NewAmsterdam Pharma Provides Corporate Update and Reports Third Quarter Financial Results

November 6, 2024 at 8:00 AM EST

– Topline data from pivotal Phase 3 TANDEM trial now expected in 4Q 2024 due to faster than expected enrollment –

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

– Strong balance sheet with $422.7 million in cash as of September 30, 2024 –

NAARDEN, The Netherlands and MIAMI, Nov. 06, 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 financial results for the three and nine months ended September 30, 2024.

"We are pleased to report another strong quarter, which was marked by continued execution across our ongoing Phase 3 clinical trials. We are excited to announce that due to faster than expected enrollment in our pivotal Phase 3 TANDEM trial evaluating a fixed-dose combination ("FDC") of obicetrapib and ezetimibe, we now expect to release topline data in the fourth quarter of 2024," said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam. "Additionally, we remain on track to announce topline data from our Phase 3 BROADWAY study by year end and continue to advance our 9,500-patient PREVAIL cardiovascular outcomes trial."

"We believe there is a substantial opportunity to address the unmet needs across cardiovascular disease, one of the leading causes of mortality worldwide. With our recently secured composition of matter patent granting exclusivity through 2043 in the United States, cash which we believe is sufficient to fund our pivotal Phase 3 readouts, and an experienced leadership team at the helm, we are well-positioned to drive our mission forward. We remain focused on our clinical execution and, if approved, ultimately commercializing obicetrapib to transform patient care for the millions of people living with hyperlipidemia," continued Dr. Davidson.

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.

- Due to faster than expected patient enrollment in the pivotal Phase 3 TANDEM trial evaluating the obicetrapib and ezetimibe FDC, in patients with heterozygous familial hypercholesterolemia ("HeFH") and/or atherosclerotic cardiovascular disease ("ASCVD") or ASCVD risk equivalents, the Company expects to announce topline data in the fourth quarter of 2024.

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 additional safety and efficacy data from the Phase 3 BROOKLYN trial for obicetrapib monotherapy at the upcoming 2024 AHA Scientific Sessions taking place November 16 – 18 in Chicago, Illinois.
- 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 fourth quarter of 2024.

Third Quarter Financial Results

- **Cash Position:** As of September 30, 2024, NewAmsterdam recorded cash of $422.7 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 conducted earlier this year, the achievement of a clinical development milestone 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 $29.1 million in revenue for the three months ended September 30, 2024, compared to $2.9 million in the same period in 2023. This increase is primarily due to the achievement of a clinical development milestone from Menarini during the current period.
- **Research and Development ("R&D") Expenses**: R&D expenses were $35.7 million for the three months ended September 30, 2024, compared to $43.4 million for the same period in 2023. This decrease was primarily due to a decrease in clinical expenses related to clinical trials which are completed or nearing completion.

- **Selling, General and Administrative ("SG&A") Expenses**: SG&A expenses were $18.4 million in three months ended September 30, 2024, compared to $9.1 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 three months ended September 30, 2024 was $16.6 million compared to net loss of $47.1 million for the same period in 2023. The individual components of the change are described above.

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.

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Financial Tables

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

	September 30, 2024	December 31, 2023
(In thousands of USD)		
Assets		
Current assets:		
Cash	422,729	340,450
Prepayments and other receivables	15,145	6,341
Total current assets	437,874	346,791
Property, plant and equipment, net	231	46
Operating right of use asset	493	55
Intangible assets	593	170
Long term prepaid expenses	-	35
Total assets	439,191	347,097
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	7,039	16,923
Accrued expenses and other current liabilities	10,580	11,398
Deferred revenue, current	4,495	8,942
Lease liability, current	240	60
Derivative warrant liabilities	18,901	12,574
Total current liabilities	41,255	49,897
Deferred revenue, net of current portion	-	1,019
Lease liability, net of current portion	266	-
Derivative earnout liability	18,808	7,788
Total liabilities	60,329	58,704
Commitments and contingencies (Note 10)		
Shareholders' Equity (deficit):		
Ordinary shares, €0.12 par value; 400,000,000 shares authorized; 92,165,605 and 82,469,768 shares issued and outstanding as at September 30, 2024 and December 31, 2023, respectively	11,435	10,173
Additional paid-in capital	829,399	590,771
Accumulated loss	(466,394)	(316,973)
Accumulated other comprehensive income	4,422	4,422
Total shareholders' equity	378,862	288,393
Total liabilities and shareholders' equity	439,191	347,097

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2024	2023	2024	2023
(In thousands of USD, except share and per share amounts)				
Revenue	29,111	2,941	32,791	13,287
Operating expenses:				
Research and development expenses	35,702	43,371	116,511	118,132
Selling, general and administrative expenses	18,412	9,128	49,340	27,048
Total operating expenses	54,114	52,499	165,851	145,180

Operating loss	(25,003)	(49,558)	(133,060)	(131,893)
Other income (expense):				
Interest income	4,443	3,059	12,396	8,615
Fair value change – earnout and warrants	(770)	2,521	(30,028)	(4,004)
Foreign exchange gains/(losses)	4,682	(3,155)	1,270	(160)
Loss before tax	(16,648)	(47,133)	(149,422)	(127,442)
Income tax expense	(1)	—	(1)	—
Loss and comprehensive loss for the period	(16,647)	(47,133)	(149,421)	(127,442)
Net loss per ordinary share:				
Basic and diluted net loss per ordinary share	$ (0.18)	$ (0.57)	$ (1.61)	$ (1.55)
Basic and diluted weighted average number of ordinary shares outstanding	94,754,140	82,466,584	92,666,874	82,058,225

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
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)
As at June 30, 2023	82,324,331	10,154	579,112	(220,345)	4,422	373,343
Exercise of warrants	100	0	1	—	—	1
Exercise of stock options	145,337	19	166	—	—	185
Share-based compensation	—	—	5,439	—	—	5,439
Total loss and comprehensive loss for the period	—	—	—	(47,133)	—	(47,133)
As at September 30, 2023	82,469,768	10,173	584,718	(267,478)	4,422	331,835
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
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)
As at June 30, 2024	90,015,357	11,151	821,613	(449,747)	4,422	387,439
Exercise of Pre-Funded Warrants	2,105,248	279	(279)	—	—	—
Exercise of stock options	45,000	5	53	—	—	58
Share-based compensation	—	—	8,012	—	—	8,012
Total loss and comprehensive loss for the period	—	—	—	(16,647)	—	(16,647)
As at September 30, 2024	92,165,605	11,435	829,399	(466,394)	4,422	378,862

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

	For the nine months ended September 30,	
	2024	**2023**
(In thousands of USD)		
Operating activities:		
Loss for the period	(149,421)	(127,442)
Non-cash adjustments to reconcile loss before tax to net cash flows:		
Depreciation and amortization	62	36
Non-cash rent expense	8	5
Fair value change - derivative earnout and warrants	30,028	4,004
Foreign exchange (gains)/losses	(1,270)	160
Share-based compensation	24,204	18,566
Changes in working capital:		
Changes in prepayments (current and non-current) and other receivables	(8,769)	988
Changes in accounts payable	(9,751)	(7,824)
Changes in accrued expenses and other current liabilities	(708)	11,266
Changes in deferred revenue	(5,466)	(7,903)
Net cash (used in)/provided by operating activities	**(121,083)**	**(108,144)**
Investing activities:		
Purchase of property, plant and equipment, including internal use software	(669)	(21)
Net cash used in investing activities	**(669)**	**(21)**
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	8,622
Proceeds from exercise of options	498	290
Payment of withholding taxes related to net share settlement of exercised options	(989)	—
Net cash provided by financing activities	**202,896**	**8,912**
Net change in cash	81,144	(99,253)
Foreign exchange differences	1,135	(168)
Cash at the beginning of the period	340,450	467,728
Cash at the end of the period	**422,729**	**368,307**
Noncash financing and investing activities		
Right-of-use assets obtained in exchange for new operating lease liabilities	562	—