LAVA Reports Second Quarter 2024 Financial Results and Business Update

August 20, 2024

- Continued progress in Phase 1/2a dose escalation for LAVA-1207, including the monotherapy arm, now enrolling in dose level 12, and the pembrolizumab combination
- Favorable safety profile for LAVA-1207
- Next data update for LAVA-1207 program expected in Q4 2024
- Strong balance sheet with cash of $86.8 million supports runway into mid-2026

UTRECHT, The Netherlands and PHILADELPHIA, Aug. 20, 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, today announced financial results for the second quarter ended June 30, 2024 and provided an update on recent corporate highlights.

"LAVA has continued to make progress in the Phase 1/2a study for LAVA-1207, our lead Gammabody® product candidate in mCRPC. Patients in the Phase 1/2a study are being treated with LAVA-1207 monotherapy at dose level 12," said Stephen Hurly, President and Chief Executive Officer of LAVA. "In Q2 2024, we initiated dosing in the pembrolizumab combination arm and have dosed our first patients. We expect to release the next data for LAVA-1207 at a medical meeting later this year. We are also excited to start our clinical trial for LAVA-1266 for AML/MDS later this year."

Portfolio Highlights:

LAVA-1207 – In Phase 1/2a (NCT05369000) – Next update planned for Q4 2024

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

- **Monotherapy Arm**: Enrolling in dose level 12 with no ≥ Grade 2 Cytokine Release Syndrome (CRS) since the implementation of step-dosing in Q1 2024
- **KEYTRUDA® (pembrolizumab) Combination:** Initiated dosing in the LAVA-1207 + pembrolizumab dose-escalation arm (KEYNOTE-F73) to potentially enhance the anti-tumor activity of LAVA-1207. This arm also utilizes the established step-dosing regimen
- **Low Dose Interleukin-2 (IL-2, LDIL-2) Combination:** LDIL-2 is intended to potentially increase the number of Vγ9Vδ2 T cells for engagement by LAVA-1207. Evaluation is underway

LAVA-1266 – Trial initiation activities underway

Designed to target CD123+ tumor cells for the treatment of hematological malignancies, including acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS)

- **Next Step:** Planning to initiate the Phase 1 trial of LAVA-1266 by year-end 2024 in Australia

Pfizer PF-08046052 – In Phase 1 (NCT05983133)

Potential first-in-class EGFR and bispecific gamma delta T cell-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

Johnson and Johnson Innovative Medicine Collaboration – In Research

Discovery and development of novel bispecific gamma delta T cell engager for the treatment of blood cancer

- **Current Status:** Lead candidate bispecific candidate antibody selected for development. Efforts are underway by Johnson and Johnson Innovative Medicine to advance candidate toward the clinic

Second Quarter 2024 Financial Results

We will transition from foreign private issuer to U.S. domestic filer status beginning on January 1, 2025 and expect to incur increased costs associated

with being a U.S. domestic filer, including expenses related to financial reporting, preparation of financial statements in accordance with U.S. GAAP and compliance with U.S. federal proxy rules.

- As of June 30, 2024, LAVA had cash, cash equivalents and investments totaling $86.8 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 mid-2026.
- Revenue from contracts with customers was zero and $5.1 million for the quarters ended June 30, 2024 and 2023, respectively, and $7.0 million and $6.4 million for the six months ended June 30, 2024 and 2023, respectively. Revenue of $5.1 million for the quarter ended June 30, 2023 was comprised of $2.6 million in revenue for reimbursement of research activities and delivery of initial supply in connection with the Pfizer Agreement, and $2.5 million in revenue related to a triggered milestone payment in connection with the Janssen Agreement.
- Cost of providing services and sales of goods was zero and $2.4 million for the quarters ended June 30, 2024 and 2023, respectively, and zero and $3.3 million for the six months ended June 30, 2024 and 2023, respectively. The cost in both periods of 2023 was primarily related to the cost of the initial supply delivery to Pfizer and related stability studies.
- Research and development expenses were $6.3 million and $12.6 million for the quarters ended June 30, 2024 and 2023, respectively, and $12.3 million and $22.5 million for the six months ended June 30, 2024 and 2023, respectively. The decrease in both periods 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 $3.0 million and $3.7 million for the quarters ended June 30, 2024 and 2023, respectively, and $6.0 million and $7.6 million for the six months ended June 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 $8.3 million and $12.7 million, or $0.31 and $0.48 net loss per share, for the quarters ended June 30, 2024 and 2023, respectively, and $8.8 million and $26.6 million, or $0.33 and $1.01 net loss per share, for the six months ended June 30, 2024 and 2023, respectively.

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

	Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Revenue:				
Revenue from contracts with customers	$ —	$ 5,139	$ 6,992	$ 6,363
Cost of sales of goods	—	(2,361)	—	(2,546)
Cost of providing services	—	(27)	—	(772)
Gross profit	**—**	**2,751**	**6,992**	**3,045**
Operating expenses:				
Research and development	(6,336)	(12,599)	(12,345)	(22,542)
General and administrative	(3,025)	(3,697)	(5,960)	(7,587)
Total operating expenses	**(9,361)**	**(16,296)**	**(18,305)**	**(30,129)**
Operating loss	**(9,361)**	**(13,545)**	**(11,313)**	**(27,084)**
Interest income, net	811	698	1,621	1,315
Foreign currency exchange gain (loss), net	339	244	997	(703)
Total non-operating income	**1,150**	**942**	**2,618**	**612**
Loss before income tax	**(8,211)**	**(12,603)**	**(8,695)**	**(26,472)**
Income tax expense	(85)	(97)	(154)	(168)
Loss for the period	**$ (8,296)**	**$ (12,700)**	**$ (8,849)**	**$ (26,640)**
Items that may be reclassified to profit or loss				
Foreign currency translation adjustment	(329)	(243)	(1,392)	1,303
Total comprehensive loss	**$ (8,625)**	**$ (12,943)**	**$ (10,241)**	**$ (25,337)**

Loss per share:				
Loss per share, basic and diluted	$ (0.31)	$ (0.48)	$ (0.33)	$ (1.01)
Weighted-average common shares outstanding, basic and diluted	26,822,139	26,289,087	26,805,793	26,289,087

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

	June 30, 2024	December 31, 2023
Assets		
Non-current assets:		
Property and equipment, net	$ 1,230	$ 1,602
Right-of-use assets	737	892
Other non-current assets and security deposits	144	319
Total non-current assets	**2,111**	**2,813**
Current assets:		
Receivables and other	582	1,459
Prepaid expenses and other current assets	2,223	1,627
VAT receivable	568	240
Investments	51,714	51,340
Cash and cash equivalents	35,086	44,231
Total current assets	**90,173**	**98,897**
Total assets	**$ 92,284**	**$ 101,710**
Equity and Liabilities		
Equity:		
Share capital	$ 3,716	$ 3,715
Equity-settled employee benefits reserve	13,729	12,005
Foreign currency translation reserve	(12,291)	(10,899)
Additional paid-in capital	194,448	194,424
Accumulated deficit	(156,724)	(148,067)
Total equity	**42,878**	**51,178**
Non-current liabilities:		
Deferred revenue	35,000	35,000
Lease liabilities	295	591
Total non-current liabilities	**35,295**	**35,591**
Current liabilities:		
Trade payables and other	4,161	4,446
Borrowings	5,383	5,282
Lease liabilities	485	440
Accrued expenses and other current liabilities	4,082	4,773
Total current liabilities	**14,111**	**14,941**
Total liabilities	**49,406**	**50,532**
Total equity and liabilities	**$ 92,284**	**$ 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.

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 with interleukin-2 (IL-2). The Company is expanding 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 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.

LAVA's 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® and the timing of initiating the Phase 1 trial of LAVA-1266, the timing of regulatory submissions, including an IND for LAVA-1266 in AML and MDS, LAVA's cash runway and the sufficiency of resources to pursue development activities, availability of information regarding clinical development plans, progress and data from clinical trials, the ability of LAVA's product candidates to treat various tumor targets, including CRC, NSCLC, PDAC and HNSCC, and improve patient outcomes 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 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 Ukraine or the Israel-Hamas war. 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.

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