



LAVA Therapeutics Provides Business Update and Reports Fourth Quarter and Year-End 2022 Financial Results

April 11, 2023

- Initial clinical data for LAVA-051 suggest a favorable safety profile and initial anti-tumor activity in the ongoing dose escalation Phase 1/2a clinical trial in patients with relapsed and refractory chronic lymphocytic leukemia and multiple myeloma
- Initial clinical data for LAVA-1207, a Phase 1/2a dose escalation clinical trial in patients with therapy refractory metastatic castration-resistant prostate cancer, suggest a favorable safety profile and initial signs of clinical activity, with PSA levels stabilizing or decreasing in highly pre-treated patients
- Announced license agreement with Seagen for the development of LAVA-1223 in exchange for \$50 million upfront; up to approximately \$650 million in potential milestones; and royalties
- Strong balance sheet with cash and investments of \$132.9 million as of December 31, 2022, expected to provide cash runway into 2026

UTRECHT, The Netherlands, and PHILADELPHIA, April 11, 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 fourth quarter and year ended December 31, 2022.

"2022 was a very productive year for LAVA, marked by steady progress in the clinical development of our lead programs, LAVA-051 and LAVA-1207," said Stephen Hurly, president and chief executive officer of LAVA Therapeutics. "We are encouraged by the initial safety and activity signals and will continue dose escalation in these programs as we work toward a recommended Phase 2 dose. We will also continue to advance our pipeline of bispecific gamma-delta T cell engagers for patients with cancer."

"On the corporate front, we strengthened our management team with the additions of two seasoned executives, Dr. Charles Morris as chief medical officer and Fred Powell as chief financial officer. Both executives joined LAVA following several decades of experience and proven track records of success in their prior roles. The Company also appointed three highly accomplished independent members to the Board of Directors, which reflects an important progression in the Company's evolution," continued Hurly.

Recent Pipeline Highlights

LAVA-051

Gammabody designed to target CD1d-expressing tumors, including multiple myeloma (MM), chronic lymphocytic leukemia (CLL) and acute myeloid leukemia (AML)

- Initial clinical data for LAVA-051 and presented clinical pharmacokinetic and pharmacodynamic data from the first five patient cohorts of the Phase 1 dose-escalation study that suggest a favorable safety profile, which allowed us to expand the enrollment of patients into planned additional cohorts.
- Potential signs of clinical activity were observed as well as linear PK and on-mechanism PD parameters consistent with Vγ9Vδ2-T cell engagement.
- Clinical trial sites are actively enrolling in North America and Europe.

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)

- Initial clinical data suggests a favorable safety profile, with no occurrence of high-grade (>2) cytokine release syndrome.
- Initial signs of anti-tumor activity were observed, with iRECIST stable disease (iSD) in 8 out of 14 evaluable patients at week 8 and PSA levels stabilizing or decreasing in heavily pre-treated patients.
- Clinical trial sites are actively enrolling in sites in North America and Europe.

Corporate Update

- LAVA strengthened its executive management team with the following appointments:
 - [Dr. Charles Morris](#) was appointed as chief medical officer. Dr. Morris is a medical oncologist with over 25 years of oncology drug development experience and has a proven track record of advancing novel oncology product

candidates from clinical development through global regulatory approvals.

- **Fred Powell** was appointed chief financial officer and brings over 25 years of experience as a global CFO in the biopharmaceutical industry, having served in this capacity for several publicly traded biopharmaceutical companies.
 - Three new independent directors were appointed to the LAVA Board of Directors: Peter A. Kiener, DPhil, Mary Wadlinger and Christy Oligier. Guido Magni, M.D., Ph.D., and Stefan Luzi, Ph.D., stepped down from the Board.
- In September 2022, we announced an exclusive global license agreement with Seagen pursuant to which we granted a worldwide exclusive license to Seagen to develop, manufacture and commercialize SGN-EGFRd2 (LAVA-1223), an advanced preclinical asset that utilizes LAVA's proprietary Gammabody technology to target EGFR-expressing solid tumors. Under the terms of the agreement, LAVA received a \$50 million upfront payment and could receive up to approximately \$650 million in potential development, regulatory and commercial milestones, and royalties ranging from the high single digits to the mid-teens on future sales.

Fourth Quarter and Year-End 2022 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 our consolidated financial statements, "Note 23 — Revision of Immaterial Misstatements," included in Item 18 of our annual report on Form 20-F.

- As of December 31, 2022, LAVA had cash, cash equivalents and investments totaling \$132.9 million compared to cash and cash equivalents of \$133.2 million as of December 31, 2021. The cash balance is expected to be sufficient to fund the Company's activities into 2026.
- Research and license revenue was \$2.6 million and \$1.1 million for the quarters ended December 31, 2022 and 2021, respectively, and \$19.4 million and \$5.4 million for the years ended December 31, 2022 and 2021, respectively. The full-year increase was primarily due to \$17.9 million in revenue from the Company's collaboration with Seagen Inc.
- Research and development expenses were \$10.5 million and \$6.6 million for the quarters ended December 31, 2022 and 2021, respectively, and \$40.1 million and \$36.9 million for the years ended December 31, 2022 and 2021, respectively. The higher quarterly and full-year expense was due to ongoing activities of the clinical trials for LAVA-051 and LAVA-1207, which were offset by a one-time license fee of \$14.4 million triggered in the first quarter of 2021 by the IPO.
- General and administrative expenses were \$3.7 million and \$3.8 million for the quarters ended December 31, 2022 and 2021, respectively, and \$14.1 million and \$12.0 million for the years ended December 31, 2022 and 2021, respectively. The increase for the full year 2022 was due to higher personnel-related expenses and the costs of being a public company for a full year compared to only 9 months in 2021.
- Net losses were \$15.0 million and \$8.2 million for the quarters ended December 31, 2022 and 2021, respectively, or \$0.57 and \$0.32 net loss per share for the quarters ended December 31, 2022 and 2021, respectively, and \$31.9 million and \$42.4 million for the years ended December 31, 2022 and 2021, respectively, or \$1.23 and \$2.14 net loss per share for the years ended December 31, 2022 and 2021, respectively.

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

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2022	2021	2022	2021
Revenue:				
Research and license revenue	\$ 2,640	\$ 1,066	\$ 19,391	\$ 5,350
Total revenue	2,640	1,066	19,391	5,350
Operating expenses:				
Research and development	(10,486)	(6,634)	(40,105)	(36,945)
General and administrative	(3,714)	(3,768)	(14,124)	(12,018)
Total operating expenses	(14,200)	(10,402)	(54,229)	(48,963)
Operating loss	(11,560)	(9,336)	(34,838)	(43,613)
Non-operating (expenses) income	(3,369)	1,174	3,180	1,415

Loss before income tax	(14,929)	(8,162)	(31,658)	(42,198)
Income tax expense	(67)	(57)	(249)	(157)
Net loss	\$ (14,996)	\$ (8,219)	\$ (31,907)	\$ (42,355)
Net loss per share:				
Net loss per share, basic and diluted	\$ (0.57)	\$ (0.32)	\$ (1.23)	\$ (2.14)
Weighted average common shares outstanding, basic and diluted	26,289,087	25,775,538	25,924,005	19,758,169

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

	<u>December 31,</u>	<u>December 31,</u>
	<u>2022</u>	<u>2021</u>
Assets:		
Non-current assets	\$ 2,892	\$ 2,742
Other current assets	7,665	3,302
Cash, cash equivalents and investments	132,868	133,203
Total assets	\$ 143,425	\$ 139,247
Equity and Liabilities:		
Total Equity	\$ 86,040	\$ 118,367
Deferred revenue	35,000	1,527
Lease liabilities	810	581
License liabilities	4,732	10,056
Borrowings	4,640	4,284
Trade payables and other	4,010	2,553
Accrued expenses and other current liabilities	8,193	1,879
Total liabilities	57,385	21,880
Total equity and liabilities	\$ 143,425	\$ 139,247

About LAVA Therapeutics

LAVA Therapeutics N.V. is a clinical-stage immuno-oncology company utilizing 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. LAVA-051, the Company's lead candidate for the treatment of multiple myeloma, chronic lymphocytic leukemia and acute myeloid leukemia, is enrolling patients in a Phase 1/2a clinical study ([NCT04887259](https://clinicaltrials.gov/ct2/show/study/NCT04887259)). A Phase 1/2a clinical study to evaluate LAVA-1207 in patients with metastatic castration-resistant prostate cancer (mCRPC) is also enrolling ([NCT05369000](https://clinicaltrials.gov/ct2/show/study/NCT05369000)). For more information, please visit www.lavatherapeutics.com, and follow us on [LinkedIn](#), [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 our product candidates, preclinical data, clinical development and scope of clinical trials, including the availability of data therefrom, the potential use of our product candidates to treat various tumor targets, any payments to us under our license agreement with Seagen and our 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 our 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, our ability to obtain regulatory approval for and commercialize our product candidates, our ability to leverage our initial programs to develop additional product candidates using our Gammabody™ platform, and the failure of LAVA's collaborators to support or advance collaborations or our product candidates. The COVID-19 pandemic may disrupt our business and that of the third parties on which we depend, including delaying or otherwise disrupting our clinical trials and preclinical studies, manufacturing, and supply chain or impairing employee productivity. In addition, there may be adverse effects on our business condition and results from general economic and market conditions and overall fluctuations in the United States and international equity markets, including deteriorating market conditions due to investor concerns regarding inflation and 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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