

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): August 7, 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
(IRS Employer
Identification No.)

Goomieer 2-35
Naarden
The Netherlands
(Address of Principal Executive Offices)

+31 (0) 35 206 2971
(Registrant's Telephone Number, Including Area Code)

1411 DC
(Zip Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications 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-commencement 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 Symbol(s)	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 2.02 Results of Operations and Financial Condition.

On August 7, 2024, NewAmsterdam Pharma Company N.V. (the “Company”) issued a press release announcing corporate updates and its financial results for the quarter ended June 30, 2024. A copy of the press release is furnished as Exhibit 99.1 hereto.

In accordance with General Instruction B.2 of Form 8-K, the information included in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1 hereto), shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	NewAmsterdam Pharma Company N.V. Press Release, dated August 7, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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.

Date: August 7, 2024

By: /s/ Michael Davidson

Name: Michael Davidson, M.D.

Title: Chief Executive Officer

NewAmsterdam Pharma Provides Corporate Update and Reports Second Quarter Financial Results

-- Reported positive topline data from pivotal Phase 3 BROOKLYN trial evaluating obicetrapib in patients with HeFH; achieved primary endpoint of LS mean reduction in LDL-C versus placebo, as well as statistically significant reductions in other biomarkers, with safety results comparable to placebo --

-- Extended US IP protection into 2043 with a new composition of matter patent --

-- On-track to report topline data from pivotal Phase 3 BROADWAY trial in 4Q 2024 --

-- Completed enrollment of pivotal Phase 3 TANDEM trial evaluating fixed-dose combination of obicetrapib and ezetimibe; topline data expected in 1Q 2025 --

-- Strong financial position; \$430.7 million in cash --

Naarden, the Netherlands and Miami, USA; August 7, 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 financial results for the three and six months ended June 30, 2024.

“I am extremely pleased with our execution over the first half of 2024 and continue to be motivated by the team’s relentless commitment to unlocking the value of obicetrapib. We were thrilled to recently announce positive and statistically significant topline data from the pivotal Phase 3 BROOKLYN trial, which targeted heterozygous familial hypercholesterolemia (“HeFH”), a historically difficult-to-treat patient population, and underscores obicetrapib’s potential to address the significant unmet need for lipid lowering therapies,” said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam. “Results from BROOKLYN achieved LDL-C lowering consistent with our phase 2 studies, along with a safety profile comparable to placebo, and with over half of patients on obicetrapib achieving the LDL-C guideline directed treatment goal of less than 70 mg/dl, we believe obicetrapib has potential to improve patient care for those living with dyslipidemia.”

“In addition, we recently hosted an R&D Day event where we detailed the differentiated target product profile of obicetrapib, discussed our commercial strategy, and unveiled REMBRANDT, a Phase 3 clinical study evaluating the fixed-dose combination (“FDC”) of obicetrapib and ezetimibe on coronary atherosclerotic plaque buildup in adults with or at high risk of atherosclerotic cardiovascular disease (“ASCVD”),” Dr. Davidson continued. “Supported by our recently issued composition of matter patent, which extends patent protection in the US for obicetrapib into 2043, and \$430.7 million of cash, we are advancing our mission from a position of strength. Looking at the second half and beyond, we are eager to build on the results of BROOKLYN with topline data from BROADWAY and TANDEM expected in the fourth quarter of 2024 and first quarter of 2025, respectively, while concurrently advancing our PREVAIL cardiovascular outcomes trial (“CVOT”).”

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 in patients at risk of CVD for whom existing therapies are not sufficiently effective or well-tolerated.

- In July 2024, NewAmsterdam announced positive topline data from the Phase 3 BROOKLYN clinical trial evaluating obicetrapib in patients with HeFH.
 - The BROOKLYN trial met its primary endpoint, with the obicetrapib arm 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% ($p < 0.0001$). The observed changes in other biomarkers, including high-density lipoprotein cholesterol (“HDL-C”), non-HDL-C, lipoprotein(a) (“Lp(a)”), and apolipoprotein B (“ApoB”), met statistical significance and were consistent with data reported from

the Company's prior clinical trials.

- o In the trial, obicetrapib was observed to be well-tolerated, with safety results comparable to placebo and no increase in blood pressure, nor any difference from placebo in liver enzymes, hs-CRP, or renal function.
- o NewAmsterdam plans to present full results from BROOKLYN at an upcoming medical conference and to publish the data in a major medical journal.
- In July 2024, NewAmsterdam completed patient enrollment in the pivotal Phase 3 TANDEM clinical trial evaluating the FDC of obicetrapib plus ezetimibe in adult patients with HeFH and/or ASCVD or multiple risk factors for ASCVD.
- In May and June 2024, respectively, NewAmsterdam presented new clinical and preclinical data highlighting the potential for obicetrapib as a novel, oral, low-dose therapy for hypercholesterolemia, at the European Atherosclerosis Society (EAS) 92nd Congress and National Lipid Association (NLA) 2024 Scientific Sessions.
- In May 2024, NewAmsterdam announced the initiation of REMBRANDT, a Phase 3 clinical trial evaluating the FDC of obicetrapib and ezetimibe against placebo on coronary atherosclerotic plaque characteristics in adults with or at high-risk for ASCVD.

Corporate Updates

- In July 2024, NewAmsterdam appointed Mark C. McKenna and Wouter Joustra to its Board of Directors and announced the departure of Sander Sloodweg from its Board of Directors.
- In June 2024, NewAmsterdam announced the United States Patent and Trademark Office ("USPTO") issued U.S. Patent No. 12,006,305, titled "Salts of Obicetrapib and Processes for their Manufacture and Intermediates Thereof." The 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 approved. The issuance of this composition of matter patent provides intellectual property protection for obicetrapib until July 2043.
- In May 2024, NewAmsterdam hosted an R&D Day event featuring presentations from Company management and key opinion leader cardiovascular disease specialists to discuss obicetrapib's clinical development path, NewAmsterdam's commercial readiness and strategy, and the cardiovascular disease landscape and opportunities for innovative new products. An archived replay of the event is available on the Investor Relations page of the NewAmsterdam website at ir.newamsterdampharma.com.

Upcoming Potential Milestones

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 FDC of obicetrapib and ezetimibe. NewAmsterdam currently expects to achieve the following upcoming milestones:

- Announce full data from Phase 3 BROOKLYN trial for obicetrapib monotherapy at an upcoming medical conference and publish the data in a major medical journal.
- Announce topline data from the Phase 3 BROADWAY trial for obicetrapib monotherapy in the fourth quarter of 2024. BROADWAY is evaluating obicetrapib in adult patients with HeFH and/or established ASCVD, whose LDL-C is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy.
- Announce topline data from the Phase 3 TANDEM trial evaluating a FDC of obicetrapib and ezetimibe in the first quarter of 2025.

Second Quarter Financial Results

- **Cash Position:** As of June 30, 2024, NewAmsterdam recorded cash of \$430.7 million, compared to \$340.5 million as of December 31, 2023. The increase in cash is primarily driven by the proceeds of the follow-on offering and warrant exercises partially offset by cash outflows related to research and development costs as the Company continues development of obicetrapib and increased spending on selling, general and
-

administrative expenses to support the Company's growing organization.

- **Revenue:** NewAmsterdam recognized \$2.3 million in revenue for the three months ended June 30, 2024, compared to \$1.7 million in the same period in 2023. This increase is due to an increase in the amount of previously deferred revenue which was recognized as revenue in the current period.
- **Research and Development ("R&D") Expenses:** R&D expenses were \$38.4 million for the three months ended June 30, 2024, compared to \$34.3 million for the same period in 2023. This increase was primarily due to clinical expenses related to the Company's ongoing Phase 3 clinical trials.
- **Selling, General and Administrative ("SG&A") Expenses:** SG&A expenses were \$16.5 million in three months ended June 30, 2024, compared to \$9.9 million for the same period in 2023. This increase was primarily due an increase in personnel costs related to expansion of the team to support the growth of the organization and investments in capabilities to support the Company's planned commercial launch of obicetrapib, if approved.
- **Net loss:** Net loss for the three months ended June 30, 2024 was \$39.0 million, or \$0.41 per diluted share, compared to net loss of \$38.3 million, or \$0.47 per diluted share, for the same period in 2023.

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

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 intellectual property and its ability to enforce, and sufficiency of, its patents, 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 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.

Company Contact

Matthew Philippe

P: 1-917-882-7512

matthew.philippe@newamsterdampharma.com

Media Contact

Spectrum Science on behalf of NewAmsterdam

Bryan Blatstein

P: 1-917-714-2609

bblatstein@spectrumsience.com

Investor Contact

Precision AQ on behalf of NewAmsterdam

Austin Murtagh

P: 1-212-698-8696

austin.murtagh@precisionaq.com

Financial Tables

NewAmsterdam Pharma Company N.V.
Condensed Consolidated Balance Sheets
(Unaudited)

<i>(In thousands of USD)</i>	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash	430,708	340,450
Prepayments and other receivables	14,644	6,341
Total current assets	445,352	346,791
Property, plant and equipment, net	234	46
Operating right of use asset	554	55
Intangible assets	542	170
Long term prepaid expenses	8	35
Total assets	446,690	347,097
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	5,275	16,923
Accrued expenses and other current liabilities	10,194	11,398
Deferred revenue, current	6,059	8,942
Lease liability, current	234	60
Derivative warrant liabilities	23,545	12,574
Total current liabilities	45,307	49,897
Deferred revenue, net of current portion	222	1,019
Lease liability, net of current portion	328	-
Derivative earnout liability	13,394	7,788
Total liabilities	59,251	58,704
Commitments and contingencies (Note 10)		
Shareholders' Equity (deficit):		
Ordinary shares, €0.12 par value; 400,000,000 shares authorized; 90,015,357 and 82,469,768 shares issued and outstanding as at June 30, 2024 and December 31, 2023, respectively	11,151	10,173
Additional paid-in capital	821,613	590,771
Accumulated loss	(449,747)	(316,973)
Accumulated other comprehensive income	4,422	4,422
Total shareholders' equity	387,439	288,393
Total liabilities and shareholders' equity	446,690	347,097

NewAmsterdam Pharma Company N.V.
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
(Unaudited)

	<u>For the three months ended June 30,</u>		<u>For the six months ended June 30,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
<i>(In thousands of USD, except per share amounts)</i>				
Revenue	2,279	1,717	3,680	10,346
Operating expenses:				
Research and development expenses	38,379	34,341	80,809	74,761
Selling, general and administrative expenses	16,475	9,858	30,928	17,920
Total operating expenses	54,854	44,199	111,737	92,681
Operating loss	(52,575)	(42,482)	(108,057)	(82,335)
Other income (expense):				
Interest income	4,870	4,613	7,953	5,556
Fair value change – earnout and warrants	9,692	(350)	(29,258)	(6,525)
Foreign exchange gains/(losses)	(994)	(72)	(3,412)	2,995
Loss before tax	(39,007)	(38,291)	(132,774)	(80,309)
Income tax expense	—	—	—	—
Loss and comprehensive loss for the period	(39,007)	(38,291)	(132,774)	(80,309)
Net loss per ordinary share				
Basic and diluted	\$ (0.41)	\$ (0.47)	\$ (1.45)	\$ (0.98)

NewAmsterdam Pharma Company N.V.
Condensed Consolidated Statements of Shareholders' Equity (Deficit)
(Unaudited)

(In thousands of USD, except share amounts)

	Shares	Amount	Additional Paid-In Capital	Accumulated Loss	Cumulative Translation Adjustments	Total Shareholders' Equity
	81,559,78					
Balance at December 31, 2022	<u>0</u>	<u>10,055</u>	<u>555,625</u>	<u>(140,036)</u>	<u>4,422</u>	<u>430,066</u>
Exercise of warrants	208,032	27	2,671	—	—	2,698
Share-based compensation	—	—	7,663	—	—	7,663
Total loss and comprehensive loss for the period	—	—	—	(42,018)	—	(42,018)
	81,767,81					
As at March 31, 2023	<u>2</u>	<u>10,082</u>	<u>565,959</u>	<u>(182,054)</u>	<u>4,422</u>	<u>398,409</u>
Exercise of warrants	541,609	70	7,444	—	—	7,514
Exercise of stock options	14,910	2	103	—	—	105
Share-based compensation	—	—	5,606	—	—	5,606
Total loss and comprehensive loss for the period	—	—	—	(38,291)	—	(38,291)
	82,324,33					
As at June 30, 2023	<u>1</u>	<u>10,154</u>	<u>579,112</u>	<u>(220,345)</u>	<u>4,422</u>	<u>373,343</u>
	82,469,76					
Balance at December 31, 2023	<u>8</u>	<u>10,173</u>	<u>590,771</u>	<u>(316,973)</u>	<u>4,422</u>	<u>288,393</u>
Issuance of Ordinary Shares and Pre-Funded Warrants, net of issuance costs	5,871,909	759	189,207	—	—	189,966
Exercise of warrants	926,698	121	19,674	—	—	19,795
Exercise of stock options	452,461	60	(609)	—	—	(549)
Share-based compensation	—	—	7,965	—	—	7,965
Total loss and comprehensive loss for the period	—	—	—	(93,767)	—	(93,767)
	89,720,83					
As at March 31, 2024	<u>6</u>	<u>11,113</u>	<u>807,008</u>	<u>(410,740)</u>	<u>4,422</u>	<u>411,803</u>
Exercise of warrants	294,521	38	6,268	—	—	6,306
Share-based compensation	—	—	8,337	—	—	8,337
Total loss and comprehensive loss for the period	—	—	—	(39,007)	—	(39,007)
	90,015,35					
As at June 30, 2024	<u>7</u>	<u>11,151</u>	<u>821,613</u>	<u>(449,747)</u>	<u>4,422</u>	<u>387,439</u>

NewAmsterdam Pharma Company N.V.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	For the six months ended June 30,	
	2024	2023
<i>(In thousands of USD)</i>		
Operating activities:		
Loss for the period	(132,774)	(80,309)
<i>Non-cash adjustments to reconcile loss before tax to net cash flows:</i>		
Depreciation and amortization	34	22
Non-cash rent expense	3	3
Fair value change - derivative earnout and warrants	29,258	6,525
Foreign exchange (gains)/losses	3,412	(2,995)
Share-based compensation	16,208	13,174
<i>Changes in working capital:</i>		
Changes in prepayments (current and non-current) and other receivables	(8,276)	4,038
Changes in accounts payable	(11,656)	1,410
Changes in accrued expenses and other current liabilities	(1,110)	1,925
Changes in deferred revenue	(3,680)	(4,961)
Net cash (used in)/provided by operating activities	(108,581)	(61,168)
Investing activities:		
Purchase of property, plant and equipment, including internal use software	(594)	(12)
Net cash used in investing activities	(594)	(12)
Financing activities:		
Proceeds from offering of Ordinary Shares and Pre-Funded Warrants	190,481	—
Transaction costs on issue of Ordinary Shares and Pre-Funded Warrants	(515)	—
Proceeds from exercise of warrants	13,421	8,621
Proceeds from exercise of options	440	105
Payment of withholding taxes related to net share settlement of exercised options	(989)	—
Net cash provided by financing activities	202,838	8,726
Net change in cash	93,663	(52,454)
Foreign exchange differences	(3,405)	1,432
Cash at the beginning of the period	340,450	467,728
Cash at the end of the period	430,708	416,706
Noncash financing and investing activities		
Right-of-use assets obtained in exchange for new operating lease liabilities	562	—

