



LAVA Provides Business Updates and Reports Fourth Quarter and Year-End Financial Results

March 20, 2024

- LAVA-1207 progressing in Phase 1/2a study, with pembrolizumab combination expected to begin in Q2 2024
- In March 2024, Pfizer paid LAVA \$7 million for achieving a clinical milestone for EGFRd2 (PF-08046052/formerly LAVA-1223)
- LAVA 1266 tracking to Q2 2024 IND submission
- Strong balance sheet with cash of \$95.6 million supports runway into 2026

UTRECHT, The Netherlands and PHILADELPHIA, March 20, 2024 (GLOBE NEWSWIRE) -- [LAVA Therapeutics N.V.](https://www.lavatherapeutics.com) (NASDAQ: LVTX, "LAVA," "the Company"), a clinical-stage immuno-oncology company focused on developing its proprietary Gammabody® platform of bispecific gamma-delta (δ 2) T cell engagers, today announced recent corporate highlights and financial results for the fourth quarter and year ended December 31, 2023.

"In 2023, we advanced our portfolio of proprietary Gammabody® programs. LAVA-1207 has enrolled dose level 9 in our Phase 1/2a trial of patients with metastatic castration-resistant prostate cancer (mCRPC). We will soon be enrolling the patients in our pembrolizumab combination arm. We continue to be encouraged by the favorable safety profile and preliminary signs of anti-tumor activity. We plan to provide new data for LAVA-1207 at an upcoming medical conference in the second half of 2024," said Stephen Hurly, President and Chief Executive Officer of LAVA. "We are also very excited by Pfizer's clinical progress. They have been a great partner and we look forward to continuing to support them. We plan to submit an IND for LAVA-1266, our investigational asset designed to target CD123 for the treatment of acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS), in Q2 2024," continued Mr. Hurly. "These advances represent important steps for our proprietary Gammabody® T-cell engagers as we evaluate their potential to treat cancer. We believe that 2024 will be a significant year and we look forward to sharing our ongoing progress with investors and stakeholders."

LAVA 1207 – In Phase 1/2a – Next update expected H2 2024 targeting a medical conference

Designed to mediate potent killing of prostate-specific membrane antigen (PSMA)-positive prostate cancer cells

- The first-in-human Phase 1/2a clinical trial is enrolling patients in monotherapy and combination arms
- Completed enrollment in dose level 9 monotherapy arm.
- Expect to begin enrolling in the dose escalation and dose expansion arm, in combination with KEYTRUDA® (pembrolizumab) in the coming months
- Evaluating low dose Interleukin-2 ("IL-2") in the Phase 1/2a study in order to increase the number of V γ 9V δ 2 T cells for engagement by LAVA-1207
- With the goal of maintaining low rates of cytokine release syndrome (CRS) and to minimize the risk of CRS events >grade 2, we have introduced premedication and step-dosing to the protocol.
- Three dose limiting toxicities (DLTs) were observed in patients receiving IL-2 in addition to LAVA-1207, in a cohort with multiple doses of IL-2 per cycle. Since we amended the DLT criteria and initiated step dosing, we have not observed any CRS or DLTs in patients dosed with IL-2 to date.
- Additional biomarker studies are underway to understand the relationship between δ 2 T cells and tumor response, and to investigate other factors that may impact patient selection and show early evidence of anti-tumor activity.

EGFRd2 (PF-08046052/formerly LAVA-1223) – In Phase 1

Designed to trigger the potent and preferential killing of EGFR-positive tumor cells in solid tumors such as colorectal cancer (CRC), non-small cell lung cancer (NSCLC), and head and neck squamous cell carcinoma (HNSCC)

- Potential first-in-class agent
- Dose escalation trial is underway to evaluate the safety and tolerability of EGFRd2 (PF-08046052) as a monotherapy in advanced EGFR-expressing solid tumors
- In March 2024, Pfizer paid LAVA \$7 million for achieving a clinical milestone

LAVA-1266 – IND Submission Expected in Q2 2024

Designed to target CD123 for the treatment of hematological malignancies, including AML and MDS

- Currently engaged in IND enabling activities

- Planning for IND submission in Q2 2024

Fourth Quarter and Year-End 2023 Financial Results

- As of December 31, 2023, LAVA had cash, cash equivalents and investments totaling \$95.6 million compared to cash, cash equivalents and investments of \$132.9 million as of December 31, 2022. The Company believes its current cash, cash equivalents and investments will be sufficient to fund operations into 2026.
- Revenue from contracts with customers was \$0.4 million and \$2.6 million for the quarters ended December 31, 2023 and 2022, respectively, and \$6.8 million and \$19.4 million for the years ended December 31, 2023 and 2022, respectively. In connection with the license agreement with Pfizer (formerly Seagen), we recognized \$0.3 million in revenue for the three months ended December 31, 2023, related to reimbursement for research activities and initial supply-related stability studies, and \$2.6 million for the three months ended December 31, 2022. The decrease of revenue from contracts with customers for the year ended December 31, 2023 compared to 2022 was primarily due to a \$15.2 million nonrefundable upfront payment received in 2022 in connection with the Pfizer agreement.
- Cost of sales of goods and providing services was \$0.2 million and zero for the quarters ended December 31, 2023 and 2022, respectively, and \$3.5 million and zero for the years ended December 31, 2023 and 2022, respectively. The cost in 2023 was due to the initial drug supply delivery to Pfizer and related stability studies.
- Research and development expenses were \$3.4 million and \$10.5 million for the quarters ended December 31, 2023 and 2022, respectively, and \$33.8 million and \$40.1 million for the years ended December 31, 2023 and 2022, respectively. The decrease for both periods was primarily due to reduced manufacturing scale-up costs, negotiated reduction in contract manufacturing invoices, and reduced clinical trial activities due to the discontinuation of the activities for LAVA-051, announced in June 2023.
- General and administrative expenses were \$2.3 million and \$3.6 million for the quarters ended December 31, 2023 and 2022, respectively, and \$12.7 million and \$14.1 million for the years ended December 31, 2023 and 2022, respectively. The decrease for both periods was primarily due to lower personnel-related expenses due to a reduction in general and administrative headcount in 2023.
- Net loss was \$6.5 million and \$14.9 million for the quarters ended December 31, 2023 and 2022, respectively, or \$0.24 and \$0.57 net loss per share for the quarters ended December 31, 2023 and 2022, respectively. Net losses were \$42.0 million and \$31.9 million for the years ended December 31, 2023 and 2022, respectively, or \$1.57 and \$1.23 net loss per share for the years ended December 31, 2023 and 2022, respectively.

LAVA Therapeutics N.V.
Consolidated Interim Statements of Loss
and Comprehensive Loss
(in thousands, except share and per share amounts) (unaudited)

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2023	2022	2023	2022
Revenue:				
Revenue from contracts with customers	\$ 353	\$ 2,640	\$ 6,769	\$ 19,391
Cost of sales of goods	—	—	(2,546)	—
Cost of providing services	(154)	—	(936)	—
Gross profit	199	2,640	3,287	19,391
Operating expenses:				
Research and development	(3,360)	(10,540)	(33,814)	(40,105)
General and administrative	(2,281)	(3,579)	(12,726)	(14,124)
Total operating expenses	(5,641)	(14,119)	(46,540)	(54,229)
Operating loss	(5,442)	(11,479)	(43,253)	(34,838)
Interest income (expense), net	846	471	2,970	257
Foreign currency exchange (loss) gain, net	(1,841)	(3,840)	(1,412)	2,923
Total non-operating income	(995)	(3,369)	1,558	3,180
Loss before income tax	(6,437)	(14,848)	(41,695)	(31,658)
Income tax expense	(61)	(67)	(279)	(249)
Loss for the year	\$ (6,498)	\$ (14,915)	\$ (41,974)	\$ (31,907)

Items that may be reclassified to profit or loss

Foreign currency translation adjustment	2,155	7,471	2,073	(6,749)
Total comprehensive loss	\$ (4,343)	\$ (7,444)	\$ (39,901)	\$ (38,656)
Loss per share:				
Loss per share, basic and diluted	\$ (0.24)	\$ (0.57)	\$ (1.57)	\$ (1.23)
Weighted-average common shares outstanding, basic and diluted	26,769,937	26,289,087	26,732,556	25,924,005

LAVA Therapeutics N.V.
Consolidated Statements of Financial Position
(in thousands) (unaudited)

	As of December 31,	
	2023	2022
Assets		
Non-current assets:		
Property and equipment, net	\$ 1,602	\$ 1,432
Right-of-use assets	892	651
Other non-current assets and security deposits	319	809
Total non-current assets	2,813	2,892
Current assets:		
Receivables and other	1,459	3,254
Prepaid expenses and other current assets	1,627	4,411
VAT receivable	240	—
Investments	51,340	32,535
Cash and cash equivalents	44,231	100,333
Total current assets	98,897	140,533
Total assets	\$ 101,710	\$ 143,425
Equity and Liabilities		
Equity:		
Share capital	\$ 3,715	\$ 3,715
Equity-settled employee benefits reserve	12,005	8,942
Foreign currency translation reserve	(10,899)	(12,972)
Additional paid-in capital	194,424	194,424
Accumulated deficit	(148,067)	(108,069)
Total equity	51,178	86,040
Non-current liabilities:		
Deferred revenue	35,000	35,000
Lease liabilities	591	431
Total non-current liabilities	35,591	35,431
Current liabilities:		
Trade payables and other	4,446	3,965
VAT payable	—	45
Borrowings	5,282	4,640
Lease liabilities	440	379
License liabilities	—	4,732
Accrued expenses and other current liabilities	4,773	8,193
Total current liabilities	14,941	21,954
Total liabilities	50,532	57,385
Total equity and liabilities	\$ 101,710	\$ 143,425

About LAVA Therapeutics

LAVA Therapeutics N.V. is a clinical-stage immuno-oncology company focused on advancing its proprietary Gammabody® platform to develop a portfolio of bispecific gamma-delta T cell engagers for the potential treatment of solid tumors and hematologic malignancies. The Company utilizes bispecific antibodies engineered to selectively kill cancer cells by triggering Vγ9Vδ2 (Vgamma9 Vdelta2) T cell antitumor effector functions upon cross-linking to tumor-associated antigens.

A Phase 1/2a dose escalation study ([NCT05369000](#)) to evaluate the lead program, LAVA-1207, in patients with metastatic castration-resistant prostate cancer (mCRPC) is actively enrolling in Europe and the United States in a study evaluating monotherapy and combination treatment with interleukin-2 (IL-2). The Company is also planning to expand the Phase 1/2a study to include a combination arm with KEYTRUDA® (pembrolizumab), through a clinical collaboration with Merck & Co., Inc., Rahway, NJ, USA. The Company licensed PF-08046052 (formerly SGN-EGFRd2/LAVA-1223) to Pfizer Inc. for clinical development and commercialization. The pipeline also includes several pre-clinical programs. For more information, please

visit www.lavatherapeutics.com, and follow us on [LinkedIn](#), [X](#), and [YouTube](#).

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co. LLC, Rahway, NJ, USA

Gammabody® is a registered trademark of LAVA Therapeutics N.V.

LAVAs Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements, including with respect to the Company's anticipated growth and clinical development plans including the timing and results of clinical trials. Words such as "anticipate," "believe," "could," "will," "may," "expect," "should," "plan," "intend," "estimate," "potential," "suggests" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on LAVA's expectations and assumptions as of the date of this press release and are subject to various risks and uncertainties that may cause actual results to differ materially from these forward-looking statements. Forward-looking statements contained in this press release include but are not limited to statements relating to the therapeutic potential, development and potential uses of LAVA's product candidates, the timing of initiation of clinical trials, including the expansion phase of the Phase 1/2a trial to evaluate LAVA-1207 in combination with KEYTRUDA®, the potential of premedication and step-dosing to minimize the risk of CRS in our Phase 1/2a clinical trial for LAVA-1207, use of biomarkers and assays for patient selection, the relationship between $\gamma\delta 2$ T cells and antitumor activity, the timing of regulatory submissions, availability of information regarding clinical development plans, progress and data from clinical trials, the potential uses of LAVA's product candidates to treat various tumor targets, including AML, MDS, mCRPC, CRC, NSCLC, and HNSCC, and improve patient outcomes, LAVA's cash runway and the sufficiency of resources to pursue development activities. Many factors, risks and uncertainties may cause differences between current expectations and actual results, including, among other things, the Company's ability to leverage its initial programs to develop additional product candidates using our Gammabody® platform, and the failure of LAVA's collaborators to support or advance collaborations or LAVA's product candidates, the timing and results of LAVA's research and development programs and preclinical and clinical trials, the possibility that clinical trials may fail to establish sufficient efficacy, the risk that adverse events or safety signals may occur, in clinical trials, the risk that results obtained in clinical trials to date may not be indicative of results obtained in ongoing or future trials, the risk that adverse regulatory actions or other setbacks could occur in clinical trials even after promising results in earlier clinical trials or preclinical studies, the Company's ability to obtain regulatory approval for an commercialize its product candidates, the risk that setbacks in development could occur in clinical trials even after promising results in earlier trials or preclinical studies, and the risk that setbacks in development could occur as a result of the difficulty and uncertainty of pharmaceutical product development and other factors. There may be adverse effects on the Company's business condition and results from general economic and market conditions and overall fluctuations in the United States and international equity markets, including as a result of inflation, heightened interest rates, recent and potential future pandemics and other health crises, the Russian invasion of Ukraine and the Israel- Hamas war, and recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures. These and other risks are described in greater detail under the caption "Risk Factors" and included in LAVA's filings with the Securities and Exchange Commission. LAVA assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

CONTACTS

Investor Relations

ir@lavatherapeutics.com

LifeSci Advisors (IR/Media)

Joyce Allaire

Jallaire@lifesciadvisors.com