LAVA Reports Third Quarter 2024 Financial Results and Announces Pipeline Reprioritization and Cash Runway Extension into 2027

December 10, 2024

- Reprioritized pipeline to focus on LAVA-1266, with continued support for partnered programs with Pfizer (PF-08046052) and Johnson and Johnson (JNJ-89853413) and plan to discontinue development of LAVA-1207
- Fourth quarter pipeline advances include initiation of the Phase 1 trial for LAVA-1266, for hematologic malignancies, and a $5.0 million milestone payment from Johnson and Johnson
- Cash runway extended into 2027, based on a cash balance of $78.9 million, as of September 30, 2024

UTRECHT, The Netherlands and PHILADELPHIA, Dec. 10, 2024 (GLOBE NEWSWIRE) -- LAVA Therapeutics N.V. (NASDAQ: LVTX, "LAVA," "the Company"), a clinical-stage immuno-oncology company focused on developing its proprietary Gammabody® platform of bispecific gamma delta T cell engagers, reported financial results for the third quarter ended September 30, 2024 and announced a strategic pipeline reprioritization.

"LAVA's goal is to develop immuno-oncology medicines to improve the lives of cancer patients. While we are disappointed that LAVA-1207 did not reach our predetermined success criteria, we are reprioritizing our pipeline to focus on LAVA-1266, for acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS), and will continue to support our partnered programs. We are pleased by the progress of our partnered programs, including a preclinical data presentation by Johnson and Johnson at ASH 2024 and ongoing enrollment in the Phase 1 program by Pfizer," said Stephen Hurly, President and Chief Executive Officer of LAVA Therapeutics. "LAVA is well capitalized, with approximately $79 million in cash, and with this pipeline reprioritization, we expect our cash balance to fund the Company into 2027."

"We thank the patients, investigators, and our employees for supporting the LAVA-1207 clinical study," said Charlie Morris, MD, Chief Medical Officer of LAVA Therapeutics. "The longer time to progression, with several patients on trial beyond 6 months, and duration of treatment observed for patients with higher circulating gamma delta2 T cells are consistent with the mechanism of action and supports continued clinical investigation of the platform."

Portfolio Highlights:

LAVA-1266 – In Phase 1 Trial (ACTRN12624001214527)

Designed to target CD123+ tumor cells for the treatment of hematological malignancies

- **Key indications**: Acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS)
- **Current Status**: Phase 1 dose escalation study initiated in Australia

Johnson & Johnson Partnered Program (JNJ-89853413) – Phase 1 Trial (NCT06618001)

Designed to target CD33 and Vδ2 T cells with a bispecific gamma delta T cell engager

- **Key Indications**: include hematological cancers
- **Current Status:** Johnson and Johnson has filed with health authorities to start a Phase 1 study. Johnson & Johnson presented preclinical data for JNJ-89853413 at the Annual Meeting of the American Society of Hematology (ASH 2024) on December 7, 2024 (Abstract 2054: 2054).
- **Milestone**: Development milestone of $5 million received from Johnson and Johnson in Q4 2024 related to the IND filing for JNJ-89853413

Pfizer Partnered Program –(PF08046052) – In Phase 1 Trial (NCT05983133)

Potential first-in-class epidermal growth factor receptor (EGFR) and bispecific gamma delta T cell receptor-targeted therapy for solid tumors

- **Key Indications**: Include colorectal cancer (CRC), non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC) and pancreatic ductal adenocarcinoma (PDAC)
- **Current Status:** Monotherapy Phase 1 dose escalation study underway to evaluate the safety and tolerability in advanced EGFR-expressing solid tumors
- **Milestone**: Clinical development milestone of $7 million received from Pfizer in Q1 2024

LAVA-1207 – Discontinued

Designed to target prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC)

- The Phase 1 study of LAVA-1207 did not reach LAVA's internal benchmarks and the program and drug will be made available for patients currently receiving LAVA-1207 for as long as considered necessary by their treating physician. The decision to discontinue LAVA-1207 is not due to safety concerns. Clinical signals recorded in several patients, including PSA reductions and extended time on study for patients with higher baseline circulating Vd2 T cells, as well as the encouraging safety and tolerability profile, are consistent with the intended mechanism of action and support further investigation of the platform. Learnings, especially related to the favorable overall safety profile and tolerability of LAVA-1207, will be incorporated into further development of the Company's pipeline programs.

Third Quarter 2024 Financial Results

- As of September 30, 2024, LAVA had cash, cash equivalents and investments totaling $78.9 million, compared to cash, cash equivalents and investments of $95.6 million as of December 31, 2023. The Company believes its current cash, cash equivalents and investments will be sufficient to fund operations into 2027.
- Revenue from contracts with customers was zero and $0.1 million for the quarters ended September 30, 2024 and 2023, respectively, and $7.0 million and $6.4 million for the nine months ended September 30, 2024 and 2023, respectively. Revenue of $0.1 million for the quarter ended September 30, 2023 was related to reimbursement for research activities and initial stability studies for clinical supplies.
- Research and development expenses were $8.5 million and $7.9 million for the quarters ended September 30, 2024, and 2023, respectively, and $20.8 million and $30.5 million for the nine months ended September 30, 2024 and 2023, respectively. The increase for the quarter ended September 30, 2024, as compared to 2023 was the result of increased pre-clinical and clinical trial expenses due to increased clinical trial activities for LAVA-1207, partly offset by reduced manufacturing costs for LAVA-1266 and other product candidates. The decrease between the nine months ended September 30, 2024 and 2023, respectively, was primarily due to lower pre-clinical and clinical trial expenses due to the discontinuation of LAVA-051, announced in June 2023, and reduced personnel-related expenses due to a reduction in research and development headcount in the second half of 2023.
- General and administrative expenses were $2.8 million and $2.9 million for the quarters ended September 30, 2024 and 2023, respectively, and $8.7 million and $10.4 million for the nine months ended September 30, 2024 and 2023, respectively. The decrease in both periods was primarily due to lower non-cash share-based compensation expenses and personnel-related expenses due to a reduction in general and administrative headcount in the second half of 2023.
- Net losses were $12.3 million and $8.8 million, or $0.46 and $0.34 net loss per share, for the quarters ended September 30, 2024 and 2023, respectively, and $21.1 million and $35.5 million, or $0.79 and $1.35 net loss per share, for the nine months ended September 30, 2024 and 2023, respectively.

LAVA will transition from foreign private issuer to U.S. domestic filer status beginning on January 1, 2025. The Company expects to incur increased costs associated with this transition, including expenses related to financial reporting, preparation of financial statements in accordance with U.S. GAAP, and compliance with U.S. federal proxy rules.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenue:				
Revenue from contracts with customers	$ —	$ 53	$ 6,992	$ 6,416
Cost of sales of goods	—	—	—	(2,546)
Cost of providing services	—	(10)	—	(782)
Gross profit	**—**	**43**	**6,992**	**3,088**
Operating expenses:				
Research and development	(8,500)	(7,912)	(20,844)	(30,454)
General and administrative	(2,785)	(2,858)	(8,745)	(10,445)
Total operating expenses	**(11,285)**	**(10,770)**	**(29,589)**	**(40,899)**
Operating loss	**(11,285)**	**(10,727)**	**(22,597)**	**(37,811)**
Interest income, net	805	809	2,426	2,124
Foreign currency exchange (loss) gain, net	(1,720)	1,132	(723)	429
Total non-operating (loss) income	**(915)**	**1,941**	**1,703**	**2,553**

Loss before income tax	**(12,200)**	**(8,786)**	**(20,894)**	**(35,258)**
Income tax expense	(96)	(50)	(250)	(218)
Loss for the period	**$ (12,296)**	**$ (8,836)**	**$ (21,144)**	**$ (35,476)**
Items that may be reclassified to profit or loss				
Foreign currency translation adjustment	1,688	(1,385)	296	(82)
Total comprehensive loss	**$ (10,608)**	**$ (10,221)**	**$ (20,848)**	**$ (35,558)**
Loss per share:				
Loss per share, basic and diluted	$ (0.46)	$ (0.34)	$ (0.79)	$ (1.35)
Weighted-average common shares outstanding, basic and diluted	26,846,006	26,289,087	26,814,113	26,289,087

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

	September 30, 2024	December 31, 2023
Assets		
Non-current assets:		
Property and equipment, net	$ 1,188	$ 1,602
Right-of-use assets	517	892
Deferred tax assets	—	—
Other non-current assets and security deposits	114	319
Total non-current assets	**1,819**	**2,813**
Current assets:		
Receivables and other	536	1,459
Prepaid expenses and other current assets	1,629	1,627
VAT receivable	489	240
Investments	51,921	51,340
Cash and cash equivalents	26,963	44,231
Total current assets	**81,538**	**98,897**
Total assets	**$ 83,357**	**$ 101,710**
Equity and Liabilities		
Equity:		
Share capital	$ 3,716	$ 3,715
Equity-settled employee benefits reserve	14,360	12,005
Foreign currency translation reserve	(10,603)	(10,899)
Additional paid-in capital	194,450	194,424
Accumulated deficit	(168,930)	(148,067)
Total equity	**32,993**	**51,178**
Non-current liabilities:		
Deferred revenue	35,000	35,000
Lease liabilities	164	591
Total non-current liabilities	**35,164**	**35,591**
Current liabilities:		
Trade payables and other	2,815	4,446
Borrowings	5,756	5,282
Lease liabilities	370	440
Accrued expenses and other current liabilities	6,259	4,773
Total current liabilities	**15,200**	**14,941**
Total liabilities	**50,364**	**50,532**
Total equity and liabilities	**$ 83,357**	**$ 101,710**

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 anti-tumor effector functions upon cross-linking to tumor-associated antigens.

LAVA's pipeline includes three internal and partnered clinical stage bispecific gamma-delta T cell engagers for the treatment of solid tumor and

hematological cancers including LAVA 1266, targeting CD123+ cancers; PF-08046052, targeting EGFR (NCT05983133); and JNJ-89853413, targeting hematological cancers (NCT06618001). The pipeline also includes pre-clinical programs. For more information on LAVA, please visit our website at www.lavatherapeutics.com, or follow us on LinkedIn, X, and YouTube.

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

LAVA's Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements, regarding the Company's business 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 strategy and potential uses of LAVA's product candidates including the timing of initiation of clinical trials and achievement of clinical milestones, and the Company's ability to realize the expected benefits of its strategic pipeline reprioritization, including generation of clinical data for LAVA-1266, LAVA's cash runway and the sufficiency of resources to pursue development activities, expectations related to increased costs associated with transitioning from foreign private issuer status to a U.S. domestic filer status, availability of information regarding clinical development plans, progress and data from clinical trials, and the ability of LAVA's product candidates to treat various tumor targets and improve patient outcomes. 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 its 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 and commercialize its product candidates, 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, and hostilities, including between Russia and escalating tension in the Middle East. These and other risks are described in greater detail under the caption "Risk Factors" in LAVA's most recent Annual Report on Form 20-F and other filings the Company makes 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.

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