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

November 16, 2023

- LAVA-1207 in mCRPC continues Phase 1/2a dose escalation study in monotherapy arm and in combination with IL-2
- Seagen initiated a Phase 1 study of SGN-EGFRd2 (LAVA-1223) to evaluate the safety and tolerability utilizing the Gammabody® platform as a monotherapy in advanced EGFR expressing solid tumors
- Selection of undisclosed lead candidate by Janssen Biotech triggered an onboarding milestone payment
- LAVA plans to submit IND for Gammabody targeting CD123 in 1H 2024 (LAVA-1266)
- Strong balance sheet with cash runway into 2026

UTRECHT, The Netherlands and PHILADELPHIA, Nov. 16, 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 September 30, 2023.

“We continue to advance our lead program, LAVA-1207, in patients with mCRPC in our Phase 1/2a escalation study,” said Steve Hurly, president and chief executive officer of LAVA. “Our Gammabody ® platform continues to receive the support of investigators and patients, and enrollment remains on track. We are also pleased with the progress of our partnered programs, particularly the initiation of the Phase 1 study of SGN-EGFRd2 (LAVA-1223) in advanced solid tumors which provides additional validation of our platform. With an expected cash runway into 2026, LAVA remains well-positioned to bring meaningful benefits to patients in areas of high unmet need and to 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, pharmacodynamics, immunogenicity, and preliminary anti-tumor activity of LAVA-1207 in patients with mCRPC are being evaluated in an ongoing dose escalation phase 1/2a, first-in-human study.

- Trial enrollment is progressing across 10 clinical trial sites in Europe and the United States.
- The Company expects to report additional data for the dose escalation phase of the trial in the third quarter of 2024, which if positive, we expect these results to allow us to rapidly design and enter into a dose expansion study to support a potential pivotal future trial.

Partnered Programs

Seagen- SGN-EGFRd2 (LAVA-1223)

- During the third quarter, Seagen began recruitment in a Phase 1 study evaluating the safety and tolerability of SGN-EGFRd2 (LAVA-1223) as a monotherapy administered intravenously in advanced solid tumors. The study design has three parts: Parts A and B of the study will identify dosage for SGN-EGFRd2 and Part C will use the findings in Parts A and B for a dose to determine safety and efficacy of SGN-EGFRd2. Eligible patients for Part A include patients with colorectal cancer, non-small cell lung cancer or head and neck squamous cancer that is relapsed, refractory, or be intolerant to standard of care therapies. For more information, please refer to clinicaltrials.gov (NCT05983133).

Janssen Biotech - Undisclosed Candidate

- Earlier this year, Janssen selected a lead candidate aimed at an undisclosed tumor-associated antigen for further development towards a phase 1 clinical trial. A milestone payment was received in July 2023.

Third 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 September 30, 2023, LAVA had cash, cash equivalents and investments totaling $104.6 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 less than $0.1 million and $15.3 million for the quarters ended September 30,

2023 and 2022, respectively, and $3.1 million and $16.8 million for the nine months ended September 30, 2023 and 2022, respectively. In connection with the license agreement with Seagen, we recognized less than $0.1 million in revenue for the three months ended September 30, 2023, related to reimbursement for research activities and initial supply related stability studies. Revenue from contracts with customers was $15.3 million for the three months ended September 30, 2022, related to the Seagen Agreement. Of that amount, $15.2 million related to the nonrefundable upfront payment and $0.1 million related to reimbursement for research activities.

- Cost of providing services and sales of goods was less than $0.1 million and zero for the quarters ended September 30, 2023 and 2022, respectively, and $3.3 million and zero for the nine months ended September 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 $7.9 million and $13.7 million for the quarters ended September 30, 2023 and 2022, respectively, and $30.5 million and $29.6 million for the nine months ended September 30, 2023 and 2022, respectively. The decrease was primarily due to reduced manufacturing scale-up costs and clinical trial activities due to the discontinuation of the activities for LAVA-051, announced in June 2023.
- General and administrative expenses were $2.9 million and $3.1 million for the quarters ended September 30, 2023 and 2022, respectively, and $10.4 million and $10.5 million for the nine months ended September 30, 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.
- Net loss was $8.8 million and net profit was $0.9 million for the quarters ended September 30, 2023 and 2022, respectively, or $0.34 net loss and $0.04 net profit per share for the quarters ended September 30, 2023 and 2022, respectively. Net losses were $35.5 million and $17 million for the nine months ended September 30, 2023 and 2022, respectively, or $1.35 and $0.66 net loss per share for the nine months ended September 30, 2023 and 2022, respectively.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenue from contracts with customers	$ 53	$ 15,261	$ 6,416	$ 16,751
Cost of sales of goods	—	—	(2,546)	—
Cost of providing services	(10)	—	(782)	—
Gross profit	**43**	**15,261**	**3,088**	**16,751**
Operating expenses:				
Research and development	(7,912)	(13,697)	(30,454)	(29,565)
General and administrative	(2,858)	(3,135)	(10,445)	(10,545)
Total operating expenses	**(10,770)**	**(16,832)**	**(40,899)**	**(40,110)**
Operating loss	**(10,727)**	**(1,571)**	**(37,811)**	**(23,359)**
Interest income (expense), net	809	39	2,124	(214)
Foreign currency exchange gain, net	1,132	2,515	429	6,763
Total non-operating income	**1,941**	**2,554**	**2,553**	**6,549**
(Loss) Profit before income tax	**(8,786)**	**983**	**(35,258)**	**(16,810)**
Income tax expense	(50)	(47)	(218)	(182)
(Loss) Profit for the period	**$ (8,836)**	**$ 936**	**$ (35,476)**	**$ (16,992)**
Items that may be reclassified to profit or loss				
Foreign currency translation adjustment	(1,385)	(5,359)	(82)	(14,220)
Total comprehensive loss	**$ (10,221)**	**$ (4,423)**	**$ (35,558)**	**$ (31,212)**
(Loss) Profit per share:				
(Loss) Profit per share, basic	$ (0.34)	$ 0.04	$ (1.35)	$ (0.66)
Weighted-average common shares outstanding, basic	26,289,087	25,845,802	26,289,087	25,800,973
(Loss) Profit per share, diluted	$ (0.34)	$ 0.04	$ (1.35)	$ (0.66)
Weighted-average common shares outstanding, diluted	26,289,087	26,446,259	26,289,087	25,800,973

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

	September 30, 2023	December 31, 2022
Assets		
Non-current assets:		
Property and equipment, net	$ 1,715	$ 1,432
Right-of-use assets	1,062	651
Other non-current assets and security deposits	326	809
Total non-current assets	**3,103**	**2,892**
Current assets:		
Receivables and other	1,077	3,254
Prepaid expenses and other current assets	1,906	4,411
VAT receivable	307	—
Investments	41,964	32,535
Cash and cash equivalents	62,663	100,333
Total current assets	**107,917**	**140,533**
Total assets	**$ 111,020**	**$ 143,425**
Equity and Liabilities		
Equity:		
Share capital	$ 3,715	$ 3,715
Equity-settled employee benefits reserve	11,421	8,942
Foreign currency translation reserve	(13,054)	(12,972)
Additional paid-in capital	194,424	194,424
Accumulated deficit	(141,910)	(108,069)
Total equity	**54,596**	**86,040**
Non-current liabilities:		
Deferred revenue	35,000	35,000
Lease liabilities	671	431
Total non-current liabilities	**35,671**	**35,431**
Current liabilities:		
Trade payables and other	9,384	3,965
VAT payable	—	45
Borrowings	4,944	4,640
Lease liabilities	580	379
License liabilities	—	4,732
Accrued expenses and other current liabilities	5,845	8,193
Total current liabilities	**20,753**	**21,954**
Total liabilities	**56,424**	**57,385**
Total equity and liabilities	**$ 111,020**	**$ 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 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, expectations regarding enrollment in clinical trials, the potential use of the Company's product candidates to treat various tumor targets, 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, including combinations of LAVA product candidates to increase the number of Vγ9Vδ2-T cells, the Company's ability to leverage its initial programs to develop additional product candidates using our Gammabody® platform, including the expectation of submitting an IND for LAVA-1266 in 1H2024 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 or in the Middle East, 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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