
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the month of March 2022

(Commission File No. 001-40241)

LAVA Therapeutics N.V.
(Translation of registrant's name into English)

Yalelaan 60
3584 CM Utrecht, The Netherlands
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101 (b) (1):

Yes No

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101 (b) (7):

Yes No

LAVA Therapeutics, N.V.

On March 24, 2022, LAVA N.V. issued a press release announcing the Company's financial results for the three months and year ended December 31, 2021. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein. Exhibit 99.1 to this Report is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (Exchange Act) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act.

EXHIBIT LIST

Exhibit **Description**

99.1 [Press Release dated March 24, 2022](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereto duly authorized.

LAVA Therapeutics, N.V.

(Registrant)

Date: March 28, 2022

By: /s/ Edward Smith

Edward Smith

Chief Financial Officer

LAVA Therapeutics Provides Business Update and Reports Fourth Quarter and Year End 2021 Financial Results

- *LAVA-051 shows encouraging initial safety and pharmacodynamic observations; on track for more dose escalation data from Phase 1/2a trial in Q2 2022*
- *LAVA-1207 Phase 1/2a trial in mCRPC on track to report initial data in H2 2022*
- *New pipeline program: LAVA-1266, a CD123-directed Gammabody™ for hematological malignancies*
- *Strong balance sheet with cash and investments of \$133.2 million as of December 31, 2021*

Utrecht, The Netherlands and Philadelphia, USA – MAR. 24, 2022 – [LAVA Therapeutics N.V.](#) (Nasdaq: [LVTX](#)), an immuno-oncology company focused on developing its proprietary [Gammabody™ platform](#) of bispecific gamma delta T cell engagers to transform the treatment of cancer, today announced recent corporate highlights and financial results for the fourth quarter and year ended December 31, 2021.

"I am incredibly proud of our LAVA team and the steady advancements we've made in the continued development of our Gammabody™ pipeline, despite the challenging times of the last year," said Stephen Hurly, president and chief executive officer. "With the encouraging LAVA-051 initial safety and pharmacodynamic observations and the LAVA-1207 study now actively recruiting patients, we are focused on execution and delivering potential product and platform-validating milestones this year and preparing our early-stage Gammabody™ pipeline for the clinic. We remain focused on our mission to efficiently develop transformative treatments for those suffering from cancer."

Recent Business and Pipeline Highlights

LAVA-051 Shows Encouraging Initial Safety and Pharmacodynamic Observations: In March 2022, LAVA announced interim data from the first three single patient cohorts of the Phase 1 dose escalation portion of its Phase 1/2a clinical trial, which we believe demonstrated that the doses of LAVA-051 used in these initial cohorts were safe and well-tolerated with no dose limiting toxicities or cytokine release syndrome observed. Per the study protocol, the cohort three dose was 33-times that of the cohort one dose. Vg9Vd2 (Vgamma9 Vdelta2) T cell receptor occupancy of LAVA-051 increased with LAVA-051 dose increases and peripheral blood Vg9Vd2 T cells also expressed higher levels of activation markers after LAVA-051 dosing. One patient with chronic lymphocytic leukemia (CLL) experienced multiple enlarged tender diseased lymph nodes one week after first dosing that subsequently regressed, reminiscent of tumor flare. Dosing in the study is continuing, with subsequent cohorts planned to enroll at least three patients per cohort. Additional data from the Phase 1 dose escalation phase of the trial is expected in the second



quarter of 2022 and data from the Phase 2a expansion cohorts are expected in the second half of 2022.

The Phase 1/2a clinical trial (NCT04887259) is currently evaluating LAVA-051 in patients with relapsed or refractory chronic lymphocytic leukemia (CLL) and multiple myeloma (MM). Later in the trial, LAVA will also include patients with acute myeloid leukemia (AML). The trial is designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity and preliminary antitumor activity of LAVA-051. In October 2021, the company announced that the U.S. Food and Drug Administration (FDA) granted orphan drug designation to LAVA-051 for the treatment of CLL.

Enrollment in LAVA-1207 Phase 1/2a Trial Underway: In February 2022, LAVA announced it had initiated dosing in the Company's open-label, multi-center, Phase 1/2a clinical trial evaluating LAVA-1207 in patients with metastatic castration-resistant prostate cancer (mCRPC) and enrollment is ongoing. LAVA-1207 is a Gammabody™ that conditionally activates Vg9Vd2 T cells upon crosslinking to prostate-specific membrane antigen (PSMA) to trigger the potent and preferential killing of PSMA-positive tumor cells. The trial is designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity and preliminary antitumor activity of LAVA-1207 in patients with mCRPC. The Phase 1 dose-escalation phase of the study will determine the recommended Phase 2 dose/schedule to be used in the subsequent Phase 2a expansion cohort to confirm safety and tolerability of LAVA-1207 in mCRPC patients. Data from the Phase 1 dose escalation phase of the trial are expected in the second half of 2022 and data from the Phase 2a expansion cohort are expected in the first half of 2023.

Early-Stage Pipeline Development: In addition to LAVA's two lead programs, the Company is developing a portfolio of earlier stage Gammabody™ programs including LAVA-1223, a Gammabody™ directed at the epidermal growth factor receptor (EGFR) for the treatment of solid tumors, for which a clinical trial application (CTA) is planned for late 2022. There is potential for targeting several EGFR-expressing tumors with LAVA-1223, including: colorectal cancer, head and neck squamous cell carcinoma, non-small cell lung cancer and pancreatic cancer.

LAVA today announces the addition of LAVA-1266, a CD123 Gammabody™, to its pipeline for the treatment of hematological malignancies. A CTA is planned for late 2023. CD123 is overexpressed in a wide range of hematological malignancies, including AML, B-cell acute lymphoblastic leukemia, hairy cell leukemia, Hodgkin lymphoma, blastic plasmacytoid dendritic cell neoplasm, B-cell chronic lymphoproliferative disorders and myelodysplastic syndrome.

Fourth Quarter and Annual Financial Results

- As of December 31, 2021, LAVA had cash, cash equivalents and investments totaling \$133.2 million compared to cash and cash equivalents of \$15.8 million as of December 31,
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2020. The increase was primarily 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 was solely attributable to the company's collaboration with Janssen Biotech, Inc. which was entered into in May 2020.
- Research and development expenses were \$6.9 million and \$37.2 million for the quarter and year ended December 31, 2021, respectively, compared to \$5.2 million and \$15.7 million for the quarter and year ended December 31, 2020. The increase for the quarter was primarily due to increases in clinical trial, headcount and other costs incurred in connection with advancing our lead Gammabody™ clinical candidates, LAVA-051 and LAVA-1207, into human clinical trials. The increase for the year also includes \$14.4 million in license fees triggered by the IPO, most of which will be paid on the first and second anniversaries of our IPO and may be paid in either cash or common stock of the Company.
- General and administrative expenses were \$3.9 million and \$12.2 million for the quarter and year ended December 31, 2021, compared to general administrative expenses of \$0.4 million and \$2.7 million for the quarter and year ended December 31, 2020. The increases for the quarter and year were primarily due to increases in personnel-related costs, non-cash share-based compensation expense and additional insurance, professional and consultant fees incurred in connection with being a publicly traded company in the United States.
- Net losses were \$9.9 million and \$3.7 million, or \$0.38 and \$12.97 loss per share for the quarters ended December 31, 2021 and 2020, respectively and were \$45.3 million and \$15.5 million, or \$2.30 and \$38.85 loss per share for the years ended December 31, 2021 and 2020, 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,	
	2021	2020	2021	2020
Revenue:				
Research and license revenue	\$ 1,000	\$ 2,000	\$ 5,000	\$ 3,500
Total revenue	1,000	2,000	5,000	3,500
Operating expenses:				
Research and development	(6,882)	(5,190)	(37,193)	(15,701)
General and administrative	(3,910)	(429)	(12,160)	(2,719)
Total operating expenses	(10,792)	(5,619)	(49,353)	(18,420)
Operating loss	(9,792)	(3,619)	(44,353)	(14,920)
Non-operating expenses	(1)	7	(837)	(543)
Loss before income tax	(9,793)	(3,612)	(45,190)	(15,463)
Income tax expense	(58)	(43)	(157)	(43)
Net loss	\$ (9,851)	\$ (3,655)	\$ (45,347)	\$ (15,506)
Net loss per share:				
Net loss per share, basic and diluted	\$ (0.38)	\$ (12.97)	\$ (2.30)	\$ (38.85)
Weighted average common shares outstanding, basic and diluted	25,775,538	281,775	19,758,169	399,126

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

	As of December 31,	
	2021	2020
Assets:		
Non-current assets	\$ 2,742	\$ 2,264
Other current assets	3,302	2,404
Cash, cash equivalents and investments	133,203	15,818



Total assets	\$ 139,247	\$ 20,486
Equity and Liabilities:		
Total Equity	\$ 118,367	\$ 7,621
Deferred revenue	1,527	6,176
Lease liabilities	581	478
License liabilities	10,056	—
Borrowings	4,284	3,604
Trade payables and other	2,553	934
Accrued expenses and other current liabilities	1,879	1,673
Total liabilities	20,880	12,865
Total equity and liabilities	\$ 139,247	\$ 20,486

About LAVA Therapeutics

LAVA Therapeutics N.V. is an 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 tumors and hematological malignancies. The Company's innovative approach utilizes bispecific antibodies engineered to selectively kill cancer cells via the triggering of Vg9Vd2 (Vgamma9 Vdelta2) T cell antitumor effector functions upon cross-linking to tumor associated antigens. A Phase 1/2a clinical study evaluating LAVA-051 in patients with certain hematological malignancies is currently enrolling (NCT04887259). The company currently anticipates additional data from the Phase 1 dose escalation phase of the LAVA-051 study in the second quarter of 2022 and data from the Phase 2a expansion cohorts in the second half of 2022. A Phase 1/2a clinical study to evaluate LAVA-1207 in patients with metastatic castration-resistant prostate cancer (mCRPC) is enrolling with data from the Phase 1 dose escalation phase of the trial expected in the second half of 2022 and data from the Phase 2a expansion cohort in the first half of 2023. 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 in respect to the company's anticipated growth and clinical developments plans, including the timing of clinical trials. Words such as "anticipate," "believe," "could," "will," "may," "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 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 preclinical data, clinical development and scope of clinical trials, and the potential use of our product candidates to treat various tumor targets. 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, 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. 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.

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