NewAmsterdam Pharma Provides Corporate Update and Reports First Quarter Financial Results

May 9, 2024 at 8:00 AM EDT

-- Enrolled over 9,500 patients in Phase 3 PREVAIL global CVOT--

-- On-track to report topline data from Phase 3 BROOKLYN trial in HeFH in 3Q 2024 and Phase 3 BROADWAY trial in ASCVD in 4Q 2024 --

-- Dosed first patients in TANDEM, pivotal Phase 3 trial evaluating fixed-dose combination of obicetrapib and ezetimibe; topline data expected in 1Q 2025 --

-- Company to host R&D event on May 16, 2024, beginning at 9:00 a.m. ET in New York City –

-- Strong financial position; ending the quarter with $481.1 million in cash --

NAARDEN, the Netherlands and MIAMI, May 09, 2024 (GLOBE NEWSWIRE) -- 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 corporate updates and financial results for the quarter ended March 31, 2024.

"Recent months were marked by important milestones across our organization as we execute our multi-pronged clinical development strategy for obicetrapib and begin to prepare for a global launch," said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam. "We recently completed enrollment in PREVAIL, our cardiovascular outcomes trial ("CVOT"), and initiated TANDEM, a pivotal Phase 3 trial evaluating a fixed-dose combination of obicetrapib and ezetimibe. These trials, alongside BROOKLYN and BROADWAY, are expected to provide important insights into obicetrapib's ability to potentially improve upon the existing standard of care, by helping patients achieve their target LDL-C goals and, ultimately, avoid catastrophic outcomes. We are grateful to patients and physicians globally for their partnership, and we look forward to reporting pivotal data, beginning with topline results from BROOKLYN and BROADWAY in the third and fourth quarters of this year, respectively."

Dr. Davidson continued, "In parallel, we are working diligently to lay the foundation for a future global launch of obicetrapib, if approved. We believe that the market opportunity for obicetrapib is substantial; millions of people are living with hypercholesterolemia and many of those with atherosclerotic cardiovascular disease ("ASCVD") or heterozygous familial hypercholesterolemia ("HeFH") are not achieving LDL-C targets, despite the availability of statin therapies and PCSK9 inhibitors. We look forward to sharing additional details on our pre-launch activities and commercial strategy at our R&D Day on May 16th and, if our Phase 3 program is successful and regulatory approval is received, to delivering obicetrapib to improve health outcomes for CVD patients worldwide."

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 March 2024, NewAmsterdam announced the initiation of, and the dosing of the first patient in, TANDEM, a pivotal Phase 3 clinical trial to evaluate a fixed-dose combination of obicetrapib and ezetimibe in adult patients with HeFH and/or ASCVD or multiple risk factors for ASCVD, whose LDL-C is not adequately controlled despite being on maximally tolerated lipid-modifying therapies.
- In April 2024, NewAmsterdam announced that it has met the enrollment target for the pivotal Phase 3 PREVAIL CVOT evaluating obicetrapib in adult patients with a history of ASCVD, whose LDL-C is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy. Driven by strong patient and physician interest globally, NewAmsterdam extended enrollment to the end of April and randomized over 9,500 patients.
- Also in April 2024, at the 2024 American College of Cardiology Congress, NewAmsterdam presented additional data from the Phase 2 ROSE2 clinical trial, which evaluated the impact of obicetrapib in combination with ezetimibe as an adjunct to high-intensity statin therapy on multiple lipid biomarkers, including LDL particle number and small dense LDL-C.

Corporate Updates

- In January 2024, NewAmsterdam appointed William H. Lewis, J.D., M.B.A as Chair of its Board of Directors. Mr. Lewis has more than 30 years of executive experience in the pharmaceutical and finance industries both in the U.S. and internationally and has been widely recognized for his commitment to a patient-first approach to drug discovery, development, and commercialization.
- In February 2024, NewAmsterdam completed an upsized public offering of 5,871,909 ordinary shares and 4,736,841 pre-funded warrants, generating net proceeds of $190.0 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. NewAmsterdam intends to use the additional capital to support the continued development and ongoing commercial readiness of obicetrapib. The offering attracted several new and existing investors.
- In April 2024, NewAmsterdam appointed Juliette Audet as Chief Business Officer. Simultaneous with this announcement,

Ms. Audet resigned from the Company's Board of Directors. Ms. Audet is a seasoned life sciences executive with extensive pharmaceutical business development, finance and operational expertise. In her prior role as a Partner at Forbion, she was part of the team that built NewAmsterdam and she played a key role in out licensing obicetrapib, setting up operations and recruiting NewAmsterdam's management team.

Upcoming Potential Milestones

NewAmsterdam currently expects to achieve the following upcoming milestones:

- Announce topline data from the Phase 3 BROOKLYN trial for obicetrapib monotherapy in the third quarter of 2024. BROOKLYN is evaluating obicetrapib in patients with HeFH, whose LDL-C is not adequately controlled, despite being on maximally tolerated lipid-lowering therapy.
- 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 fixed-dose combination of obicetrapib and ezetimibe in first quarter of 2025.

Upcoming Investor Events

NewAmsterdam management will participate in a fireside chat at the RBC Capital Markets Global Healthcare Conference on Tuesday, May 14 at 4:35 p.m. ET in New York City.

Additionally, NewAmsterdam will host an R&D Day event on Thursday, May 16, 2024, beginning at 9:00 a.m. ET in New York City. The event will feature a panel discussion and presentations from management to discuss obicetrapib's clinical development path, the Company's commercial readiness and strategy, and the cardiovascular disease landscape and opportunities for innovative new products.

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

First Quarter Financial Results

- **Cash Position:** As of March 31, 2024, NewAmsterdam recorded cash of $481.1 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 $1.4 million in revenue for the quarter ended March 31, 2024, compared to $8.6 million in the same period in 2023. This decrease was primarily due to the recognition of license revenue related to a clinical development milestone in the quarter ended March 31, 2023 while no clinical development milestones were achieved in the same period in 2024.
- **Research and Development ("R&D") Expenses**: R&D expenses were $42.4 million in the quarter ended March 31, 2024, compared to $40.4 million for the same period in 2023. This increase was primarily due to an increase in clinical expenses related to the Company's ongoing Phase 3 clinical trials, partially offset by a decrease in manufacturing costs.
- **Selling, General and Administrative ("SG&A") Expenses**: SG&A expenses were $14.5 million in the quarter ended March 31, 2024, compared to $8.1 million for the same period in 2023. This increase was primarily due to 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 quarter ended March 31, 2024 was $93.8 million, or $1.06 per diluted share, compared to net loss of $42.0 million, or $0.51 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, 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 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 CVD patients and TANDEM, to evaluate obicetrapib and ezetimibe as a fixed-dose combination. The Company began enrolling patients in BROADWAY in January 2022, in BROOKLYN in July 2022, and in TANDEM in March 2024; completing 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. NewAmsterdam completed enrollment of PREVAIL in April 2024 and randomized over 9,500 patients.

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 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.

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Financial Tables

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

(In thousands of USD)	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash	481,147	340,450
Prepayments and other receivables	6,675	6,341
Total current assets	487,822	346,791
Property, plant and equipment, net	101	46
Operating right of use asset	38	55
Intangible assets	486	170
Long term prepaid expenses	16	35

Total assets	488,463	347,097
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	8,536	16,923
Accrued expenses and other current liabilities	9,970	11,398
Deferred revenue, current	8,116	8,942
Lease liability, current	43	60
Derivative warrant liabilities	33,061	12,574
Total current liabilities	59,726	49,897
Deferred revenue, net of current portion	444	1,019
Derivative earnout liability	16,490	7,788
Total liabilities	76,660	58,704
Commitments and contingencies (Note 10)		
Shareholders' Equity (deficit):		
Ordinary shares, €0.12 par value; 400,000,000 shares authorized; 89,720,836 and 82,469,768 shares issued and outstanding as at March 31, 2024 and December 31, 2023, respectively	11,113	10,173
Additional paid-in capital	807,008	590,771
Accumulated loss	(410,740)	(316,973)
Accumulated other comprehensive income (loss)	4,422	4,422
Total shareholders' equity	411,803	288,393
Total liabilities and shareholders' equity (deficit)	488,463	347,097

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

	For the three months ended March 31,	
	2024	**2023**
(In thousands of USD, except per share amounts)		
Revenue	1,401	8,629
Operating expenses:		
Research and development expenses	42,430	40,420
Selling, general and administrative expenses	14,453	8,062
Total operating expenses	56,883	48,482
Operating loss	(55,482)	(39,853)
Other income (expense):		
Interest income	3,083	943
Fair value change – earnout and warrants	(38,950)	(6,175)
Foreign exchange gains/(losses)	(2,418)	3,067
Loss before tax	(93,767)	(42,018)
Income tax expense	—	—
Loss and comprehensive loss for the period	(93,767)	(42,018)
Net loss per ordinary share		
Basic and diluted	$ (1.06)	$ (0.51)

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**
Balance at December 31, 2022	81,559,780	10,055	555,625	(140,036)	4,422	430,066
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)
As at March 31, 2023	81,767,812	10,082	565,959	(182,054)	4,422	398,409
Balance at December 31, 2023	82,469,768	10,173	590,771	(316,973)	4,422	288,393

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)
As at March 31, 2024	89,720,836	11,113	807,008	(410,740)	4,422	411,803

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

	For the three months ended March 31,	
	2024	**2023**
(In thousands of USD)		
Operating activities:		
Loss for the period	(93,767)	(42,018)
Non-cash adjustments to reconcile loss before tax to net cash flows:		
Depreciation and amortization	15	9
Non-cash rent expense	1	2
Fair value change - derivative earnout and warrants	38,950	6,175
Foreign exchange (gains)/losses	2,418	(3,067)
Share-based compensation	7,918	7,616
Changes in working capital:		
Changes in prepayments (current and non-current) and other receivables	956	(1,413)
Changes in accounts payable	(8,311)	(2,920)
Changes in accrued expenses and other current liabilities	(1,381)	6,997
Changes in deferred revenue	(1,401)	(3,244)
Net cash (used in)/provided by operating activities	**(54,602)**	**(31,863)**
Investing activities:		
Purchase of property, plant and equipment, including internal use software	(385)	(7)
Net cash used in investing activities	**(385)**	**(7)**
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	8,763	2,392
Proceeds from exercise of options	440	—
Payment of withholding taxes related to net share settlement of exercised options	(989)	—
Net cash provided by financing activities	**198,180**	**2,392**
Net change in cash	143,193	(29,478)
Foreign exchange differences	(2,496)	3,062
Cash at the beginning of the period	340,450	467,728
Cash at the end of the period	**481,147**	**441,312**
Noncash financing and investing activities		
Receivable related to exercise of warrants	1,271	—