

THERAPEUTICS

LAVA Therapeutics Provides Business Update and Reports First Quarter Financial Results

May 20, 2021

IPO bolsters balance sheet to \$160 million in cash and cash equivalents; expected to fund operations at least into the second half of 2023

Clinical development plans on schedule in both hematological and solid tumor programs

Leadership strengthened through key management and board appointments

UTRECHT, The Netherlands and PHILADELPHIA, May 20, 2021 (GLOBE NEWSWIRE) -- LAVA Therapeutics N.V. (Nasdaq: LVTX), a biotechnology company focused on applying its expertise in gamma-delta bispecific T cell engagers (bsTCEs) to transform cancer therapy, today reported its business update and first quarter 2021 financial results.

"We continue to make important strides across all aspects of our business as we transition to a clinical stage organization," said Stephen Hurly, chief executive officer of LAVA Therapeutics. "With the recent additions to our leadership team and board and the proceeds from our IPO, we are well-positioned to advance our pipeline as we work toward our mission of transforming cancer therapy for patients."

Recent Business and Pipeline Highlights

Phase 1/2a Clinical Trial of LAVA-051 for Multiple Hematological Malignancies on Track: LAVA is on track to initiate its open-label, multi-center, Phase 1/2a clinical trial of LAVA-051 for the treatment of relapsed and/or refractory chronic lymphocytic leukemia (CLL), multiple myeloma (MM) and acute myeloid leukemia (AML) in the first half of 2021. The trial is designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity and preliminary antitumor activity of LAVA-051.

Preclinical Data Supporting Anti-Tumor Activity of LAVA-051 Presented at AACR Virtual 2021 Annual Meeting: In April 2021, LAVA presented preclinical data on LAVA-051 at the virtual American Association for Cancer Research (AACR) Annual Meeting. The data demonstrated that LAVA-051 exerted substantial antitumor activity against patient derived CLL, MM and AML cells that express CD1d. In addition, improved survival was observed in *in vivo* AML and MM mouse xenograft models treated with LAVA-051.

Successful Initial Public Offering Completed: In March 2021, LAVA priced its initial public offering (IPO) at \$15.00 per share. In connection with the offering, the Company issued 7,125,712 common shares resulting in gross proceeds, before deducting underwriting discounts and commissions and offering expenses payable by LAVA, of approximately \$107 million.

Leadership Team Strengthened by Appointment of Edward Smith as Chief Financial Officer: In March 2021, LAVA further strengthened its management team with the appointment of Edward F. Smith as its chief financial officer. Ed has more than 20 years of executive finance and operational leadership experience in publicly traded biotechnology companies from early stage through commercialization. Ed most recently served as chief financial officer of Marinus Pharmaceuticals and is currently a member of the board of directors of Benitec Biopharma, Inc.

Industry Veterans Appointed to Board of Directors:

- In February 2021, LAVA appointed Dr. Kapil Dhingra as chairman of the board of directors. Kapil is a medical oncologist and physician-scientist and brings more than 30 years of experience in oncology clinical research and drug development within the biotechnology and pharmaceutical industries. Most recently, he served as vice president, head of the oncology disease biology leadership team and head of oncology clinical development at Hoffmann-La Roche, during which he led numerous drug approvals, including Herceptin®, Tarceva® and Avastin®. In addition to LAVA, he is currently a member of the boards of directors of Black Diamond Therapeutics, Inc., Replimune, Inc., Five Prime Therapeutics, Inc., Autolus Therapeutics plc, and Median Technologies.
- In April 2021, LAVA appointed biopharmaceutical finance executive, Karen Wilson, to its board of directors and as chair of
 its Audit Committee. Karen brings more than 30 years of finance and leadership experience in the life sciences industry,
 most recently serving as senior vice president of finance at Jazz Pharmaceuticals plc. In addition to LAVA, she currently
 serves on the board of directors of Angion Biomedica, Connect Biopharma and Vaxart, Inc.

First Quarter Financial Results

- Cash and cash equivalents were €134.7 million as of March 31, 2021, compared to €12.9 million as of December 31, 2020. The increase in cash and cash equivalents was attributable to proceeds from the Series C financing and subsequent IPO during the first quarter of 2021, partially offset by operating expenses.
- Research and license revenue increased to €0.9 million for the three months ended March 31, 2021 compared to no such revenue for the three months ended March 31, 2020. Research and license revenue is solely attributable to the company's collaboration with Janssen Biotech, Inc., which was entered into in May 2020.
- Research and development expenses were €15.7 million for the three months ended March 31, 2021, an increase of €12.8 million, compared to €2.9 million for the three months ended March 31, 2020. The increase was primarily due to license fees of €12.1 million triggered by the IPO, most of which will be paid on the first and second anniversaries of the IPO and may be paid in either cash or common stock of the Company. In addition, personnel-related costs increased €0.5 million due to increased headcount.
- General and administrative expenses were €1.4 million for the three months ended March 31, 2021, an increase of €0.7 million, compared to general administrative expenses of €0.7 million for the three months ended March 31, 2020. The increase is primarily due to the increase in personnel-related costs of €0.3 million and the non-cash share-based compensation expense of €0.3 million due to the increase in headcount.
- Net loss was €16.6 million, or €10.19 per share, for the first quarter of 2021, compared to €3.7 million, or €8.22 per share, for the first quarter of 2020.

About LAVA

LAVA Therapeutics N.V. is a clinical stage biotechnology company developing a portfolio of bispecific gamma-delta T cell engagers (gamma-delta bsTCEs) for the treatment of solid tumors and hematological malignancies based on its proprietary platform. The company's innovative approach utilizes bispecific antibodies engineered to selectively kill cancer cells and induce gamma-delta T cell-mediated immunity through activation of Vγ9Vδ2 T cells upon cross-linking to tumor associated antigens. A Phase 1/2a clinical study evaluating LAVA-051 in patients with certain hematologic malignancies is anticipated to generate top line clinical data in the first half of 2022. The Company expects to initiate a Phase 1/2a clinical study to evaluate LAVA-1207 in patients with prostate cancer in the second half of 2021. For more information, please visit www.layatherapeutics.com.

LAVA's Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements, including in respect of the company's anticipated growth and clinical developments plans, including the timing of enrollment in and progress of clinical trials and reporting of results thereof. Words such as "anticipate," "believe," "could," "expect," "should," "plan," "intend," "estimate," "potential" 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. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about the progress, timing, clinical development and scope of clinical trials and the reporting of clinical data for LAVA's product candidates, and the potential use of our product candidates to treat various tumor targets. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during preclinical trials, changes in expected or existing competition, changes in the regulatory environment, failure of LAVA's collaborators to support or advance collaborations or product candidates and unexpected litigation or other disputes, among others. In addition, 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. LAVA assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Unaudited Condensed Consolidated Interim Statements of Profit or Loss EUR (000's)

		Three Months Ended March 31,				
	Notes	2021		2020		
Research and license revenue		€	921	€		
Operating expenses:						
Research and development			(15,739)		(2,935)	
General and administrative			(1,415)		(682)	
Total operating expenses			(17,154)		(3,617)	
Operating loss			(16,233)		(3,617)	
Total non-operating expenses			(320)		(58)	
Loss before income tax			(16,553)		(3,675)	
Income tax benefit (expense)			(21)		(3)	
Loss for the period		€	<u>(16,574</u>)	€	(3,678)	
Loss per share, in Euros						
Loss per share, basic and diluted		€	(10.19)	€	(8.22)	
Weighted average common shares outstanding, basic and diluted			1,626,598	4	447,525	

Condensed Consolidated Interim Statements of Financial Position EUR (000's)

		M	March 31, 2021		December 31, 2020	
	Notes					
		(unaudited)				
Assets						
Non-current assets		€	1,875	€	1,843	
Other current assets			1,013		1,959	
Cash and cash equivalents			134,745		12,881	
Total assets		€	137,633	€	16,683	
Equity and Liabilities						
Total Equity		€	113,471	€	6,207	
Deferred revenue			4,109		5,030	
Lease liabilities			384		389	
License liabilities			12,073		-	
Borrowings			3,010		2,935	
Trade payables and other			1,464		760	
Accrued expenses and other current liabilities			3,122		1,362	
Total liabilities			24,162		10,476	
Total equity and liabilities		€	137,633	€	16,683	

Contact

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