LAVA Therapeutics Provides Business Update and Reports Second Quarter 2023 Financial Results

August 22, 2023

- *Significant progress with lead program LAVA-1207 in mCRPC reaching dose level 8*
- *Significant progress with collaborators including selection of lead candidate by Janssen Biotech and IND clearance for SGN-EGFRd2 (LAVA-1223) by Seagen*
- *Portfolio reprioritization and extension of cash runway into 2026*

UTRECHT, The Netherlands and PHILADELPHIA, Aug. 22, 2023 (GLOBE NEWSWIRE) -- LAVA Therapeutics N.V. (Nasdaq: LVTX), a clinical-stage immuno-oncology company focused on developing its proprietary Gammabody® platform of bispecific gamma-delta T cell engagers, today announced recent corporate highlights and financial results for the quarter ended June 30, 2023.

“We are focused on driving forward our lead program, LAVA-1207 in patients with mCRPC and are pleased our Gammabody® platform continues to receive the support of investigators and patients as enrollment remains on track. In addition, we are pleased with the progress of our partnered programs providing additional validation as well as extending our cash runway,” said Steve Hurly, president and chief executive officer of LAVA. “We remain well-positioned to bring meaningful benefits to patients in areas of high unmet need and deliver shareholder value.”

LAVA-1207

Gammabody® designed to target the prostate-specific membrane antigen (PSMA) to trigger the potent and preferential killing of PSMA-positive tumor cells in patients with metastatic castration-resistant prostate cancer (mCRPC). The safety, tolerability and preliminary efficacy of LAVA-1207 in patients with mCRPC are being evaluated in an ongoing dose escalation phase 1/2a, first-in-human study.

- Recruitment is on track and dose escalation continues across 10 sites in a globalized trial in Europe and the United States.
- Currently recruiting dose level 8 for monotherapy treatment.
- Currently recruiting dose level 7 with low-dose interleukin-2.
- The Company expects to report additional safety and efficacy data for the dose escalation phase of the trial in the next twelve months, which may inform the design of a future pivotal trial.

Partnered Programs

- An investigational new drug application clearance for SGN-EGFRd2 (LAVA-1223) in advanced solid tumors was received from the U.S. Food and Drug Administration. Seagen plans to initiate the Phase 1 trial in 2023 (NCT05983133).
- A milestone payment from Janssen Biotech, Inc. (Janssen) was triggered under the terms of the research collaboration agreement (Janssen Agreement) entered in May 2020 when Janssen selected a lead candidate aimed at an undisclosed tumor-associated antigen for further development towards clinical settings. The milestone payment was received in July 2023.

Portfolio Reprioritization and Cash Runway

- In June 2023, LAVA announced the discontinuation of the Phase 1/2a clinical trial of LAVA-051 in patients with relapsed/refractory (R/R) CLL and MM based upon a review of the competitive landscape. The discontinuation was not due to safety concerns.
- Existing patients being evaluated in the Phase 1/2a clinical trial will complete the course of their treatment.
- Portfolio reprioritization resulted in a 36% staff reduction and significant cost savings associated with the discontinuation of LAVA-051. The reduced operating costs align with the Company’s goal of increasing investment in the LAVA-1207 program and extending LAVA’s cash runway into 2026.

Second Quarter 2023 Financial Results

The financial information provided below reflects changes made to previously issued consolidated financial statements to revise immaterial prior-period misstatements. Further information regarding the revision is included in LAVA’s consolidated financial statements, "Note 12 — Revision of Immaterial Misstatements," included in Exhibit 99.1 to the report on Form 6-K to be filed with the SEC on the date hereof.

- As of June 30, 2023, LAVA had cash, cash equivalents and investments totaling $112.4 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 $5.1 million and $0.5 million for the quarters ended June 30, 2023 and 2022,

respectively, and $6.4 million and $1.5 million for the six months ended June 30, 2023 and 2022, respectively. In connection with the license agreement with Seagen, we recognized $2.6 million in revenue for the three months ended June 30, 2023, related to reimbursement for research activities and delivery of initial supply. In connection with the Janssen Agreement, we recognized $2.5 million in revenue for the three months ended June 30, 2023, related to a triggered milestone payment. Revenue from contracts with customers was $0.5 million for the three months ended June 30, 2022, related to the Janssen Agreement.

- Cost of providing services and sales of goods was $2.4 million and $0 for the quarters ended June 30, 2023 and 2022, respectively, and $3.3 million and $0 for the six months ended June 30, 2023 and 2022, respectively. The increase in cost was due to the cost of the initial supply delivery to Seagen and related stability studies.
- Research and development expenses were $12.6 million and $8.4 million for the quarters ended June 30, 2023 and 2022, respectively, and $22.5 million and $15.9 million for the six months ended June 30, 2023 and 2022, respectively. The increase for both periods was primarily due to increased manufacturing scale-up costs and ongoing activities of the clinical trials. In the three months ended June 30, 2023, we have also included $1.4 million in expenses for discontinuance of the activities for LAVA-051.
- General and administrative expenses were $3.7 million and $3.2 million for the quarters ended June 30, 2023 and 2022, respectively, and $7.6 million and $7.4 million for the six months ended June 30, 2023 and 2022, respectively. The increase for both periods was primarily due to the reversal in 2022 of share-based compensation expenses for unvested forfeited options partially offset by lower personnel-related expenses in 2023 due to a reduction in general and administrative headcount.
- Net losses were $12.7 million and $26.6 million for the quarters ended June 30, 2023 and 2022, respectively, or $0.48 and $0.31 net loss per share for the quarters ended June 30, 2023 and 2022, respectively, and $25.3 million and $26.8 million for the six months ended June 30, 2023 and 2022, respectively, or $1.01 and $0.70 net loss per share for the six months ended June 30, 2023 and 2022, respectively.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenue from contracts with customers	$ 5,139	$ 468	$ 6,363	$ 1,490
Cost of sales of goods	(2,361)	—	(2,546)	—
Cost of providing services	(27)	—	(772)	—
Gross profit	**2,751**	**468**	**3,045**	**1,490**
Operating expenses:				
Research and development	(12,599)	(8,371)	(22,542)	(15,868)
General and administrative	(3,697)	(3,173)	(7,587)	(7,410)
Total operating expenses	**(16,296)**	**(11,544)**	**(30,129)**	**(23,278)**
Operating loss	**(13,545)**	**(11,076)**	**(27,084)**	**(21,788)**
Interest income (expense), net	698	(90)	1,315	(253)
Foreign currency exchange gain (loss) net	244	3,136	(703)	4,248
Total non-operating income	**942**	**3,046**	**612**	**3,995**
Loss before income tax	**(12,603)**	**(8,030)**	**(26,472)**	**(17,793)**
Income tax expense	(97)	(76)	(168)	(135)
Loss for the period	**$ (12,700)**	**$ (8,106)**	**$ (26,640)**	**$ (17,928)**
Items that may be reclassified to profit or loss				
Foreign currency translation adjustment	(243)	(6,659)	1,303	(8,862)
Total comprehensive loss	**$ (12,943)**	**$ (14,765)**	**$ (25,337)**	**$ (26,790)**
Loss per share:				
Loss per share, basic and diluted	$ (0.48)	$ (0.31)	$ (1.01)	$ (0.70)
Weighted-average common shares outstanding, basic and diluted	26,289,087	25,780,811	26,289,087	25,778,190

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

	June 30, 2023	December 31, 2022
Assets		
Non-current assets:		
Property and equipment, net	$ 1,905	$ 1,432
Right-of-use assets	1,771	651
Other non-current assets and security deposits	346	809
Total non-current assets	**4,022**	**2,892**
Current assets:		
Receivables and other	3,994	3,254
Prepaid expenses and other current assets	1,738	4,411
Investments	24,797	32,535
Cash and cash equivalents	87,607	100,333
Total current assets	**118,519**	**140,533**
Total assets	**$ 122,541**	**$ 143,425**
Equity and Liabilities		
Equity:		
Share capital	$ 3,715	$ 3,715
Equity-settled employee benefits reserve	12,132	8,942
Foreign currency translation reserve	(11,669)	(12,972)
Additional paid-in capital	194,424	194,424
Accumulated deficit	(134,709)	(108,069)
Total equity	**63,893**	**86,040**
Non-current liabilities:		
Deferred revenue	35,000	35,000
Lease liabilities	1,316	431
Total non-current liabilities	**36,316**	**35,431**
Current liabilities:		
Trade payables and other	5,067	3,965
VAT payable	-	45
Borrowings	4,954	4,640
Lease liabilities	682	379
License liabilities	-	4,732
Accrued expenses and other current liabilities	11,629	8,193
Total current liabilities	**22,332**	**21,954**
Total liabilities	**58,648**	**57,385**
Total equity and liabilities	**$ 122,541**	**$ 143,425**

About LAVA Therapeutics

LAVA Therapeutics N.V. is a clinical-stage immuno-oncology company focused on developing its proprietary Gammabody® platform to develop a portfolio of bispecific gamma-delta T cell engagers for the potential treatment of solid 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 clinical study to evaluate LAVA-1207 in patients with metastatic castration-resistant prostate cancer (mCRPC) is actively enrolling in Europe and the United States (NCT05369000). The Company's collaborations include a license agreement with Seagen for the clinical development of SGN-EGFRd2 (LAVA-1223). For more information, please visit www.lavatherapeutics.com, and follow us on LinkedIn, X (formerly known as Twitter), and YouTube.

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 about the expected safety profile of LAVA's product candidates, preclinical data, clinical development and the scope of clinical trials, including the availability of data therefrom, our ability to expand our product pipeline, the timing of initiation of clinical trials, including expectations regarding regulatory filings, expectations regarding enrollment in clinical trials, the number of Vγ9Vδ2-T cells available for engagement by LAVA's product candidates and the

ability to increase those cells, including but not limited to the addition of low-dose interleukin-2, the potential use of the Company's product candidates to treat various tumor targets, any payments to us under our license agreements with third parties the Company's ability to deliver value to shareholders, LAVA's expectations regarding the consequences and effects of the Company's pipeline reprioritization and the Company's ability to recognize the expected benefits, and the Company's expected cash runway. Many factors, risks and uncertainties may cause differences between current expectations and actual results including, among other things, the timing and results of LAVA's research and development programs and preclinical and 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 Company's ability to obtain regulatory approval for and commercialize its product candidates, 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. 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, rising interest rates, recent and potential future pandemics and other health crises, hostilities between Russia and Ukraine, 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.

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