LAVA Provides Business Updates and Reports First Quarter 2024 Financial Results

May 21, 2024

- LAVA-1207 dose escalation progressing in Phase 1/2a trial in prostate cancer, with pembrolizumab combination expected to begin in Q2 2024
- Received $7.0 million clinical development milestone from Pfizer for PF-08046052 (formerly LAVA-1223) in Phase 1
- LAVA-1266 on track for Q2 2024 IND submission
- Strong balance sheet with cash of $94.6 million supports runway into 2026

UTRECHT, The Netherlands and PHILADELPHIA, May 21, 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 recent corporate highlights and financial results for the first quarter ended March 31, 2024.

"LAVA continues to advance our pipeline of Gammabody programs and is excited to initiate the combination arm of pembrolizumab with LAVA-1207 this quarter. We look forward to sharing an update on the LAVA-1207 program during the second half of 2024," said Stephen Hurly, President and Chief Executive Officer of LAVA. "We are also pleased by Pfizer's continued progress with the Phase 1 program for PF-08046052 and the achievement of a clinical development milestone in March."

"We are encouraged by the positive impact on the LAVA-1207 trial since we have implemented step dosing, as no ≥ Grade 2 CRS events have been reported since this change. We look forward to initiating the combination with pembrolizumab, and we continue to evaluate LAVA-1207 with low dose IL-2 and step dosing," added Charles Morris, Chief Medical Officer of LAVA.

Portfolio Highlights:

LAVA-1207 – In Phase 1/2a (NCT05369000) – Next update H2 2024

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

- **Monotherapy**: Enrolling patients at dose level 10. No ≥ Grade 2 Cytokine Release Syndrome (CRS) since the implementation of step dosing in Q1 2024
- **KEYTRUDA® (pembrolizumab) Combination:** Expecting to enroll the first patient in Q2 2024 in the LAVA-1207 + pembrolizumab dose-escalation arm (KEYNOTE-F73)
- **Low Dose IL-2** (interleukin-2, LDIL-2, to increase the number of Vγ9Vδ2 T cells for engagement by LAVA-1207): Evaluating whether to continue treating patients with LDIL-2 with step dosing
- **Biomarker Studies:** Evaluating the potential association between Vγ9Vδ2 T cell counts and tumor responses

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)
- **Dose Escalation Trial**: Underway to evaluate the safety and tolerability of PF-08046052 as a monotherapy in advanced EGFR-expressing solid tumors
- **Milestone**: Pfizer paid LAVA $7 million for achieving a clinical development milestone in March 2024

LAVA-1266 – IND Submission Expected in Q2 2024

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

- **IND Submission**: Preparations underway

First Quarter 2024 Financial Results

- As of March 31, 2024, LAVA had cash, cash equivalents and investments totaling $94.6 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 2026.

- Revenue from contracts with customers was $7.0 million and $1.2 million for the quarters ended March 31, 2024 and 2023, respectively. Revenue of $7.0 million for the quarter ended March 31, 2024 was related to the achievement by Pfizer of a clinical development milestone for PF-08046052. Revenue of $1.2 million for the quarter ended March 31, 2023 was related to the reimbursement for research activities and delivery of initial supply product materials in connection with the Pfizer Agreement.
- Cost of providing services and sales of goods was zero and $0.9 million for the quarters ended March 31, 2024 and 2023, respectively. The $0.9 million for the quarter ended March 31, 2023 was related to the cost of the initial supply delivery to Pfizer and related stability studies.
- Research and development expenses were $6.0 million and $9.9 million for the quarters ended March 31, 2024 and 2023, respectively. The decrease 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 $2.9 million and $3.9 million for the quarters ended March 31, 2024 and 2023, respectively. The decrease was primarily due to lower personnel-related expenses due to a reduction in general and administrative headcount in the second half of 2023.
- Net loss was $0.5 million and $13.9 million, or $0.02 and $0.53 net loss per share, for the quarters ended March 31, 2024 and 2023, 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 March 31,	
	2024	**2023**
Revenue:		
Revenue from contracts with customers	$ 6,992	$ 1,224
Cost of sales of goods	—	(745)
Cost of providing services	—	(185)
Gross profit	**6,992**	**294**
Operating expenses:		
Research and development	(6,009)	(9,943)
General and administrative	(2,935)	(3,890)
Total operating expenses	**(8,944)**	**(13,833)**
Operating loss	**(1,952)**	**(13,539)**
Interest income, net	810	617
Foreign currency exchange gain (loss), net	658	(947)
Total non-operating income	**1,468**	**(330)**
Loss before income tax	**(484)**	**(13,869)**
Income tax expense	(69)	(71)
Loss for the period	**$ (553)**	**$ (13,940)**
Items that may be reclassified to profit or loss		
Foreign currency translation adjustment	(1,064)	1,546
Total comprehensive loss	**$ (1,617)**	**$ (12,394)**
Loss per share:		
Loss per share, basic and diluted	$ (0.02)	$ (0.53)
Weighted-average common shares outstanding, basic and diluted	26,794,215	26,289,087

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

	March 31, 2024	December 31, 2023

Assets		
Non-current assets:		
Property and equipment, net	$ 1,359	$ 1,602
Right-of-use assets	796	892
Other non-current assets and security deposits	256	319
Total non-current assets	**2,411**	**2,813**
Current assets:		
Receivables and other	737	1,459
Prepaid expenses and other current assets	1,188	1,627
VAT receivable	170	240
Investments	51,386	51,340
Cash and cash equivalents	43,187	44,231
Total current assets	**96,668**	**98,897**
Total assets	**$ 99,079**	**$ 101,710**
Equity and Liabilities		
Equity:		
Share capital	$ 3,715	$ 3,715
Equity-settled employee benefits reserve	12,959	12,005
Foreign currency translation reserve	(11,962)	(10,899)
Additional paid-in capital	194,432	194,424
Accumulated deficit	(148,479)	(148,067)
Total equity	**50,665**	**51,178**
Non-current liabilities:		
Deferred revenue	35,000	35,000
Lease liabilities	387	591
Total non-current liabilities	**35,387**	**35,591**
Current liabilities:		
Trade payables and other	3,437	4,446
Borrowings	5,295	5,282
Lease liabilities	450	440
Accrued expenses and other current liabilities	3,845	4,773
Total current liabilities	**13,027**	**14,941**
Total liabilities	**48,414**	**50,532**
Total equity and liabilities	**$ 99,079**	**$ 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®, 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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