."

Phase 3 BROOKLYN Trial Results

The BROOKLYN trial met its primary endpoint, achieving an LS mean reduction of 36.3% ($p < 0.0001$) compared to placebo at day 84, which was sustained at day 365 with an LS mean LDL-C reduction of 41.5% ($p < 0.0001$). Secondary efficacy endpoints, including lipoprotein(a) ("Lp(a)"), which was 45.9% ($p<0.0001$) compared to placebo at day 84 and 54.3% ($p=0.16$) at day 365, apolipoprotein B ("ApoB"), high-density lipoprotein cholesterol ("HDL-C") and non-HDL-C met statistical significance and results were consistent with data reported from NewAmsterdam's prior clinical trials. The p-value for the LS mean for all secondary endpoints compared to placebo was <0.0001 following 84 days of treatment with obicetrapib.

	% LS mean change from baseline		Obicetrapib LS mean % change compared to placebo	p-value
	Placebo (n=118)	Obicetrapib (n=236)		
LDL-C	0.3%	-36.1%	-36.3%	<0.0001
Lp(a)	10.5%	-35.4%	-45.9%	<0.0001
Non-HDL-C	2.8%	-31.6%	-34.5%	<0.0001
ApoB	2.9%	-21.5%	-24.4%	<0.0001
Total LDL particles	10.7%	-41.8%	-52.5%	<0.0001
Small LDL particles	32.4%	-70.0%	-102.4%	<0.0001
HDL-C	1.3%	140.0%	138.7%	<0.0001

Note: As of day 84, except for particle data as of day 180

“We are very encouraged by these additional results from BROOKLYN, where we observed obicetrapib’s lipid- and lipoprotein-lowering capabilities in a difficult to treat patient population that, despite being on multiple lipid-lowering therapies, still has elevated LDL-C,” said John Kastelein, M.D., Ph.D., FESC, Chief Scientific Officer of NewAmsterdam. “We are also pleased with the overall tolerability profile, including adverse events of special interest.”

Obicetrapib was observed to be well tolerated, with safety results comparable to placebo and no increase in blood pressure. The treatment discontinuation rate for the obicetrapib arm was 7.6% versus 14.4% for placebo. Adverse events of special interest are summarized in the table below.

	Placebo N=118 n (%)	Obicetrapib 10 mg N=236 n (%)
New diabetes or worsening glycemic control (%)	26 (22.0)	48 (20.5)
HbA1c increase >0.5% from baseline	6 (5.1)	8 (3.4)
Cardiovascular events	5 (4.2)	6 (2.6)

The data presentation is available through the publications and presentations section of the NewAmsterdam Pharma website at newamsterdampharma.com/publications.

Design of the Pivotal Phase 3 BROOKLYN Clinical Trial

The 52-week, global, pivotal, Phase 3, randomized, double-blind, placebo-controlled multicenter study evaluated the efficacy and safety of 10 mg obicetrapib compared to placebo as an adjunct to maximally tolerated lipid-lowering therapies in patients with HeFH whose LDL-C is not adequately controlled. The study was conducted at sites in North America, Europe and Africa. A total of 354 patients were randomized 2:1 to receive 10 mg obicetrapib or placebo dosed as a once-daily oral treatment, with or without food. The mean baseline LDL-C for enrolled patients in the obicetrapib arm was 123 mg/dL despite high intensity statin use reported by approximately 79% of patients during screening, with 54% on ezetimibe and 14% on PCSK9 inhibitors. Females comprised approximately 53% of the study population and the median age of participants at baseline was 57 years.

The primary endpoint was percent change from baseline in LDL-C of obicetrapib 10 mg compared to placebo after 84 days. Secondary endpoints also included percent changes from baseline of obicetrapib 10 mg compared to placebo after 84 days in HDL-C, non- HDL-C, ApoB, and Lp(a). The trial also evaluated the safety and tolerability profile of obicetrapib.

About NewAmsterdam’s Global Pivotal Phase 3 Program

NewAmsterdam’s global, pivotal Phase 3 clinical development program consists of four studies in over 12,250 patients, three for obicetrapib monotherapy and one for a fixed-dose combination (“FDC”) of obicetrapib and ezetimibe:

- BROOKLYN evaluated obicetrapib in patients with HeFH whose LDL-C is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy. NewAmsterdam reported topline data from BROOKLYN in the third quarter of 2024.
- BROADWAY is evaluating obicetrapib in adult patients with established atherosclerotic cardiovascular disease (“ASCVD”) and/or HeFH whose LDL-C is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy. NewAmsterdam completed enrollment of over 2,500 patients in July 2023 and expects to report topline data in the fourth quarter of 2024.

- TANDEM is evaluating obicetrapib as part of a FDC tablet with ezetimibe, a non-statin oral LDL-lowering therapy, in patients with established ASCVD or multiple risk factors for ASCVD and/or HeFH whose LDL-C is not adequately controlled despite being on maximally tolerated lipid-lowering therapy. NewAmsterdam completed enrollment of over 400 patients in July 2024 and expects to report topline data in the fourth quarter of 2024.
- PREVAIL is a cardiovascular outcomes trial evaluating obicetrapib in patients with a history of ASCVD whose LDL-C is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy. NewAmsterdam completed enrollment of over 9,500 patients in April 2024.

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 trial, 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 an additional Phase 3 pivotal trial BROADWAY, 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 and in TANDEM in March 2024; completing enrollment of BROADWAY in July 2023, and TANDEM in July 2024. 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. Commercialization rights of obicetrapib in Europe, either as a monotherapy or as part of a fixed dose combination with ezetimibe, for cardiovascular diseases have been exclusively granted to the Menarini Group, an Italy-based, leading international pharmaceutical and diagnostics company.

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.

Forward-Looking Statements

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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.

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