LAVA Therapeutics N.V.

Annual Report
for the fiscal year ended December 31, 2023

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BOARD REPORT

1 INTRODUCTION

1.1 Preparation

In this annual report, unless otherwise indicated or the context otherwise requires, all references to "LAVA Therapeutics N.V.", "LAVA Therapeutics", the "Company", "we", "our", "ours", "ourselves", "us" or similar terms refer to LAVA Therapeutics N.V. and its subsidiary.

This annual report has been prepared by the Company's board of directors pursuant to Art. 2:391 of the Dutch Civil Code (DCC) and represents (i) the Company's statutory annual accounts within the meaning of Art. 2:361 sub1 DCC and (ii) to the extent applicable, the information to be added pursuant to Art. 2:392 DCC. This report relates to the fiscal year ended December 31, 2023 and, unless explicitly stated otherwise, the information presented in this report is for the year ended December 31, 2023.

The consolidated financial statements included in chapter 11.1 Consolidated Financial Statements have been prepared in accordance with International Financial Reporting Standards as adopted by the European Union (EU-IFRS) and with Part 9 of Book 2 of the Dutch Civil Code. The company financial statements included in chapter 11.2 Company Financial Statements, have been prepared in accordance with the accounting principles promulgated by Title 9 of Book 2 DCC.

Art. 2:362 sub 8 DCC allows companies that apply IFRS as endorsed by the European Union in their consolidated financial statements to use the same measurement principles in their company financial statements. The Company has prepared these Company Financial Statements using this provision.

1.2 Cautionary statement regarding forward-looking statements

This annual report contains statements that constitute forward-looking statements. Many of the forward-looking statements contained in this annual report can be identified by the use of forward-looking words such as “anticipate,” “believe,” “could,” “expect,” “should,” “plan,” “intend,” “estimate” and “potential,” among others. Forward-looking statements appear in a number of places in this annual report and include, but are not limited to, statements regarding our intent, belief or current expectations. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various important factors, including, but not limited to, those identified under the section titled “Risk Factors” in section 2.5 of this annual report. Forward-looking statements include, but are not limited to, statements about:

- our operations as a biotechnology company with limited operating history and a history of operating losses;
- our plans to develop and commercialize our current and future product candidates;
- the initiation, timing, progress and results of our current and future preclinical studies and clinical trials and our research and development programs;
- our ability to successfully acquire or in-license additional product candidates on reasonable terms;
- our ability to maintain and establish collaborations or obtain additional funding;
- our ability to obtain regulatory approval of our current and future product candidates;
- our expectations regarding the potential market size and the rate and degree of market acceptance of our current and future product candidates;
- our continued reliance on third parties to conduct clinical trials of our product candidate and future product candidates and manufacture our development candidates for preclinical studies and clinical trials;
- our ability to fund our working capital requirements and expectations regarding the sufficiency of our capital resources;

- the implementation of our business model and strategic plans for our business and product candidates;
- our ability to establish sales, marketing and distribution capabilities;
- our ability to enter into and maintain collaborations with third parties for the development or commercialization of our product candidates;
- our intellectual property position and the duration of our patent rights;
- our estimates regarding expenses, future revenues, capital requirements and our needs for additional financing;
- the impact of government laws and regulations on our business;
- our need to hire additional personnel and our ability to attract and retain such personnel;
- our ability to compete in the markets we serve;
- developments relating to our competitors and our industry; and
- other risk factors discussed under “Risk Factors.”

Forward-looking statements speak only as of the date they are made, and we do not undertake any obligation to update them in light of new information or future developments or to release publicly any revisions to these statements in order to reflect later events or circumstances or to reflect the occurrence of unanticipated events, except to the extent required by applicable law. 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 international hostilities including the Russian invasion of Ukraine and the Israel-Hamas war.

2 INFORMATION ON THE COMPANY

2.1 History and Development of the Company

LAVA Therapeutics N.V., together with its subsidiary, is a clinical-stage immuno-oncology company focused on developing its proprietary Gammabody™ platform of bispecific gamma-delta T cell engagers to transform the treatment of cancer. On February 15, 2016, we were incorporated in the Netherlands and are headquartered in Utrecht, the Netherlands. At the time of our incorporation in 2016, we acquired or exclusively in-licensed the development and commercial rights to certain clinical and preclinical programs and intellectual property from Amsterdam UMC (formerly VUmc prior to its merger with AMC effective January 2024). We also have a research services agreement with Amsterdam UMC in support of our preclinical and clinical stage programs.

In 2019, we established our wholly owned United States (U.S.) subsidiary, which began business in January 2020. LAVA Therapeutics N.V. is a limited liability public company (*naamloze vennootschap*). The address of the Company’s registered office is Yalelaan 62, 3584 CM Utrecht, the Netherlands, and its phone number is +31 85 016 3100.

We completed an initial public offering in the United States in March 2021, and our common shares began trading on the Nasdaq Global Select Market on March 25, 2021. In connection with becoming a public company, on March 29, 2021, the Company changed its name from “LAVA Therapeutics, B.V.” to “LAVA Therapeutics N.V.”

Our business is primarily conducted in the European Union and we maintain our books and records in euros (EUR) and U.S. dollars (USD) where applicable as functional currency. Our reporting currency for our financial statements and all other financial information included in this annual report is USD.

The Securities and Exchange Commission (SEC) maintains an Internet website that contains reports and other information about issuers like us who file electronically with the SEC. The address of that website is www.sec.gov. Our Company website is www.lavatherapeutics.com. The information on our website is not

incorporated by reference into this report, and one should not consider the information contained on our website to be part of this report.

2.2 Business overview

We are a clinical-stage immuno-oncology company focused on developing our proprietary Gammabody platform of bispecific gamma delta (γδ) T cell engagers to transform the treatment of cancer. Using our Gammabody platform, we are developing a portfolio of novel bispecific antibodies designed to engage and leverage the potency and precision of gamma delta (γδ) T cells to elicit a robust, anti-tumor immune response and improve outcomes for cancer patients.

Gamma Delta T Cells

Gamma delta (γδ) T cells are a "ready-to-fight" first line of defense of the human body and form a bridge between the innate and adaptive immune systems. Vgamma9 Vdelta2 (Vγ9Vδ2) T cells, the largest subpopulation of γδ T cells in peripheral blood of healthy adults, are a homogeneous effector T cell population whose prevalence has been correlated with favorable outcomes and survival in blood cancers (hematological malignancies) and solid tumors. They have the natural ability to distinguish cancer cells from healthy cells and, once activated, have the potential to trigger a rapid and potent immune response to a wide array of cancers. In addition, γδ T cells can initiate further activation of cells from both the innate and adaptive immune systems, which can lead to a long-lasting immune response and immunological memory.

Other Approaches

Other T cell engager (TCE) approaches, including bispecific antibodies that activate T cells through binding of CD3, which is present on all T cells, and adoptive transfer of T cells expressing an engineered chimeric antigen receptor (CAR), have demonstrated significant clinical activity against selected cancers. Nonetheless, the promise of TCEs for broader use as cancer therapy has not yet been fully realized. Drawbacks of these approaches include dose-limiting toxicities resulting from the excessive release of cytokines, referred to as cytokine release syndrome (CRS). CD3-based TCEs have additional limitations because of their indiscriminate activation of T cells, including both effector T cells and regulatory cells (Tregs). Activation of Tregs can dampen anti-cancer immunity, potentially resulting in decreased or no therapeutic efficacy. The therapeutic active dose and the toxic dose of CD3-based TCEs are often in close proximity, resulting in a narrow therapeutic window that may preclude full exploitation of their therapeutic potential. Adoptive transfer of CAR-T cells is complex and costly and has also been associated with significant risk of CRS and on-target off-tumor-related toxicities.

Our Proprietary Gammabody Platform

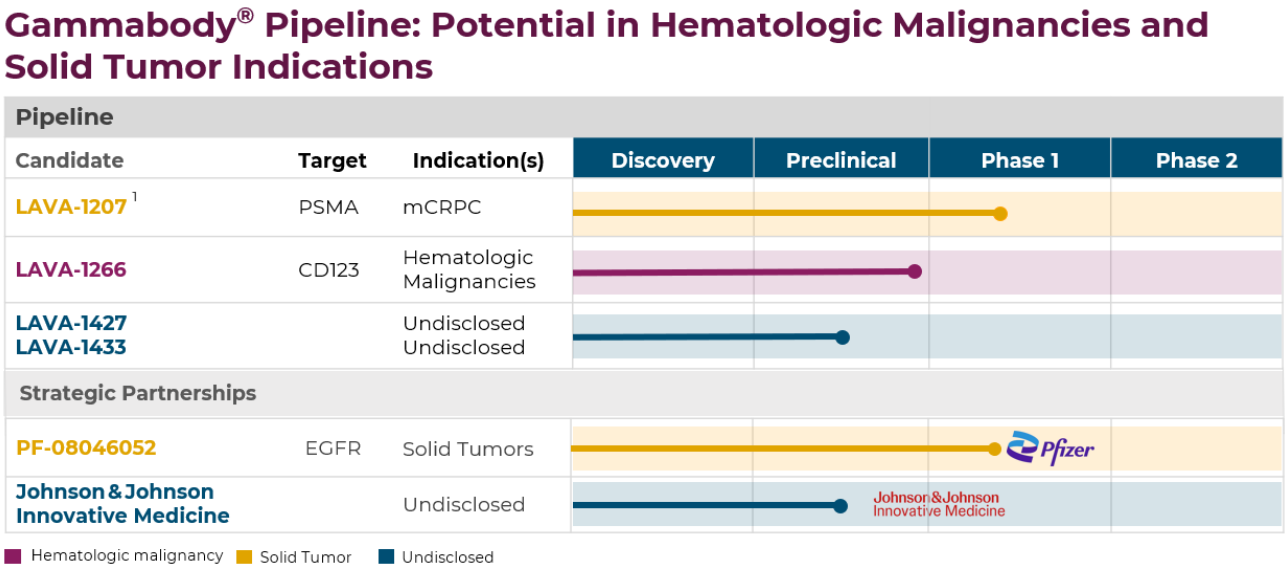
Our Gammabody platform enables us to develop off-the-shelf bispecific T cell engagers that leverage the advantages of antibody-based treatments including favorable manufacturability and developability characteristics. Our Gammabody platform is designed to recruit the body's own Vγ9Vδ2T cells resulting in tumor cell targeting and conditional cancer cell killing. One arm of the Gammabody recruits Vγ9Vδ2 T cells, while the other arm recognizes and binds to a specific tumor target present on hematological or solid tumors. We designed our Gammabody drug candidates to activate the Vγ9Vδ2 T cells once the respective arms are bound to the γδ T cell and the tumor target, thereby avoiding broad systemic activation. We believe this approach provides a significant opportunity to address unmet medical needs with the potential to elicit potent and durable responses in patients. We also believe this approach may provide a superior therapeutic window compared to other approaches by reducing the risk of on target/off tumor toxicity and avoid activation of Tregs and broad systemic activation that may result in severe CRS.

We have generated compelling preclinical data using patient tumor tissues that demonstrate the ability of our Gammabody platform to exert preferential activity against tumor cells expressing the target with relative sparing of healthy cells. Using surrogate Gammabody molecules, studies in non-human primates showed that our γδ T cell engagers were well tolerated and did not induce high-grade CRS.

Our Pipeline

We designed our Gammabody platform to be fully modular and compatible with existing anti-tumor antibodies to facilitate expedited discovery and development of novel compounds. We are currently advancing our Gammabody pipeline for the development of potential therapeutics in both hematologic malignancies and solid tumors. Our lead clinical-stage candidate, LAVA-1207, is designed to target prostate-specific membrane antigen (PSMA)-expressing cancers. It is currently undergoing testing in a first-in-human Phase 1/2a clinical trial for patients with metastatic castration resistant prostate cancer (mCPRC). We are also developing other Gammabody drug candidates, including LAVA-1266, which targets CD123 for the treatment of hematological malignancies, including acute myeloid leukemia and myelodysplastic syndrome. We expect to file an investigational new drug application (IND) for LAVA-1266 in mid-2024.

The pipeline chart below shows our current development programs and strategic partnerships:



LAVA-1207

LAVA-1207 is designed using our Gammabody platform to conditionally activate Vγ9Vδ2 T cells upon crosslinking to PSMA to trigger the potent and preferential killing of PSMA-positive tumor cells. PSMA, a transmembrane protein, is expressed by most prostate tumors, and its expression is further increased in poorly differentiated, metastatic, and hormone-refractory carcinomas. Its expression profile in prostate cancer has been clinically validated and makes PSMA an important target for therapies for this form of cancer. In preclinical experiments, LAVA-1207 was highly specific and potent in its ability to induce Vγ9Vδ2 T cell-mediated killing of PSMA-positive tumor cells.

In 2022, we dosed the first patient in a first-in-human clinical trial evaluating LAVA-1207 in patients with mCRPC. The open-label, multi-center, Phase 1/2a clinical trial evaluates safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity and preliminary anti-tumor activity of LAVA-1207. The Phase 1 dose-escalation phase is designed to determine recommended Phase 2a dose(s) for optimization in Phase 2a. Once recommended Phase 2a dose(s) have been established, the trial will expand into the Phase 2a portion to confirm safety and evaluate the preliminary anti-tumor activity of LAVA-1207 in patients with

mCRPC. Enrollment for the Phase 1/2a clinical trial for LAVA-1207 is ongoing and as of the date of this annual report, we have nine clinical trial sites open to enrollment in Europe and the United States.

In February 2023, at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU), we reported initial clinical data for the ongoing clinical trial of LAVA-1207. For the first five cohorts, these data demonstrated predictable and linear pharmacokinetics and on-mechanism pharmacodynamics and a favorable safety profile. Preliminary signs of anti-tumor activity were observed at week 8, with iRECIST stable disease (iSD) in 8 out of 14 evaluable patients and PSA levels stabilizing or decreasing in several patients. iRECIST is the response evaluation criteria in solid tumors, a set of published rules that define whether tumors in cancer patients have improved, stayed the same or worsened during treatment.

Currently, enrollment for LAVA-1207 has reached dose level ten in the EU and the United States. With the goal of maintaining low rates of CRS and minimizing the risk of events >grade 2 we have introduced premedications and step-dosing to the protocol. This is a common approach in clinical trials of other T-cell engagers. No CRS events greater than grade 2 have been observed in the monotherapy arm of the trial. A single dose limiting toxicity (DLT) of subdural hematoma was reported in cohort 6 and is the only DLT reported in the LAVA-1207 monotherapy arm. No DLTs have been reported in the monotherapy arm since we initiated step dosing and as of the date of this annual report, there have been no similar DLTs in the trial.

In June 2023, we announced that we had introduced cohorts of patients who would receive one of two schedules of low-dose interleukin-2 (LDIL-2) beginning the day after LAVA-1207 dosing for the first four doses. LDIL-2 has the potential to increase the number of Vγ9Vδ2-T cells available for engagement by LAVA-1207. Three DLTs were reported in patients receiving multiple doses of LDIL-2 in addition to LAVA-1207 in cohort 7A2, a cohort with multiple doses of LDIL-2 per cycle. These events occurred prior to the introduction of step-dosing. One event was respiratory failure and the other two were transaminase increases. One transaminase increase was transient and on a background of grade 2 CRS in a patient who had not received priming doses. We have amended the DLT criteria for the duration of transaminase increases which are clearly immune-related. This patient would no longer be considered to have had a DLT under the new criteria. The other DLT of transaminase increase was in a patient who also had severe sepsis and the event improved with improvement in the sepsis unrelated to LAVA-1207 and the event improved with the improvement of sepsis. However, as an additional contribution from LAVA-1207 could not be ruled out, the event was reported as possibly related. Since we amended the DLT criteria and initiated step dosing, we have not observed any CRS or DLTs in patients dosed with LDIL-2. We will decide whether it is safe and beneficial to treat patients with multiple doses of LDIL-2 per cycle with step dosing once we have more safety data from other cohorts.

To date, we have observed pharmacodynamics that support LAVA-1207's mechanism of action and continue to see increasing Vδ2-T cell receptor occupancy with increasing dose and we continue to see signs of preliminary anti-tumor activity including long-term stable disease and decreases in PSA level.

As we progress development of LAVA-1207, it is important that we explore and understand factors that may affect patients' likelihood of benefiting from treatment. Initial data suggest that there may be a relationship between antitumor activity in patients and Vγ9Vδ2 T cell counts at baseline. We are working to determine if any clinical characteristics predict low Vγ9Vδ2 T cell counts and, if necessary, we may exclude patients from the trial with such characteristics. Additionally, we are working on development of an assay that may be used for inclusion/exclusion of patients if necessary.

In addition to investigating the potential role of patient selection based on γδ2 T cells we are exploring the role of tumor factors in understanding patient selection and antitumor activity. Patients have a PSMA-PET scan at baseline and we will study the relationship between PET positivity and likelihood of benefit. In addition, an amendment to the protocol has been submitted to add ctDNA and CTC assessments as an additional exploratory evaluation of antitumor effect.

In January 2024, we announced we had entered into a clinical trial collaboration and supply agreement with Merck & Co., Inc. to evaluate its anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in combination with LAVA-1207. Under the terms of this agreement, we will be provided with pembrolizumab for the dose escalation and

expansion phases of LAVA's ongoing Phase 1/2a study of LAVA-1207 (NCT05369000) (KEYNOTE-F73), with the combination arm expected to be initiated in the first half of 2024.

We plan to provide new data for LAVA-1207 at an upcoming medical conference in the second half of 2024, which may inform the design of a future pivotal trial.

Disease Overview

Prostate cancer is the second most common cancer among men in the United States, with an estimated 288,000 new diagnoses in 2023. It is estimated that 50,000 men with mCRPC are treated every year in the United States. Several treatments are approved for mCRPC, including chemotherapies (docetaxel and cabazitaxel), next generation androgen receptor directed therapeutics (e.g., enzalutamide, abiraterone) and the PSMA-directed radiopharmaceutical lutetium Lu77 vipivotide tetraxetan and PARP inhibitors (for a subset of patients with certain DNA damage repair mutations), which have collectively improved the therapeutic options for patients with mCRPC. The long-term outcome for patients with mCRPC is highly variable and will depend on prognostic factors of the underlying disease, its responsiveness to the available therapies and the co-morbidities of this generally elderly population. However, there is no curative treatment available today and additional new therapies are needed. Once mCRPC has metastasized beyond regional lymph nodes, the 5-year survival rate is 32%, and it is estimated that more than 34,000 men died of mCRPC in the U.S. in 2023. Prostate cancer is well-known for its immunosuppressive tumor microenvironment and generally low tumor mutational burden. These characteristics are believed to hamper the efficacy of classical CD3-based TCEs and other immuno-oncology compounds. According to published literature, prostate cancer is the solid tumor indication with the highest relative abundance of tumor-infiltrating $V\gamma9V\delta2$ cells. This high relative abundance correlates with a lower biochemical recurrence (BCR) rate, which is related to an improved patient prognosis.

LAVA-1266

LAVA-1266 is designed using our Gammabody platform to conditionally activate $V\gamma9V\delta2$ T cells upon crosslinking to CD123 (Interleukin-3 receptor-alpha) to trigger the potent and preferential killing of CD123-positive tumor cells. CD123 is a clinically validated target and CD123 is expressed in a range of hematological malignancies, including acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), acute lymphocytic leukemia (ALL) and Hodgkin Lymphoma. There is a clear unmet need in these indications. We are currently engaged in IND enabling activities and plan to seek an IND submission for LAVA-1266 in the second quarter of 2024.

Preclinical Programs

Our internal pipeline consists of several discovery and preclinical stage investigational assets for undisclosed targets in hematologic malignancies and solid tumors. Our preclinical stage assets, LAVA-1427 and LAVA-1433, were selected as development candidates at the end of 2023 and have progressed into Good Manufacturing Practices (GMP) cell-line development. We generated high yield cell lines producing high quality bispecific gamma delta $\gamma\delta$TCEs for GMP manufacturing and further preclinical activities for potential IND/clinical trial application (CTA) filings in 2025 and beyond.

EGFRd2 (PF-8046052/formerly LAVA-1223)

In 2022, we entered into the Pfizer Agreement to develop, manufacture and commercialize EGFRd2 (PF-8046052), an advanced preclinical asset that utilizes our proprietary Gammabody technology to target EGFR-expressing solid tumors. Under the terms of the Pfizer Agreement, we received a $50 million nonrefundable upfront payment in October 2022 and are eligible to receive up to approximately $650 million upon the achievement of development, regulatory and commercial milestones, as well as royalties ranging from the single digits to the mid-teens on future sales. The Pfizer Agreement also provides Pfizer with the opportunity to exclusively negotiate rights to apply our proprietary Gammabody platform on up to two additional tumor targets, which exclusive rights, if not exercised in 2024, will expire. In 2023, we entered into a supply agreement with Pfizer to fulfill part of our obligations under the Pfizer Agreement and began shipping investigational drug supply to Pfizer in March 2023. As of September 30, 2023, all initial drug supply was

shipped to Pfizer. In 2023, Pfizer received investigational new drug application clearance for EGFRd2 (PF-8046052) in advanced solid tumors from the United States Food and Drug Administration (FDA) and initiated a Phase 1 trial (NTC0598133) of EGFRd2 (PF-8046052) to evaluate the safety and tolerability of this molecule as a monotherapy in advanced epidermal growth factor receptor (EGFR) expressing solid tumors. In March 2024, Pfizer paid us $7 million for achieving a clinical development milestone.

Discontinued program - LAVA-051

In June 2023, we announced that the LAVA-051 clinical trial, targeting the CD1d expressing hematological tumors multiple myeloma (MM,) chronic lymphocytic leukemia (CLL), and AML, would be discontinued after no patients remained on treatment. CD1d is expressed by tumor cells of most patients with CLL, MM and (myelo)monocytic subtypes of AML.

From mid-2021 through 2023, we treated patients in a first-in-human Phase 1/2a clinical trial evaluating LAVA-051 in patients with relapsed or refractory CLL and MM. Patients with AML were expected to be included later in the trial once biologically relevant dosing had been reached. The open-label, multi-center clinical trial was designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity and preliminary anti-tumor activity of LAVA-051. Subsequent dose levels enrolled patients for intravenous and subcutaneous dosing. The Phase 1 dose-escalation study was discontinued because of the evolving competitive landscape before an optimal Phase 2 dose could be reached. The Phase 1/2a clinical trial for LAVA-051 had fifteen clinical trial sites in Europe and in the United States and orphan drug designation for LAVA-051 for the treatment of CLL.

In December 2022, at the 64th American Society of Hematology Annual Meeting and Exposition (ASH), we reported initial clinical data from the first five patient cohorts of the Phase 1 dose-escalation study. These data suggested potential signs of clinical activity as well as predictable and linear PK and on-mechanism PD parameters consistent with $V\gamma9V\delta2$ engagement. Drug exposure and $V\gamma9V\delta2$ T cell receptor occupancy (RO) of LAVA-051 increased with LAVA-051 dose increases and peripheral blood $V\gamma9V\delta2$ T cells expressed increased levels of activation markers after dosing. One CLL patient experienced multiple enlarged tender diseased lymph nodes one week after first dosing that subsequently regressed, reminiscent of a tumor flare reaction that has been reported as a potential sign of anti-tumor activity in CLL patients treated with another immuno-oncology drug. The patient was assessed as stable disease at the pre-planned 12 week on-study assessment and also had a significant reduction in clonal B-cell count.

The decision to discontinue the LAVA-051 clinical trial followed the significant advances in the treatment of MM and CLL, so we prioritized the programs that we believed could have the greatest potential to benefit patients. No CRS or immune effector cell-associated neurotoxicity syndrome (ICANS) were observed in the additional patients treated in the LAVA-051 clinical trial since the ASH data were reported, and the trial was discontinued. PD parameters continued to reflect changes expected for the MOA and the receptor occupancy increased with escalating dose. The data collected from the LAVA-051 clinical trial will contribute to our research on the Gammabody platform.

The discontinuation of the clinical trial for LAVA-051 was not driven by safety concerns and the safety profile for LAVA-051 was favorable at the dose levels studied. As a result of the discontinuation, we expensed $1.4 million of clinical trial, contract manufacturing and bioanalytical costs in 2023. We also finalized a reduction in workforce of approximately 36% in the United States and the Netherlands to better align our resources with our focus on LAVA-1207 and research and development. The majority of the charges in connection with the reduction, approximately $0.5 million, were substantially completed by the end of 2023.

T cell engagers (TCEs) in cancer therapy

Current T cell engager approaches

Immuno-oncology aims to harness the power of the immune system to drive a durable anti-cancer response that starts with recognizing malignant cells as “foreign” and the ability to overcome immune evasion mechanisms employed by cancer. Despite many successes in the field, one of the remaining fundamental challenges of leveraging the immune system for cancer treatment is to specifically activate immune effector

cells against the tumor while avoiding immune activation against healthy cells. This requires, among other factors, specific effector T cell engagement and activation at the tumor site, often made ineffective in cancer patients due to tumor microenvironment (TME)-driven immune inhibition. Immunotherapy currently utilizes multiple approaches to T cell engagement including bispecific T cell engagement and CAR-T cell engagement.

The first approach utilizes bispecific antibodies that can engage all T cells, irrespective of their antigen recognition specificity. The second approach involves the adoptive transfer of engineered T cells, such as CAR-T cells, empowered with specific tumor recognition ability to generate anti-tumor activity *de novo*, independent of a pre-existing response.

In the bispecific antibody concept, the cytotoxic potential of effector T cells is redirected against the tumor. Through this approach, T cells are physically linked with tumor cells via bispecific antibodies that are composed of a T cell-binding domain and a tumor-binding domain. These TCEs primarily activate T cells through binding of CD3 in the T CR/CD3 receptor complex and can trigger broad activation of CD3-expressing T cells. These cells would otherwise individually require the specific recognition of a unique antigen in the context of polymorphic major histocompatibility complex (MHC) molecules for their activation. Thereby, TCEs can bypass the normal antigen restriction of classic T cells, causing activation independent of the epitope specificity of the T cell receptor.

The dual-targeting concept enabled by TCEs holds great therapeutic promise, but translation of the concept into treatments has proved challenging. The archetypical application, T cell redirection and engagement via CD3, was first described in the mid-1980s but did not reach patients until 2009 with the European Union approval of catumaxomab. Catumaxomab was delivered intraperitoneally, as systemic intravenous administration induced fatal toxicity at low doses due to Fc-mediated off-target T cell activation in the liver. Catumaxomab was withdrawn from the market in 2017 for commercial reasons, but the impressive clinical results of another approved CD3-based TCE, blinatumomab (CD3 × B lymphocyte antigen CD19), sparked renewed interest and investment in this approach, as reflected by the numerous TCEs currently in clinical development for hematologic and solid tumor indications.

The second approach is the CAR-T cell, or engineered cell therapy, strategy in which patient T cells are harvested and genetically engineered to carry a chimeric receptor allowing recognition of a specific target antigen on the tumor cell. Adoptive transfer of these cells results in activation of the CAR-T cells and tumor cell killing. To date, multiple CAR-T therapies have generated promising clinical data, and multiple CAR-T cell therapies targeting CD19, including KYMRIAH® (tisagenlecleucel), YESCARTA® (axicabtagene ciloleucel), TECARTUS® (brexucabtagene autoleucel) and BREYANZI® (lisocabtagene maraleucel), and the BCMA-targeted CAR-T cell therapies ABECMA® (idecabtagene vicleucel) and CARVYKTI™ (ciltacabtagene autoleucel), have been approved. Many more CAR-T therapies are being developed against different targets and leveraging effector activity of different cell types. The currently approved therapies are personalized approaches based on relatively complex and clinically aggressive technologies and procedures, in which a patient's T cells are initially extracted and then re-administered after being modified and after the patient has undergone bone marrow conditioning with high-dose chemotherapy. A next-generation approach is also in early-stage development, based on the same complex engineering and manufacturing process but aimed at having off-the-shelf allogeneic cell products that can be used for several patients without lag time.

Challenges with current TCE approaches

Current TCE approaches, including CD3 TCEs and CAR-T approaches, have demonstrated anti-cancer activity in clinical settings, but have also been limited in their use due to several key challenges, including:

- Limited therapeutic window: Side effects and dose-limiting toxicities, most prominently related to CRS and on-target/off-tumor related toxicities, have been observed in both early-stage TCE and CAR-T approaches. In January 2024, FDA notified approved CAR-T manufacturers that a classwide boxed warning regarding the risk of secondary malignancies would be required.
- High variability in effectiveness: CD3 TCEs dampen the antitumor efficacy of cytotoxic T cells through activation of immune-suppressive Tregs which has resulted in variability of clinical efficacy.

- Patient preconditioning: For CAR-T, high doses of chemotherapy are typically needed to precondition the patient by lymphodepletion. Such lymphodepletion creates space for CAR-T cells and improves their homeostatic expansion and therapeutic efficacy, but it also results in side effects associated with both high-dose chemotherapy and leukopenia.
- Manufacturing and logistics complexity: CAR-T manufacturing complexities to date mean that products cannot always be successfully produced for patients. Lengthy processes result in lag times for treatment administration, resulting in a long vein-to-vein time and a limited addressable patient population.

Gammabody Platform (bispecific γδ TCEs): a potential new class of immuno-oncology treatments

The successes of TCE approaches highlight the potential of re-directing effector T cell responses as a therapeutic strategy to improve cancer patients' outcomes. In particular, the large number of trials with bispecific TCEs in cancer supports this approach from both a clinical and commercial perspective. We are studying the engagement of gamma delta T cells in early clinical trials as a potential next-generation application of TCEs and believe our Gammabody platform may address the limitations of current TCEs to improve patient outcomes in both hematologic malignancies and solid tumors.

Vgamma9 Vdelta2 (Vγ9Vδ2) T cells in cancer therapy

Background on Vγ9Vδ2 T cells

T lymphocytes are divided into two main categories based on T cell receptor type: αß, or alpha beta, and γδ, or gamma delta, T cells. Gamma delta T cells represent approximately 1-5% of all T cells in circulation. Human gamma delta T cells are further classified based on the combination of their Vgamma (Vγ) and Vdelta (Vδ) receptor chains, with Vγ9Vδ2 T cells representing about 90% of all γδ T cells in circulation. In addition, these Vγ9Vδ2 T cells have been observed to infiltrate tumors in which greater relative abundance correlates with favorable outcome.

Although most human T cells express an alpha beta TCR, a smaller proportion of T cells express a gamma delta TCR. Conventional alpha beta TCR bearing T cells can be subdivided in two major subtypes: CD4 expressing "helper" T cells, and CD8 expressing "cytotoxic" T cells. Both alpha beta T cell populations recognize specific peptides loaded onto MHC molecules—MHC class II in the case of CD4-positive T cells, and MHC class I in the case of CD8-positive T cells. In contrast, γδ T cells typically recognize their ligands independent of classical antigen processing and MHC restriction. The γδ T cell population can be roughly divided into two large sub-populations: Vdelta1 (Vδ1) and Vdelta2 (Vδ2) TCR expressing γδ T cells. The Vδ2 population of γδ T cells is associated almost invariably with the Vgamma9-chain, resulting in a very homogeneous effector cell population. This population has a monomorphic TCR with a well-defined specificity for butyrophilin molecules (BTN3A1/2A1)-in complex with phosphoantigen, a well-defined proinflammatory functional profile and a unique capacity to also act as antigen-presenting cells upon their activation.

In contrast, Vδ1 T cells constitute a heterogeneous population of cells in part because the Vδ1 chain can pair with several Vγ chains, such as Vγ 4,5,9, and also with alpha beta-TCR, and has more variability in TCR CDRs. Consequently, Vδ1 T cell subsets recognize various antigen presenting molecules and can recognize various antigens. Vδ1 T cells also have substantial functional diversity, not only being able to exert cytotoxic effects but also playing a role in tissue homeostasis, repair and immune suppression. Both cell subsets can infiltrate tumors, but protumor functions related to IL-17 production and a regulatory phenotype have only been reported for tumor-infiltrating Vδ1 T cells, and in various tumor types, infiltration of Vδ1 1 has been shown to be related to poorer patient outcome, while Vδ2 tumor infiltration has generally been shown to correlate to positive prognosis.

When these Vγ9Vδ2 T cells are activated, they secrete pro-inflammatory cytokines that trigger downstream immune cells from the innate and adaptive immune system, including alpha beta T cells, NK cells and dendritic cells. Activated Vγ9Vδ2 T cells have a distinct ability to take up, process and present antigens to alpha beta T cells, which may prime the adaptive immune system for a memory response, potentially resulting in deep and durable responses against disease.

Targeting Vγ9Vδ2 T cells for cancer treatments

As mentioned above, Vγ9Vδ2 T cells have been observed to infiltrate tumors in a wide variety of cancer indications and can provide effective anti-tumor immune responses against both hematologic malignancies and solid tumors. These T cells contain a tumor recognition mechanism, allowing them to recognize and kill cancerous cells while leaving healthy cells unharmed. Vγ9Vδ2 T cells represent a potent and relatively homogeneous class of proinflammatory immune effector cells with an immune surveillance function.

Because Vγ9Vδ2 T cells have properties of both the innate and adaptive immune systems, they serve as a functional bridge between these two critical systems to effect tumor killing. They can be activated for immediate and potent killing of tumor cells, as well as the potential to induce a cascade response in which they trigger innate and adaptive immune cells through cytokine release and antigen presentation. The latter may induce immunological memory and result in potent and durable responses.

Vγ9Vδ2 T cells detect and kill tumor cells by indirectly detecting specific metabolites, called phosphoantigens, which often accumulate intracellularly at relatively high levels in tumor cells. These phosphoantigens bind to an intracellular domain of the cell-surface receptor, butyrophilin, triggering a conformational change and recognizing butyrophilin receptors on tumor cells by Vγ9Vδ2 T cells. Upon this interaction with tumor cells, Vγ9Vδ2 T cells are activated and release cytolytic molecules that can directly kill cancer cells and produce pro-inflammatory cytokines that can attract other immune cells and trigger anti-cancer activity.

As reported in a landmark publication in *Nature Medicine* in 2015, the presence of tumor-infiltrating gamma delta T cells has shown the highest correlation with favorable outcomes for cancer patients compared to other leukocyte subpopulations in tumors. Further, as reported in *Oncoimmunology* in 2017, infiltration of Vγ9Vδ2 T cells was confirmed in a large set of different tumors, including cancers with a low incidence of alpha beta T cell infiltration (often called: 'cold' tumors).

The unique anti-cancer potential of γδ T cells drove prior clinical trials. Various clinical trials were conducted utilizing either adoptive cell therapy of ex vivo expanded activated autologous or allogeneic γδ T cells or in vivo γδ T cell activation approaches with synthetic phosphoantigens or aminobisphosphonates. However, the results from these prior trials were not consistent or robust enough to support further development. Lack of tumor-targeted activation and observed exhaustion of γδ T cells may have dampened clinical responses. Based on our preclinical data, we believe that an important root cause for underwhelming efficacy of these approaches is the systemic non-tumor specific activation of Vγ9Vδ2 T cells. Our targeted approach utilizing a bispecific γδ TCE could materially improve clinical responses while maintaining a good safety profile.

Advantages of our Gammabody approach

Bispecific γδ TCEs represent an emerging new class of targeted immuno-oncology treatments. By engaging only Vγ9Vδ2 T cells, instead of all CD3-expressing T cells, our approach is designed to enable therapeutic options that overcome the limitations of previous and existing TCE approaches in treating cancer. We believe our approach has the following advantages:

- Unique engager of γδ T cells. Our Gammabody molecules specifically engage the proinflammatory immune effector Vγ9Vδ2 T cell population, unlike pan T cell engagers that also result in co-activation of immunosuppressive T cell populations. Our technology is designed to retain and leverage the natural ability of Vγ9Vδ2 T cells to distinguish tumor cells from healthy cells.
- Conditional activation with high precision. Our Gammabody molecules only trigger activation of Vγ9Vδ2 T cells upon simultaneous binding of the γδ T cell receptor and the antigen on tumor cells. This conditional activation provides a tumor-targeting mechanism and avoids a broad systemic, or non-tumor specific, activation of Vγ9Vδ2 T cells. Tumor-targeted activation may avoid population exhaustion, which is commonly observed after repeated generalized γδ T cell triggering using non-tumor targeted phosphoantigen-based approaches that others have applied.
- Driving a cascade response that includes both innate and adaptive immune responses. Activated Vγ9Vδ2 T cells can trigger innate and adaptive immune cells through cytokine release and antigen presentation.

Thereby, our technology has the potential to induce immunological memory and result in not only rapid cytotoxicity, but also potent and durable responses.

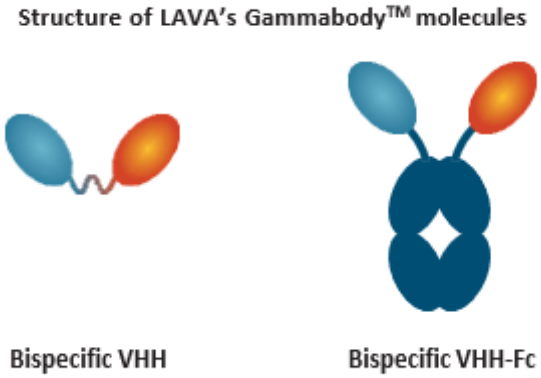
- High potency. We demonstrated high antitumor potency in vitro and ex vivo using cell lines and patient tumor samples with our Gammabody platform, with an average EC50 in the low picomolar range. These pre-clinical results suggest that clinical antitumor activity may be triggered using relatively low doses.
- Low anticipated risk of high-grade CRS. Our early-stage Phase 1 clinical trial for LAVA-051 did not observe >grade 2 CRS prior to discontinuance, and LAVA-1207 has had no >grade 2 CRS observed to date. Similarly, our (surrogate) Gammabody molecules did not result in any high-grade CRS in non-human primate studies. This is consistent with earlier clinical studies of $\gamma\delta$ Tcell-based therapeutic approaches, including those that triggered systemic activation of the entire Vγ9Vδ2 T cell population.
- Potential activity in hematologic malignancies and solid tumors, including immunologically "cold" tumors. Our Gammabody molecules can trigger activation of both peripheral blood and tumor-infiltrating Vγ9Vδ2 T cells, allowing access to and activity against hematologic malignancies and solid tumors, potentially including those that have not been successfully addressed using immune checkpoint inhibitors.
- Broad therapeutic window. Vγ9Vδ2 T cells have an inherent ability to distinguish cancerous from normal cells, which is retained in our Gammabody technology. Based on our preclinical data, we expect the optimal dose to be below the maximum tolerated dose. We believe that the high tumor selectivity and potency of our Gammabody molecules, in combination with the lower anticipated risk of high-grade CRS, may provide a broad therapeutic window.
- Fully modular, allowing for the use of existing tumor-targeting antibodies. Our platform is fully modular, enabling existing antibodies or antibody fragments to be incorporated into our Gammabody platform. This allows us to expedite the discovery and development of clinical candidates since no *de-novo* antibody panel generation is required. In addition, our platform uses standardized development procedures that are well-known to regulatory authorities.
- Well-established, standardized manufacturing process. Our current and future product candidates are off-the-shelf, manufactured using well-established, standardized processes that avoid the higher costs, complexities, product variability and treatment delays associated with the manufacturing of cellular products, such as CAR-T therapies.
- Potential combination with immune checkpoint inhibitors and other oncology approaches. Because of their distinct mechanism of action and targeted nature, Gammabody molecules have the potential to be combined with anti-PD-1/PD-L1 agents. Cohorts of patients treated with LAVA-1207 in combination with the anti-PD1 monoclonal antibody pembrolizumab is expected to begin enrollment around mid-2024. We may consider additional potential combinations including cytotoxic agents, other monoclonal antibodies and cell therapy approaches for the treatment of a wide range of cancer indications.

Our novel constructs

Our Gammabody molecules utilize humanized and highly specific single domain antibodies, which are known as VHH antibody fragments. VHH antibodies are known to have several key pharmaceutical advantages over conventional antibodies.

VHH antibodies can access unique epitopes that may not be accessible for conventional antibodies. VHH single domain antibodies are readily humanized and are known for their high stability, solubility and ease of manufacturing. The therapeutic potential of VHH single domain antibody components has been validated by the approval of caplacizumab for patients with acquired thrombotic thrombocytopenic purpura.

As depicted below, we are developing a novel proprietary platform in relatively small Gammabody formats: a bispecific format in which a Vδ2 T cell receptor-specific VHH is linked to a tumor-targeting VHH via a short and clinically validated linker, and a bispecific format with a silenced Fragment crystallizable (fc) domain (VHH-Fc). We believe that the combination of relatively small size and the Fc-mediated half-life extension facilitates tumor penetration and is therefore advantageous for the development of compounds targeting solid tumors.



Next Generation Gammabody platform

We are also developing a novel proprietary platform of next generation Gammabody formats that have the potential to further stimulate and expand Vγ9Vδ2 T cells towards cells and potentially recruit alternative effector cells.

Our manufacturing advantages

We have demonstrated that we can produce bispecific VHH antibodies in yeast, allowing for robust and low-cost production. Fc-domain-containing bispecific VHH-domain antibodies are made using the widely used Chinese Hamster Ovary (CHO) manufacturing platform and knobs-into-holes (KiH) technology. KiH technology has been widely validated and is based on the introduction of a single amino acid "knob" mutation on the one heavy chain Fc, which fits into a complementary "hole" created by a three-amino acid mutation on the other heavy chain Fc. We produce bispecific VHH-Fc in a single CHO cell line in which favored heterodimer pairing ensures high yields of the bispecific product.

We continue to improve the developability of our lead bispecific molecules and manufacturability is an important part of that. We have made several improvements in the overall protein structures to minimize for example product heterogeneity caused by post translational modifications. As a result, our patent portfolio could be extended to include such inventions. The cell line generation platform (using the industry standard CHO cell lines) for at least five development candidates has now resulted in reliable and stable manufacturing clones that produce high yields of bispecific antibodies with high heterodimer pairing. Process development, analytical method validation and GMP manufacturing optimized for our bispecific antibodies, are considered part of our platform as they have proven to be transferable from product to product. These results show a high manufacturability of our lead products, largely de-risked for future commercial manufacturing once approved.

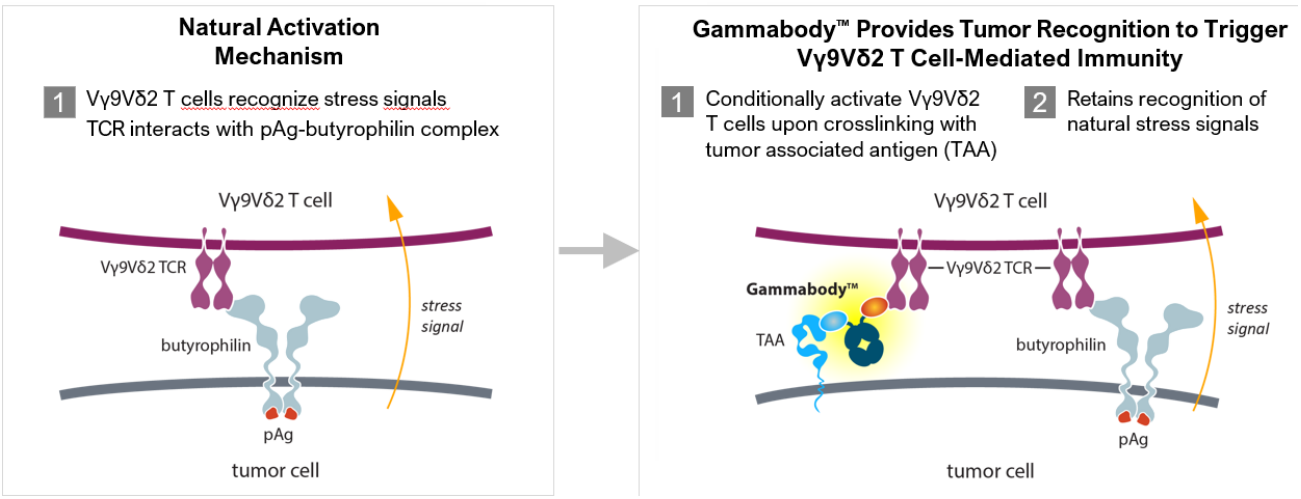
Our Gammabody platform

We have developed a proprietary Gammabody platform that optimizes tumor-targeted activation of Vγ9Vδ2 cells for tumor cell killing, retains and leverages these cells' inherent tumor cell recognition and killing capabilities and drives a downstream immune response cascade against tumor cells. Our platform combines the power and natural selectivity of Vγ9Vδ2 T cells and their ability to activate both arms of the immune system with the targeting advantages of small-sized bispecifics, providing the opportunity to significantly improve upon classical T cell engager approaches and earlier strategies for recruiting γδ T cells for cancer therapy.

In the graphic below, the left panel shows the natural activation mechanism of Vγ9Vδ2 T cells, which, through recognition of phosphoantigen-activated butyrophilins, leads to tumor cell killing. The right panel depicts our approach using our Gammabody platform. This Gammabody molecule binds Vγ9Vδ2 T cells and a tumor-associated antigen of choice. Crosslinking via our Gammabody leads to activation of Vγ9Vδ2 T cells and potent tumor cell killing. While our approach bypasses the requirement of interactions between the Vγ9Vδ2 TCR and phosphoantigen-activated butyrophilins, Gammabody molecule bound Vγ9Vδ2 T cells retain the inherent

tumor specificity of Vγ9Vδ2 T cells. Our preclinical work shows that this results in strong activity against tumor cells, but only limited activity against healthy cells expressing the same target.

LAVA's proprietary Gammabody platform engages Vγ9Vδ2 T cells for targeted cancer treatment.



Our approach targets antigens frequently expressed at higher levels on tumor cells than healthy cells. In addition, our Gammabody platform is designed to avoid the detrimental co-activation of immune-suppressive cells, such as Tregs, that is typically observed with CD3 or pan-T cell TCEs, which can dampen the development of effective antitumor responses. We have conducted preclinical experiments showing that Treg activation, as assessed by flowcytometric detection of the early activation-marker CD69, is induced by a CD3-based TCE, but not by our Gammabody. Since our platform does not activate immune suppressive cells like Tregs, we believe this dampening effect is unlikely to occur with our Gammabody molecules, increasing their potential efficacy compared to CD3-based TCEs.

We believe our Gammabody molecules drive a cascade response that potentially provides for enhanced anti-tumor efficacy. After the initial activation of Vγ9Vδ2 T cells is mediated through our Gammabody molecules, the activated Vγ9Vδ2 T cells are designed to rapidly kill tumor target cells and have the potential for:

- *Expansion.* The Vγ9Vδ2 T cells proliferate, resulting in an increased number of anti-tumor Vγ9Vδ2 T cells.
- *Broad immune activation.* The Vγ9Vδ2 T cells trigger the activation and antitumor activity of other immune cells, such as NK cells, alpha-beta T cells and dendritic cells.
- *Antigen presentation.* The Vγ9Vδ2 T cells process and present tumor antigens and acquire dendritic cell-like antigen presenting functions to trigger the development of "classical" naïve $CD4^+$ and $CD8^+$ alpha-beta Tcell responses against the tumor.

We believe that this cascade of events may enhance potency and lead to a more durable immune response.

Our clinical data are consistent with the mechanism of action seen in preclinical studies. We have demonstrated occupancy of the Vγ9Vδ2 TCR, as well as activation of Vγ9Vδ2 T cells as demonstrated by CD25 and CD69 expression.

Preclinical support for our mechanism of action and safety

We believe that our Gammabody platform possesses features that have the potential to address several shortcomings of current TCE approaches for cancer. We have conducted multiple preclinical experiments where our Gammabody molecules have shown potent, selective, sustained and serial killing of tumor cells. *In vivo* preclinical animal models and in *ex vivo* models using patient tumor and Vγ9Vδ2 T cells have shown anti-tumor activity. Our preclinical experiments have also shown that activation of the Vγ9Vδ2 T cell population is conditional upon Gammabody crosslinking.

Our non-human primates (NHPs) studies show surrogate Gammabody molecules to be safe and well-tolerated. NHP studies were performed in cynomolgus monkeys with fully cross-reactive surrogate Gammabody molecules. The bispecific $\gamma\delta$ TCEs used were designed to trigger human and monkey $\gamma\delta$ T cells with similar potency. Administration of the cross-reactive surrogate Gammabody led to high sustained plasma levels and dose-dependent accumulation in relevant tissues with no safety-related effects and no signs of high-grade CRS.

In the ongoing LAVA-1207 clinical trial, the overall rate of CRS has been low to date with no CRS events >grade 2. To maintain low rates of CRS and to minimize the risk of events >grade 2 we have introduced premedication and step-dosing to the protocol.

License agreements

Pfizer Agreement

In 2022, we entered into the Pfizer Agreement to develop, manufacture and commercialize EGFRd2 (PF-8046052/formerly LAVA-1223), an advanced preclinical asset that utilizes our proprietary Gammabody® technology to target EGFR-expressing solid tumors. Under the terms of the Pfizer Agreement, we received a $50 million nonrefundable upfront payment in October 2022, and are eligible to receive up to approximately $650 million upon the achievement of development, regulatory and commercial milestones, as well as royalties ranging from high single digits to the mid-teens on future sales.

Pfizer has also granted us a one-time option to obtain increased royalties if we exercise a buy-up option within a certain amount of time from certain key early clinical data becoming available for the first licensed product. We have a defined period after notice of such buy-up option to pay Pfizer a one-time $35 million fee (buy-up fee). In the event we exercise the buy-up option and pay the buy-up fee, we are entitled to receive tiered royalties based on commercial sales levels from low double-digit to high double-digit percentages of net sales of licensed products.

The Pfizer Agreement expires on a licensed product-by-licensed product and country-by-country basis upon the expiration of Pfizer's payment obligations. Pfizer may terminate the Pfizer Agreement in its entirety or on a country-by-country basis for convenience following a certain notice period. Either party may terminate the Pfizer Agreement upon an uncured material breach of the agreement or insolvency of the other party following a certain notice period. Depending on the reason and stage of termination, we have certain rights to obtain a license to certain intellectual property generated by Pfizer under the Pfizer Agreement for purposes of continued development and commercialization of research results and/or product candidates developed under the Pfizer Agreement.

In January 2023, we entered into a Clinical Supply Agreement with Seagen (acquired by Pfizer in December 2023) (Pfizer Clinical Supply Agreement). Under the Pfizer Clinical Supply Agreement, we had supply of the compound EGFRd2 (PF-8046052) manufactured and supplied to Pfizer. At Pfizer's request, we will also deliver to Pfizer any remaining GMP substance containing the EGFRd2 (PF-8046052) compound. Under the Pfizer Agreement and the Pfizer Clinical Supply Agreement, we are eligible to receive reimbursement of up to $6.5 million for certain agreed-to research, manufacturing and supply activities, as well as the transfer of all manufacturing-related know-how and materials to enable the manufacture of EGFRd2 (PF-8046052) compound by or for Pfizer. During 2023, all supply of EGFRd2 (PF-8046052) was shipped to Pfizer. Pfizer received investigational new drug application clearance for EGFRd2 (PF-8046052) in advanced solid tumors from the FDA in 2023 and during the third quarter Pfizer initiated a Phase 1 trial (NTC0598133) of EGFRd2 (PF-8046052) to evaluate the safety and tolerability of EGFRd2 (PF-8046052) as a monotherapy in advanced EGFR expressing solid tumors. In March 2024, Pfizer paid us $7 million for achieving a clinical development milestone.

Janssen Agreement

In May 2020, we entered into the Janssen Agreement for the discovery and development of novel bispecific antibody-based $\gamma\delta$ T cell engagers for the treatment of cancer. We received an upfront fee of $8.0 million and achieved research milestones necessary to receive $2.0 million, $1.0 million of which was received in October 2021, and $1.0 million of which was received in December 2020. Under the Janssen Agreement, we

granted Janssen an exclusive, sublicensable, worldwide license under certain of our patents, materials, and know-how, including certain rights assigned to us pursuant to the Amsterdam UMC Agreement, to exploit multi-specific antibody products which have variable domains specific to the licensed target or products which are directed to the licensed target, in all fields of use. We retain the right to use our technology to perform our obligations under the Janssen Agreement and for all purposes not granted to Janssen.

Together with Janssen, we conducted certain research and discovery activities pursuant to a mutually agreed research plan designed to develop licensed product candidates not later than the stage of candidate selection. In May 2023, within the framework of the Janssen Agreement, Janssen selected a lead bispecific antibody utilizing the Gammabody platform for an undisclosed tumor associated antigen for development and we received a financial milestone payment of $2.5 million. Pursuant to the Janssen Agreement, once this selection has been made, Janssen is responsible for the development, manufacture, and commercialization of the licensed product at Janssen's sole cost and expense. Janssen is required to use commercially reasonable efforts to exploit one licensed product. Efforts are underway by Janssen to advance the candidate towards the clinic. The payment of the $2.5 million milestone was received in July 2023. We are entitled to additional milestone payments from Janssen if the lead candidate progress through certain clinical and regulatory milestone. We are also eligible to receive up to an aggregate of $195 million upon the achievement of certain development and commercial milestones and tiered royalties based on commercial sales levels from low to mid-single digit percentages of net sales of licensed products for a fixed period beginning with the first commercial sale of such a licensed product in each country of sale and expiring ten years after such sale.

Until the earlier of termination of the Janssen Agreement and a specified period of time following the first commercial sale of a licensed product, we cannot directly or through a third-party research, develop or commercialize or exploit a competing biological product that is directed to or otherwise targets the licensed target, subject to certain exceptions and limitations for third-party acquiror products.

As a general rule, ownership of any inventions made by either party in the course of performing their respective activities pursuant to the Janssen Agreement will follow inventorship of such inventions, with certain defined exclusions. First, Janssen will own any invention made by either party in the course of performing their respective activities pursuant to the Janssen Agreement that is an improvement to Janssen's background technology, relates to an antibody directed to the licensed target, is a medical use or method of treatment or relates to a licensed product. Second, we will own any invention made by either party in the course of performing their respective activities pursuant to the Janssen Agreement that is an improvement to our background technology but that is not a licensed product or that is obtained from use of the specific antibody but not as part of a licensed product. We received from Janssen a non-exclusive, worldwide, non-royalty bearing, sublicensable license under certain know-how developed by Janssen under the Janssen Agreement, and patents claiming such know-how, for certain uses necessary to exploit the specific antibodies.

The Janssen Agreement expires on a licensed product-by-licensed product basis upon the expiration of Janssen's payment obligations. Janssen may terminate the Janssen Agreement in its entirety or on a country-by-country basis for convenience following a certain notice period, or in its entirety within a defined timeframe following our change of control. Either party may terminate the Janssen Agreement upon an uncured material breach of the agreement or insolvency of the other party following a certain notice period. Following each research stage, the Janssen Agreement will automatically terminate if the parties decide not to proceed with the subsequent research stage or, following the completion of all research stages, if Janssen decides not to bring a candidate forward into further development. Depending on the reason and stage of termination, we have certain rights to receive a license to certain intellectual property generated by Janssen under the Janssen Agreement for purposes of continued development and commercialization of research results and/or product candidates developed under the Janssen Agreement.

Amsterdam UMC agreements

In 2017, we entered into the Amsterdam UMC Agreement. Under the Amsterdam UMC Agreement, Amsterdam UMC (formerly VUmc prior to its merger with AMC effective January 2024) granted us an exclusive, although non-exclusive with respect to certain intangible know-how, worldwide, sublicensable license under certain patent rights and know-how owned by Amsterdam UMC, effectively including research

and other services provided in collaboration by Amsterdam UMC since 2017 to develop, make, and sell licensed products. In 2021, Amsterdam UMC assigned all of the patent rights previously licensed by us under the Amsterdam UMC Agreement for no additional consideration paid. Amsterdam UMC retains the right to use the patent rights and know-how for solely non-commercial research and educational purposes, but it may not conduct such work with respect to any product that is directed to a specified target for a specified time period.

Following the assignment of such patent rights, we remain obligated to pay Amsterdam UMC sub to low single-digit tiered royalties on net sales of products covered by claims included in the assigned patent rights. Royalties are payable on a country-by-country basis for a royalty term that expires upon the expiration of the last valid claim in the assigned patent rights in such country that would be infringed by the use, manufacture, or sale of a product in such country in the absence of us having rights to such patent right. In connection with our IPO, we issued to Amsterdam UMC 235,664 of our common shares and paid $0.3 million in cash. On each of the first and second anniversary of our IPO, we paid $4.7 million in cash or common shares, at our election, valued using the closing price of common shares on the date two trading days prior to the respective anniversary of our IPO. In 2022, we issued 491,352 common shares to Amsterdam UMC representing 50% of the payable in accordance with the Amsterdam UMC Agreement for the first anniversary payment. The final payment of $4.7 million was due on the second anniversary of our IPO in March 2023 and paid in cash in May 2023. We continue to collaborate with Amsterdam UMC and Amsterdam UMC makes available certain employees to us who perform research and other activities for our benefit.

The continuing obligations under the Amsterdam UMC Agreement, including our obligation to pay royalties, expires on a country-by-country basis upon the expiration of the last to expire valid claim of the assigned patents in such country. Following the expiration of our royalty obligations as to an assigned product in a country, we will retain title to the assigned patent rights and will no longer be obligated to pay royalties for such products. We control the prosecution and maintenance of the patent rights. Unless sooner terminated, the term of the license continues until the expiration of the last to expire of the patent rights, the latest of which is currently expected to expire in 2036.

In 2021, we entered into a master research services agreement with Amsterdam UMC under which Amsterdam UMC performs certain clinical research services and preclinical development for us under the direction of our Chief Scientific Officer. Under this Amsterdam UMC master research services agreement, we own all rights, title, ownership and interest in and to any inventions made, created or prepared by Amsterdam UMC. This agreement automatically terminates in the case of our bankruptcy. Either party may terminate this agreement upon 60 days' written notice for any reason or upon 60 days' written notice upon uncured material breaches of the terms of the Amsterdam UMC master research services agreement.

Merck & Co., Inc.

In January 2024, we announced we had entered into a clinical trial collaboration and supply agreement with Merck & Co., Inc. to evaluate its anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in combination with LAVA-1207. Under the terms of this agreement, we will be provided with pembrolizumab for the dose escalation and expansion phases of our ongoing Phase 1/2a study of LAVA-1207 (NCT05369000) (KEYNOTE-F73), with the combination arm expected to be initiated in the first half of 2024. Enrollment and dose escalation will also continue in the LAVA-1207 monotherapy and interleukin-2 arms of the study. Other than providing pembrolizumab to us for our ongoing LAVA 1207 1/2a study, the collaboration with Merck & Co., Inc does not have any financial impact on us.

Manufacturing, sales and marketing

Given the stage of our lead program, we will build our global commercial, medical affairs, distribution and manufacturing infrastructure, alone or with potential future partners over time for our lead clinical candidate. We do not own or operate manufacturing facilities to produce our clinical candidate, and we rely on third-party contract manufacturers for all of our required raw materials, manufacturing devices, active pharmaceutical ingredients and finished product for our preclinical research and clinical trials. The prices of our primary raw materials have not historically been volatile.

Our Strategy

We are a clinical stage immuno-oncology company focused on developing our proprietary Gammabody® platform of bispecific gamma delta (γδ) T cell engagers to transform the treatment of cancer. Using our Gammabody platform, we are developing a portfolio of novel bispecific antibodies designed to engage and leverage the potency and precision of γδ T cells to orchestrate a robust anti-tumor immune response and improve outcomes for cancer patients. We are focused on discovering, developing and ultimately commercializing proprietary, off-the-shelf, targeted Gammabody drug candidates that leverage the power of γδ T cells with the validated benefits of antibody-based treatments. Key components of our strategy include:

- Establish ourselves as the leader in developing bispecific γδ T cell engagers (TCEs) utilizing the Gammabody platform for the treatment of cancer.
- Rapidly accelerate the clinical development of our lead candidate, LAVA-1207, to support proof-of-concept and other enabling activities for our investigational candidates.
- Achieve competitive excellence by leveraging the transformational potential of our platform to advance and expand our early stage pipeline while broadening the platform's applications to additional targets and patient populations.
- Enhance our pipeline and platform through strategic partnership and collaboration opportunities.
- Leverage and continue to build our intellectual property portfolio to protect our Gammabody platform and our leadership position in bispecific γδ TCEs.

Competition

The biotechnology industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property and proprietary rights. We believe that our proprietary Gammabody platform and our product candidates, strategic collaboration and scientific and clinical expertise may provide us with competitive advantages. Any product candidates that we successfully develop and commercialize will have to compete with existing therapies and new therapies that may become available in the future. We also face potential competition from a variety of companies in the γδ T cell field.

Our competitors in the field of γδ T cell therapy include Adicet Bio, Inc., Clade Therapeutics, Editas Medicine, Inc., Eureka Therapeutics, Inc., Takeda Pharmaceutical Company Ltd, ImCheck Therapeutics SAS, Immatics N.V., IN8bio, Inc., Leucid Bio Ltd, PhosphoGam Inc., Shattuck Labs Inc., Sandhill Therapeutics, Inc, and TC BioPharm Limited. Our bispecific γδ T cell product candidates may also compete with other T cell engaging therapies as well as NK cell-engaging therapies.

In addition, many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials and delivering approved products than we do today. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also be significant competitors, particularly through collaborative arrangements with large and established companies. We also compete with these companies in recruiting, hiring and retaining qualified scientific and management talent, establishing clinical trial sites and patient registration for clinical trials, obtaining manufacturing slots at contract manufacturing organizations, and in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective (particularly if they represent cures), have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be their efficacy, safety, method of administration and availability of reimbursement.

Intellectual property

Overview

We actively seek to protect our proprietary technology, inventions, improvements to inventions and other intellectual property that is commercially important to the development of our business by a variety of means, such as seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. We also may rely on trade secrets and know-how relating to our proprietary technology platform, on continuing technological innovation and on future in-licensing opportunities to develop, strengthen and maintain the strength of our position in the field of biotechnology that may be important for the development of our business. Additional regulatory protection may also be afforded through data exclusivity, market exclusivity and patent term extensions where available.

We have developed or exclusively in-licensed numerous patent and patent applications, know-how and trade secrets relating to the development and commercialization of our product candidates and the underlying Gammabody platform. We currently own or in-license: four (4) issued U.S. patents, twenty (20) pending U.S. patent applications, thirteen (13) pending European regional-phase patent applications, six (6) pending PCT patent application, twenty (20) issued patents in other territories and eighty (80) pending patent applications in other territories that are important to the development of our business.

Our strategic initiative is to protect proprietary technology, inventions and improvements to inventions and other intellectual property that may be commercially important to the development of our business. We also intend to seek additional patent protection or rely upon trade secret rights to protect other technologies that may be used to manufacture and develop our $\gamma\delta$ T cell products. We are a party to license and assignment agreements that grant us exclusive rights to use specific technologies in our $\gamma\delta$ T cell products and in the manufacturing and development of our products. For more information, see *"Intellectual Property."*

Our future commercial success depends, in part, on our ability to: obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents; preserve the confidentiality of our trade secrets; and operate without infringing the valid enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our products may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. With respect to both our owned and licensed intellectual property, we cannot be sure that patents will issue with respect to any of the pending patent applications to which we license rights or with respect to any patent applications that we or our licensors may file in the future, nor can we be sure that any of our licensed patents or any patents that may be issued in the future to us or our licensors will be commercially useful in protecting our product candidates and methods of manufacturing the same.

Our patent portfolio

As of December 31, 2023, our patent portfolio included U.S. and foreign patents and patent applications. The patents and patent applications in our patent portfolio cover technology used in our own development programs, as well as technology used in our collaborations. We have granted Pfizer an exclusive worldwide license for the development and commercialization of EGFRd2 (PF-8046052/formerly LAVA-1223), an advanced preclinical asset that utilizes LAVA's proprietary Gammabody technology to target epidermal growth factor receptor (EGFR)-expressing solid tumors. We have granted Janssen an exclusive worldwide license for the development and commercialization of a confidential product candidate.

The issued patents and patent applications directed to our most advanced programs are summarized below:

LAVA-1207

For LAVA-1207, LAVA's patent portfolio includes six (6) pending U.S. patent applications, one (1) pending European patent applications, thirteen (13) pending foreign patent applications containing claims or supporting disclosures directed to the LAVA-1207 composition of matter and to methods of treating diseases

of interest using LAVA-1207. This issued patent and patents issuing from these pending patent applications, if any, are expected to expire between 2041 and 2044, excluding any potential patent term extensions or patent term adjustments.

LAVA-1266

For LAVA-1266, LAVA's patent portfolio includes one (1) pending U.S. patent applications, one (1) pending European patent applications, fourteen (14) pending foreign applications containing claims or supporting disclosures directed to the LAVA-1266 lead composition of matter and to methods of treating diseases of interest using LAVA-1266 is issued patent and patents issuing from these pending patent applications, if any, are expected to expire in 2042, excluding any potential patent term extensions or patent term adjustments.

We believe our manufacturing and assay development patents, patent applications and related know-how may provide us with additional intellectual property protection relating to LAVA-1207, LAVA-1266 and preclinical candidates.

Platform Technology

Our patent portfolio also includes patent families relating to our Gammabody platform, including eight (8) patent families that are generally related to the antibodies that activate $\gamma\delta$ T cells, dosing of such antibodies, uses of such antibodies for certain patient groups, and combination of such antibodies with additional therapeutic agents. For the platform technology, LAVA's portfolio includes two (2) granted U.S. patents, seven (7) pending U.S. applications, three (3) pending European applications, eleven (11) granted foreign patents, nine (9) pending foreign applications, and three (3) pending PCT applications.

Patent term and term extensions

The term of a patent, and the protection it affords, is limited. Individual patents have terms for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the United States are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application. However, as to the extension associated with FDA approval, the extension cannot be longer than five years and cannot extend the patent term beyond 14 years from the date of FDA approval. In addition, only one patent applicable to an FDA-approved drug or biologic is eligible for the extension, and only those claims covering the approved drug, a method for using it, or a method of manufacturing may be extended. The terms of foreign patents vary in accordance with provisions of applicable local law, but typically are also 20 years from the earliest effective filing date and similar provisions are available in certain foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if our product candidates receive FDA approval, we expect to apply for patent term extensions where applicable on patents covering those products.

We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available. However, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether these extensions should be granted, and if granted, the length of these extensions. All taxes, annuities or maintenance fees for a patent, as required by the USPTO and various foreign jurisdictions, must be timely paid in order for the patent to remain in force for the full term.

Our patents and patent applications may be subject to procedural or legal challenges by others. We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and we may be subject to claims that we infringe, misappropriate or otherwise violate the intellectual property rights of others, which could materially harm our business. For more information, see the section titled "Risk Factors—Risks Related to Our Intellectual Property."

Trade secrets and know-how

We also rely on trade secrets, know-how, continuing technological innovation and confidentiality agreements to develop and maintain our proprietary position and protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, including our proprietary processes for

expanding and activating therapeutic quantities of γδ T cells and modified γδ T cells. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and others who may have access to proprietary information, under which they are bound to keep all confidential information concerning our business or financial affairs developed by or made known to them during the course of the party's relationship with us confidential and not disclose such information to third parties except in specific circumstances, and in certain cases, to assign to us inventions made during the term of their employment or service. However, trade secrets can be difficult to protect. We cannot guarantee that we have entered into confidentiality agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes or that these agreements will afford us adequate protection of our intellectual property and proprietary rights. These agreements and policies may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets or substantially equivalent proprietary information and techniques may otherwise become known or be independently discovered by competitors. To the extent that our contractors, commercial partners, collaborators, employees or consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in the resulting know-how and inventions. For more information, see the section titled "Risk Factors—Risks Related to Our Intellectual Property."

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining the physical security of our premises and the physical and electronic security of our information technology systems.

Government regulation

The FDA, the European Medicines Agency (EMA) and other regulatory authorities at U.S. federal, state, and local levels, and national competent authorities in EU member states and in other foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post- approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the applicable preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct clinical studies or seek marketing approval or licensure status of current and future product candidates.

The process required by regulatory authorities, including the FDA and EMA, before biologic product candidates may be marketed in the United States and EU generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA and EMA current Good Laboratory Practices regulation and directive 2004/10/EC of the European Parliament and of the Council;
- submission to the FDA of an IND, or of a CTA to the EMA, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent IRB or ethics committee at each treatment site before the clinical trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety and effectiveness, and adequate controls for the purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA or a Marketing Authorization Application (MAA) to the EMA after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;

- satisfactory completion of a pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practices, or GCP; and
- Regulatory review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States or EU.

Preclinical and clinical development

Before testing any biologic product candidate in humans, the product candidate must undergo preclinical testing. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as *in vivo* studies to assess the potential safety and activity of the product candidate.

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA and a CTA to the EMA for trials conducted in the United States and European Union, respectively. An IND and CTA are requests for authorization to administer an investigational new drug product to humans. The central focus of an IND or a CTA submission is on the general investigational plan and the protocol(s) for clinical studies. The IND or a CTA also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND or a CTA must be cleared or approved before human clinical trials may begin.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments.

Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated checkpoints based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of regulatory approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for

safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to regulatory agencies.

Post-approval clinical trials, sometimes referred to as Phase 4 studies may be made a condition to approval of the BLA or MAA.

Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Compliance with cGMP requirements

Manufacturers of biologics must comply with applicable cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Manufacturers and others involved in the manufacture and distribution of such products also must register their establishments with FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to FDA upon their initial participation in the manufacturing process. Establishments may be subject to periodic, unannounced inspections by government authorities to ensure compliance with cGMP requirements and other laws.

Regulatory submission and review in the United States and Europe

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the regulatory authorities (FDA as part of a BLA and/or EMA for MAA, each an Application) requesting approval to market the product for one or more indications. The Application must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things.

In the United States, the Application typically requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies, and the sponsor of an approved BLA is also subject to an annual program fee. The process governing approval of medicinal products in the European Union generally follows the same lines as in the United States.

In the United States, for products considered new molecular entities, once a BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process can be significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional

testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for the approved indication(s). A Complete Response letter will describe all the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for certain indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace.

In the EU, the centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states as well as in the European Economic Area countries Iceland, Liechtenstein and Norway. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer and auto-immune diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which the centralized procedure is in the interest of public health, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting the assessment of a product to define its risk/benefit profile. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and therapeutic innovation. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

Expedited development and review programs in the United States

FDA is authorized to expedite the review of BLAs in several ways. Under the fast-track program, a sponsor may request FDA to designate the product as a fast-track product if the product is intended to treat a serious or life-threatening condition and demonstrates the potential to address unmet medical needs. Fast-track designation has opportunities for frequent interactions with the review team during product development and, once a BLA is submitted, the product may be eligible for priority review. A fast-track product may also be eligible for rolling review, where the FDA may review sections of the BLA on a rolling basis before the complete application is submitted. If the sponsor provides a schedule for the submission of the sections of the BLA, the FDA may agree to accept sections of the BLA and determine that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all the fast-

track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a fast-track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For products containing new molecular entities, priority review designation means the FDA's goal is to act on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may be eligible to receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. In these circumstances, confirmatory trials intended to confirm the effect on the endpoint must be well underway at the time of BLA submission.

Certain products that qualify as a regenerative medicine therapy may also be eligible for Regenerative Medicine Advanced Therapy, or RMAT. Like breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval based on a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites.

Fast track designation, breakthrough therapy designation, priority review, accelerated approval, and RMAT designation do not change the standards for approval but may expedite the development or approval process.

Orphan drug designation in the U.S. and Europe

In the U.S., under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product may receive orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

In the EU, Regulation (EC) No. 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or

(2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment.

An Orphan Drug Designation provides many benefits, including fee reductions, regulatory assistance and the possibility to apply for a centralized European Union marketing authorization. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for Orphan Drug Designation because, for example, the product is sufficiently profitable not to justify market exclusivity.

Post-approval requirements in the U.S. and Europe

In the United States. Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters,

corrective advertising and potential civil and criminal penalties. The FDA does, however, restrict manufacturer's communications about off-label use of their products.

In Europe. Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's GMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union under Directive 2001/83EC, as amended.

Biosimilars and reference product exclusivity

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years based on a reevaluation of the risk benefit balance by the EMA or by the competent authority of the authorizing member state. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides on justified grounds relating to pharmacovigilance to proceed with one additional five-year renewal period.

Other healthcare laws and compliance requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services (such as the Office of Inspector General and the Health Resources and Service Administration), the Department of Justice, or the DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, research, sales, marketing activities and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, transparency laws, the health information privacy and security laws, similar state laws, and regulations, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service for which payment may be made, in whole or in part, under Medicare, Medicaid or other federal healthcare programs.

The federal false claims laws, including the FCA, which can be enforced by private citizens through civil qui tam actions and civil monetary penalty laws prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, federal healthcare programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, also impose requirements relating to the privacy, security and transmission of individually identifiable health information on certain healthcare providers, healthcare clearinghouses, and health plans, known as covered entities, and independent contractors, or agents of covered entities that receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity, known as a business associates, as well as their covered subcontractors.

In Europe, we are subject to Regulation (EU) 2016/679, the General Data Protection Regulation, or GDPR, in relation to our collection, control, processing and other use of personal data. The GDPR is directly applicable in each European Union Member State, however, it provides that European Member States may introduce further conditions, including limitations which could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase, ultimately having an adverse impact on our business. These changes may lead to additional compliance costs and could increase our overall risk.

We are also subject to European Union rules with respect to cross-border transfers of personal data out of the European Union and European Economic Area (EEA). Recent developments in the EU have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographic location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, and to report annually certain ownership and investment interests held by physicians and their immediate family members. In addition, many states and foreign jurisdictions have enacted analogous versions of these laws.

Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to us, we may be subject

to significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Additionally, if any of the physicians or other providers or entities with whom we expect to do business are found not to comply with applicable laws, they may be subject to significant civil, criminal and administrative sanctions, including exclusion from government funded healthcare programs.

Coverage, pricing and reimbursement

In the United States and in foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. Coverage and reimbursement by a third-party payor may depend upon several factors, including the third-party payor's determination that use of a therapeutic is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Obtaining coverage and reimbursement approval of a product from a third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Obtaining reimbursement for our product candidate may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. Limited coverage and less than adequate reimbursement may reduce the demand for, or the price of, any product for which we obtain regulatory approval. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Additionally, in the United States there is no uniform policy among third-party payors for coverage or reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop. Further, we or our collaborators may develop companion diagnostic tests for use with our product candidates. We or our collaborators will be required to obtain coverage and reimbursement for these separate and apart from the coverage and reimbursement we seek for our other product candidates, once approved.

In the European Union, pricing and reimbursement schemes vary widely from country to country. The downward pressure on healthcare costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations may not allow favorable reimbursement and pricing arrangements.

Healthcare reform

In the United States and some foreign jurisdictions, there have been, and continue to be, legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policymakers and payors

in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the ACA and its implementing regulations substantially changed healthcare financing and delivery by both governmental and private insurers. The ACA, among other things, increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer point-of-sale discounts (increased to 70 percent, effective as of January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected expanded the types of entities eligible for the 340B drug discount program; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been executive, judicial and Congressional challenges to the ACA. Most of the ACA survived such challenges but further healthcare reform measures of the Biden administration may impact the ACA or our business. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive.

Other legislative changes have been adopted since the ACA was enacted. These changes include, among other things aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA, which will remain in effect through 2030, unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, in the United States there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. For example, the Biden administration has announced its intention to pursue certain priority policy initiatives, such as the reduction of prescription drug pricing, including legislative proposals to allow the government to negotiate drug prices for Medicare and other governmental health programs, increasing access and coverage for mental health, and lower nursing home care costs. In addition, the IRA, among other things, (i) directs the U.S. Department of Health and Human Services, or HHS, to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation.

The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare

drug price negotiation program is currently subject to legal challenges. It is unclear how the IRA will be implemented but it is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs using march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. Further, any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

The Foreign Corrupt Practices Act

The FCPA prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional regulation

In addition to the foregoing, state and federal U.S. and European Union laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices and fire hazard control. We may incur significant costs to comply with such laws and regulations now or in the future.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies, and the sponsor of an approved BLA is also subject to an annual program fee.

Once a BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the

product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more treatment sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for certain indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace.

Expedited development and review programs

FDA is authorized to expedite the review of BLAs in several ways. Under the fast-track program, a sponsor may request FDA to designate the product as a fast-track product if the product is intended to treat a serious or life-threatening condition and demonstrates the potential to address unmet medical needs. Fast-track designation has opportunities for frequent interactions with the review team during product development and, once a BLA is submitted, the product may be eligible for priority review. A fast-track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all the fast-track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a fast-track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For products containing new molecular entities, priority review designation means the FDA’s goal is to act on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on

irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

Regenerative medicine advanced therapy, or RMAT, designation like breakthrough therapy designation, provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval based on a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites.

Fast track designation, breakthrough therapy designation, priority review, accelerated approval, and RMAT designation do not change the standards for approval but may expedite the development or approval process.

Orphan drug designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Post-approval requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks;

or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and reference product exclusivity

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, several biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

Regulation and Procedures Governing Approval of Medicinal Products in the European Union

The process governing approval of medicinal products in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, nonclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication. It also requires the submission to relevant competent authorities for clinical trials authorization and to the EMA or to competent authorities in European Union Member States for a marketing authorization application, or MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union.

Clinical Trial Approval

Until December 2021, clinical trials in the European Union were approved under the Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC through national legislation of the member states. Under this system, an applicant obtained approval from the competent national authority of a European Union member state in which the clinical trial would be conducted or in multiple member states if the clinical trial was to be conducted in several member states. Additionally, the applicant could only start a clinical trial at a specific study site after the independent ethics committee has issued a favorable opinion. The CTA would be accompanied by an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the member states and further detailed in applicable guidance documents.

In December 2021, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which replaced the current Clinical Trials Directive 2001/20/EC. It overhauled the current system of approvals for clinical trials in the European Union. Specifically, the new regulation is directly applicable in all member states and aims at simplifying and streamlining the approval of clinical trials in the European Union. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single-entry point and strictly defined deadlines for the assessment of clinical trial applications.

In January 2022, Clinical Trials Directive (EC) No. 2001/20/EC and its national implementing legislation in the EU Member States was repealed and the New Clinical Trials Regulation became effective. The new Clinical Trials Regulation enables sponsors to submit one online application via a single online platform known as the Clinical Trials Information System (CTIS) for approval to run a clinical trial in several European countries, making it more efficient to carry out such multinational trials. The Regulation also makes it more efficient for EU Member States to evaluate and authorize such applications together, via the Clinical Trials Information System.

For the first year of implementation, until January 30, 2023, clinical trial sponsors could select whether to apply to start a clinical trial under the new Clinical Trials Regulations. After January 2023, clinical trial sponsors need to apply to start a clinical trial under the new Clinical Trials Regulations.

Orphan Drug Designation and Exclusivity

Regulation (EC) No. 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment.

An Orphan Drug Designation provides many benefits, including fee reductions, regulatory assistance and the possibility to apply for a centralized European Union marketing authorization. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for Orphan Drug Designation because, for example, the product is sufficiently profitable not to justify market exclusivity.

Marketing Authorization

To obtain a marketing authorization for a product under the European Union regulatory system, an applicant must submit an MAA, either to EMA using the centralized procedure or to competent authorities in European Union Member States using the other procedures (decentralized procedure, national procedure, or mutual recognition procedure).

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states as well as in the European Economic Area countries Iceland, Liechtenstein and Norway. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological

processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer and auto-immune diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which the centralized procedure is in the interest of public health, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting the assessment of a product to define its risk/benefit profile. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and therapeutic innovation. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years based on a reevaluation of the risk benefit balance by the EMA or by the competent authority of the authorizing member state. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides on justified grounds relating to pharmacovigilance to proceed with one additional five-year renewal period.

Regulatory Requirements after Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's GMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union under Directive 2001/83EC, as amended.

Other healthcare laws and compliance requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services (such as the Office of Inspector General and the Health Resources and Service Administration), the Department of Justice, or the DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, research, sales, marketing activities and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, transparency laws, the health information privacy and security laws, similar state laws, and regulations, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service for which payment may be made, in whole or in part, under Medicare, Medicaid or other federal healthcare programs.

The federal false claims laws, including the FCA, which can be enforced by private citizens through civil qui tam actions and civil monetary penalty laws prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, federal healthcare programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information on certain healthcare providers, healthcare clearinghouses, and health plans, known as covered entities, and independent contractors, or agents of covered entities that receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity, known as a business associates, as well as their covered subcontractors. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions.

In Europe, we are subject to Regulation (EU) 2016/679, the General Data Protection Regulation, or GDPR, in relation to our collection, control, processing and other use of personal data. The GDPR is directly applicable in each European Union Member State, however, it provides that European Member States may introduce further conditions, including limitations which could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase, ultimately having an adverse impact on our business. These changes may lead to additional compliance costs and could increase our overall risk.

We are also subject to European Union rules with respect to cross-border transfers of personal data out of the European Union and European Economic Area (EEA). Recent developments in the EU have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographic location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, and to report annually certain ownership and investment interests held by physicians and their immediate family members.

In addition, many states and foreign jurisdictions have enacted analogous versions of these laws.

Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to us, we may be subject to significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of

operations. Additionally, if any of the physicians or other providers or entities with whom we expect to do business are found not to comply with applicable laws, they may be subject to significant civil, criminal and administrative sanctions, including exclusion from government funded healthcare programs.

Coverage, pricing and reimbursement

In the United States and in foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. Coverage and reimbursement by a third-party payor may depend upon several factors, including the third-party payor's determination that use of a therapeutic is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Obtaining coverage and reimbursement approval of a product from a third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. Limited coverage and less than adequate reimbursement may reduce the demand for, or the price of, any product for which we obtain regulatory approval. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Additionally, in the United States there is no uniform policy among third-party payors for coverage or reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop. Further, we or our collaborators may develop companion diagnostic tests for use with our product candidates. We or our collaborators will be required to obtain coverage and reimbursement for these separate and apart from the coverage and reimbursement we seek for our other product candidates, once approved.

Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs), such as our product candidates, once approved, may be eligible for coverage under Medicare Part B. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs or biologicals, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program.

In the European Union, pricing and reimbursement schemes vary widely from country to country. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations may not allow favorable reimbursement and pricing arrangements.

Healthcare reform

In the United States and some foreign jurisdictions, there have been, and continue to be, legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to

profitably sell product candidates for which marketing approval is obtained. Among policymakers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the ACA and its implementing regulations substantially changed healthcare financing and delivery by both governmental and private insurers. Among the ACA provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- an annual, nondeductible fee on any entity meeting certain aggregated sales thresholds that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13%, both subject to an inflationary component, of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts (in addition to 5% discounts paid by Part D plans) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability for brand and generic drugs to individuals who are enrolled in Medicaid managed care plans, in addition to drugs purchased under fee-for-service Medicaid plans;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to expand Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 138% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability. To date, 38 states and Washington, DC have expanded Medicaid;
- a requirement for health plans to publish rates related to prescription drugs;
- expansion of the entities eligible for discounts under the 340B Drug Discount Program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- a requirement to annually report certain information regarding provision of any payment or item of value that applicable manufacturers provide to physicians or other covered recipients;
- establishment of a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- an FDA licensure framework for follow on biologic products.

Since its enactment, there have been executive, judicial and Congressional challenges to the ACA. Most of the ACA survived such challenges but further healthcare reform measures of the Biden administration may impact the ACA or our business. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary

maximum out-of-pocket cost and creating a new manufacturer discount program. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive.

Other legislative changes have been adopted since the ACA was enacted. These changes include, among other things aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA, which will remain in effect through 2030, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, in the United States there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. For example, the Biden administration has announced its intention to pursue certain priority policy initiatives, such as the reduction of prescription drug pricing, including legislative proposals to allow the government to negotiate drug prices for Medicare and other governmental health programs, increasing access and coverage for mental health, and lower nursing home care costs. In addition, the IRA, among other things, (i) directs the U.S. Department of Health and Human Services, or HHS, to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated “maximum fair price” for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation.

The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services. Further, any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

The Foreign Corrupt Practices Act

The FCPA prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional regulation

In addition to the foregoing, state and federal U.S. and European Union laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used

in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices and fire hazard control. We may incur significant costs to comply with such laws and regulations now or in the future.

Facilities

During the first quarter of 2023, we moved our headquarters from Yalelaan 60 to Yalelaan 62, 3584 CM Utrecht, the Netherlands. In August 2023, we notified the landlord that we would terminate a portion of the lease in the first quarter of 2024 such that we now occupy approximately 8,471 square feet of office and laboratory space under a lease that expires March 31, 2026. The lease of our previous headquarters at Yalelaan 60 expired and ended in the second quarter of 2023. We also occupy a small office space of approximately 5,621 square feet located at 520 Walnut Street, Suite 1150, Philadelphia, Pennsylvania 19106, U.S. until March 2025. We believe that our facilities are adequate to meet our current needs and that additional space can be obtained on commercially reasonable terms as needed.

2.3 Organizational structure

Lava Therapeutics N.V. has one wholly owned subsidiary, Lava Therapeutics Inc., which is incorporated in the United States of America in the State of Delaware.

2.4 Summary of key risk factors

Investing in our common shares involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this annual report, including our financial statements and the related notes and "Item 4: Operating and Financial Review and Prospects." The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. In such an event, the market price of our common shares could decline, and you may lose all or part of your investment.

Summary Risk Factors

Risks related to our financial position and capital needs

- We anticipate incurring substantial operating losses for the foreseeable future and may never achieve or maintain profitability.
- We have a limited operating history, which makes it difficult to assess our future viability.
- We will require substantial additional funding to finance our operations to complete the development and commence commercialization of our current and future product candidates. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our development programs and other operations.

Risks related to the development and commercialization of our current and future product candidates

- Our current and future product candidates, Gammabody® platform and related technologies are novel approaches to cancer treatment, which makes it difficult to predict the time and cost of development and subsequent regulatory approval.
- We are dependent on the successful clinical development, regulatory approval and commercialization of our current and future product candidates. Our product candidate could fail to demonstrate safety and efficacy at any stage of development, which could prevent or delay us from obtaining required regulatory approvals and commercializing our current and future product candidates.

- Success in preclinical studies or early-stage clinical trials may not be indicative of results in future clinical trials.
- We may be unable to expand our discovery and development pipeline, which could limit our growth and revenue potential.
- We have in the past, and in the future may enter into collaborations with third parties to conduct, supervise and monitor our preclinical studies and clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business and delay or impair our ability to obtain regulatory approval or otherwise commercialize our current and future product candidates.
- If we encounter difficulties in enrolling, qualifying or retaining patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Serious adverse events or undesirable or unexpected side effects of our current or future product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our current or future product candidates thereby limiting the commercial potential of such product candidate.
- Interim, “top-line” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.
- We face significant competition, and many of our competitors have substantially greater experience and resources than we have.

Risks related to manufacturing and reliance on third parties

- The manufacture of biotechnology products is complex, and manufacturers often encounter difficulties in production, which could negatively affect our ability to develop or commercialize our current and future product candidates.
- To date, we have relied on a single-source supplier for bulk drug substance and drug manufacturing for our product candidate and development programs. The loss of a single source supplier or its failure to supply us with bulk drug substance on a timely basis for our product candidate could impair our ability to develop our product candidate or otherwise delay the development process, which could adversely affect our business.
- We are dependent on third-party service providers to perform critical activities related to the research, development and manufacturing of our product candidate and development candidates. If these third-party service providers fail to perform, our clinical trial or development programs could be delayed with materially adverse effects on our business, financial condition, results of operations and prospects.

Risks related to our intellectual property

- If we are unable to obtain and maintain patent and other intellectual property protection for our current and future product candidates and technology, or if the scope of protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and technology may be adversely affected.
- Obtaining and maintaining our patent rights depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies and we may be unsuccessful in complying with such requirements.
- Patent terms may be inadequate to protect our competitive position on our current and future product candidates for an adequate amount of time.

- Even if we are successful in obtaining and maintaining robust intellectual property rights, such protections do not necessarily address all potential threats to the competitive advantages maintained by our business.

Risks related to our business operations, employee matters and managing growth

- Our business and operations may be adversely affected by global economic downturns, inflation, increases in interest rates, natural disasters, public health crises, political crises, geopolitical events, such as the Russian invasion of Ukraine, the Israel-Hamas war or other macroeconomic conditions, which could negatively impact our business and financial performance.
- If any of our collaborations terminate or if we or a collaborator materially breach our or its obligations, or if a collaboration does not progress due to manufacturing issues, clinical trial results or for other reasons, the development efforts of our Gammabody platform could be delayed or our reputation could be impacted or business, prospects, operating results, and financial conditions could be materially harmed.
- We may expand our organization, and we may experience difficulties in managing this growth. In addition, if we lose key management or other scientific or clinical personnel, or if we fail to recruit additional highly skilled personnel, our business, results of operations and financial condition could be adversely affected.
- There are risks inherent in our business that may subject us to potential product liability suits and other claims.
- If the security of the personal information that we or our third-party service providers collect, store or process is compromised, we may be exposed to liability and loss of business.
- We may be classified as a passive foreign investment company (PFIC) for United States (U.S.) federal income tax purposes, which could result in adverse U.S. federal income tax consequences to U.S. investors in our common shares.

Risks related to regulatory compliance

- The regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our current and future product candidates.
- Even if a product candidate receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community.

Risks related to ownership of our common shares

- The market price of our common shares has been and may continue to be volatile.
- Shareholders may not be able to exercise pre-emption rights and, as a result, may experience substantial dilution upon future issuances of common shares.

Risks related to financial reporting

- We have identified material weaknesses in our internal control over financial reporting. These material weaknesses could result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected.

2.5 Risk factors

2.5.1 Risks related to our financial position and capital needs

We are a clinical-stage immuno-oncology company and have incurred significant operating losses since inception. We anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.

We are a clinical-stage immuno-oncology company and have incurred significant operating losses since inception. Our net loss was $42.0 million and $31.9 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $148.1 million. To date, we have

recognized license and milestone revenues from our collaborators and may achieve additional milestones to be recognized over the next 12 months. We have not recorded any revenues from product sales. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future.

Since inception, we have devoted substantially all of our efforts to preclinical and clinical research and development of our product candidates and technology, organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting clinical trials. We have not obtained regulatory approval for, or commercialized, any product candidates and it could be several years, if ever, before we have a commercialized product. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- continue the ongoing and planned development of our product candidates, including LAVA-1207 and other early-stage development candidates;
- initiate, conduct and complete any ongoing, anticipated or future preclinical studies and clinical trials for our current and future product candidates;
- develop processes and scale manufacturing production for our current and future product candidates in accordance with current Good Manufacturing Practices (cGMP);
- seek regulatory and marketing approvals for LAVA-1207 and any of our other development candidates that successfully complete clinical trials;
- discover and develop additional bispecific gamma delta ($\gamma\delta$) engagers and make further investments in our Gammabody platform to identify additional product candidates;
- maintain, protect and expand our intellectual property portfolio, including incurring costs associated with opposing and invalidating competitor patents and licensing other technologies for our product candidates;
- establish a sales, marketing, manufacturing and distribution, supply chain and other commercial infrastructure in the future to commercialize any current or future product candidate for which we may obtain marketing approval;
- expand our operations in the U.S. and Europe;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- acquire or in-license additional product candidates and technologies;
- develop a potential companion diagnostic; and
- face general economic and market conditions and overall fluctuations in the United States and international equity markets, such as deteriorating conditions due to investor concerns regarding inflation and Russian invasion of Ukraine, the Israel-Hamas war and other geopolitical conditions.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. We may however never succeed in generating significant revenue and, even if we do, may never generate revenues that are sufficient to offset our expenses and achieve profitability.

Because of the numerous risks and uncertainties associated with product candidate development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform clinical trials or preclinical studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our current and future product candidates, our expenses could increase.

Moreover, even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our

company and could impair our ability to raise capital, maintain our research and development efforts, and expand our business or continue our operations.

Global economic uncertainty, changes in geopolitical conditions, changes in trade agreements and disputes and other macroeconomic factors and changes could adversely affect our operations and liquidity.

Our *operations* and performance are impacted by global, regional and U.S. economic and geopolitical conditions. General worldwide economic conditions have experienced significant instability in recent years, including due to recent global economic uncertainty and turbulent financial market conditions. Russia's ongoing military invasion of Ukraine has triggered significant sanctions from U.S. and European countries and disruptions to financial markets around the world. Resulting changes in U.S. trade policy could trigger retaliatory actions by Russia, its allies and other affected countries, including China, resulting in a "trade war." In addition, changes in political conditions in China and changes in the state of China-U.S. relations, including any tensions relating to potential military conflict between China and Taiwan, are difficult to predict and could adversely affect our business. Furthermore, if other countries, including the United States, become further involved in the conflict, we could face significant adverse effects to our business and financial condition.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, such as the collapse of Silicon Valley Bank in 2023, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems.

Our access to our cash and cash equivalents in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs of capital and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and cash equivalents could adversely impact our ability to meet our operating expenses, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts could have material adverse impacts on our operations and liquidity.

The above factors, including a number of other known and unknown economic and geopolitical factors in the United States and abroad, could ultimately have material adverse effects on our business, financial condition, results of operations and prospects.

Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.

Since inception, our operations to date have been limited to developing our Gammabody platform, financing and staffing our company, identifying and developing LAVA-1207 and other product candidates, business planning and providing general and administrative support to these operations. The Phase 1/2a clinical trial for our product candidate, LAVA-051 in chronic lymphocytic leukemia (CLL), multiple myeloma (MM) was discontinued in June 2023. Our solid tumor product candidate, LAVA-1207, is being evaluated in a Phase 1/2a clinical trial in metastatic castration-resistant prostate cancer (mCRPC). We have not yet, and may never, successfully complete a clinical trial, obtain marketing approval, manufacture commercial scale cGMP-product (including through a third party), or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing product candidates.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will eventually need to transition

from a company with a research and clinical focus to a company capable of supporting commercial activities, if any of our current and future product candidates are approved. We may not be successful in such a transition.

We will require substantial additional funding to finance our operations to complete the development and commence commercialization of our current and future product candidates. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the Phase 1/2a clinical trial for LAVA-1207, initiate later-stage clinical development, continue to research, develop and initiate clinical trials for other product candidates, considering in-licensing new programs and obtain and maintain intellectual property and other proprietary rights. In addition, if we obtain regulatory approval for any of our current or future product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution, as well as expenses related to any milestone and royalty payment.

Furthermore, our operations have consumed substantial amounts of cash since inception, and we expect our expenses to continue to increase in connection with the costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations and planned research and clinical development activities. Because the design and outcome of our ongoing and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. Although it is difficult to forecast all of our future liquidity requirements, based on our current research and development plans, we believe that our existing cash, cash equivalents and investments will be sufficient to fund our operations through at least the next 12 months. Moreover, we will need to obtain substantial additional funding in connection with our continuing operations and planned research and clinical development activities.

Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. Disruptions in the financial markets and other global events may make equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. If we are unable to obtain sufficient funding in a timely manner or on commercially acceptable terms, we may have to delay, reduce the scope of, or eliminate one or more of our development programs, and consider other cost reduction initiatives, such as downsizing our operations or suspending, curtailing, or withholding initiation or expansion of clinical trials or research. In addition, in the event we are not able to generate sufficient funds, we may be unable to continue as a going concern and our business, financial condition and/or results of operations could be materially and adversely affected which could result in a decrease in the price of our common shares and, ultimately, insolvency. In addition, any perceived or actual inability by us to finance our clinical development activities and other business activities may cause the market price of our common shares to decline.

We will need to raise additional capital, which may not be available on acceptable terms, or at all. Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our current and future product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We do not have any committed external source of funds. To the extent that we raise additional capital, if available, through the sale of equity or convertible debt securities, your ownership interest in our company may be diluted, and the terms of these securities may include liquidation

or other preferences that adversely affect the rights of our existing shareholders. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common shares to decline and existing shareholders may not agree with our financing plans or the terms of such financings. Adequate additional financing may not be available to us on acceptable terms, or at all.

If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us, if at all. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product candidate development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

Exchange rate fluctuations could negatively affect our financial condition.

Our consolidated financial statements are presented in U.S. dollars (USD). We operate via our Dutch and U.S. entities, but we also conduct business in Switzerland, Spain and Italy. Therefore, we have expenses denominated in USD, euros and Swiss francs in connection with, among other things, our sponsored clinical trials, purchase of drug product for our clinical trial, process development and the prosecution and maintenance of our intellectual property portfolio. As a result, our business and share price may be affected by fluctuations between the euro, the USD and the Swiss franc, which may have a significant impact on our reported results of operations and cash flows from period to period.

2.5.2 Risks related to the development and commercialization of our product candidates

Our product candidate, development candidates and related technologies, including LAVA-1207, which are based on bispecific $\gamma\delta$ T cell engagers, are novel approaches to cancer treatment, which makes it difficult to predict the time and cost of development and subsequent regulatory approval. Currently, there are no bispecific $\gamma\delta$ T cell engagers that have been approved for cancer treatment by the United States Food and Drug Administration (FDA) or European Medicines Agency (EMA).

We have concentrated our product candidates and research and development efforts on our Gammabody platform, which we believe represents a novel approach to cancer treatment. Our future success depends on our successful development of our bispecific $\gamma\delta$ T cell engager product candidates and related technology.

To date, $\gamma\delta$ T cells and products that induce $\gamma\delta$ T cell activation have only been evaluated in a limited number of early clinical trials. These clinical trials were primarily designed to evaluate safety and tolerability, and not designed to produce statistically significant results as to efficacy. Although prior clinical trials by other companies have shown early signs of $\gamma\delta$ T cell efficacy, and other clinical trials have produced encouraging results regarding bispecifics, our Phase 1/2a clinical trials for LAVA-051 and LAVA-1207, and our collaboration with Pfizer for EGFRd2 (PF-08046052/formerly LAVA-1223) are the only clinical trials conducted that utilize our Gammabody technology. Furthermore, we are exploring factors that may affect patients' response to treatment, including the potential impact of prior treatments and we may amend patient selection criteria based on the findings. We are continuing to study the relationship between antitumor activity in clinical trial patients and Vg9Vd2 T cell counts at baseline, and these evolving learnings may affect development of our product candidate and our platform. Even after the completion of our Phase 1/2a clinical trials for LAVA-1207, our Gammabody product candidates will have only been tested in a small number of patients. Results from these clinical trials may not be indicative of the safety and tolerability or efficacy of our product candidates as we expand into larger clinical trials.

There can be no assurance that we will not experience problems or delays in developing LAVA-1207 and additional development candidates, in particular, as a result of the limited number of prior studies and clinical

trials of γδ T cells, and that such problems or delays will not cause unanticipated costs, or that such development problems can be solved. Our Gammabody platform and LAVA-1207 product candidate are in early stages of development and may never be commercialized. Although we intend to leverage our experience with LAVA-051 and LAVA-1207 in our preclinical and clinical development of other product candidates, we may be unable to reduce development timelines or costs for our other Gammabody programs. For instance, we may encounter unforeseen problems and delays for current and future product candidates that are either or both specific to a product candidate or extend to multiple product candidates.

We may not ultimately be able to provide the regulatory authorities with clinical evidence to support a claim of safety, efficacy, purity, and potency sufficient to approve our Gammabody product candidates for any indication. This may occur for reasons such as early clinical trials do not meet their endpoints, later clinical trials fail to reproduce favorable data obtained in earlier clinical trials, the results of such trials are not statistically significant, or the FDA, EMA or other regulatory body disagrees with how we interpret the data from these clinical trials, or does not accept these therapeutic effects as valid endpoints in pivotal clinical trials necessary for market approval. Moreover, we will also need to demonstrate that our product candidates are safe. We have only recently begun to receive safety data on our clinical trials. We do not have data on possible harmful long-term effects of our Gammabody product candidates and do not expect to have this data in the near future. As a result, our ability to generate clinical safety and efficacy data sufficient to support submission of a marketing application or commercialization of our Gammabody product candidates is subject to significant uncertainty and risk.

Furthermore, actual or perceived safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of patients to participate in clinical trials, or if approved by applicable regulatory authorities, of physicians to subscribe to the novel treatment mechanics.

In particular, T cell engagers have been observed to cause safety issues, including cytokine release syndrome (CRS), which have, in certain cases, resulted in a delay or abandonment of those clinical programs. At present, only a few bispecific T cell engagers, including blinatumomab, are approved by the FDA. In our discontinued Phase 1/2a clinical trial of LAVA-051 we did not observe CRS greater than grade 2. In our ongoing Phase 1/2a clinical trial of LAVA-1207, we have observed low grade CRS (≤ grade 2) which affects the clinical protocol design of our global clinical trial and may affect potential future clinical trials in the United States and other jurisdictions. Because our product candidates and development programs are based on the same core Gammabody platform, if any of our product candidates encounter safety or efficacy problems, developmental delays or regulatory issues or other problems, these could impact the development plans for our other product candidates.

Also, competitors who are developing other bispecific γδ T cell engagers may experience problems with their product candidates that could identify problems with T cell engagers, which could potentially harm our ability to develop and commercialize our product candidates and harm our business. Our class of bispecific γδ T cell engagers could have, or be perceived to have, additional complications due to their unique mechanism of action (MoA). Consequently, we cannot be certain that our product candidates will be successful in clinical studies or that they will receive regulatory approval even if they are successful in clinical studies. If our current and future product candidates face such complications or other challenges that we are unable to satisfactorily resolve, our ability to commercialize and generate product revenue will be significantly and adversely affected.

We are dependent on the successful clinical development and regulatory approval of our product candidate and future product candidates. We cannot give any assurance that LAVA-1207 or any of our future product candidates will receive regulatory approval, and if we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, which will adversely affect our ability to generate product revenue.

We are in early-stage clinical development with one product candidate, LAVA-1207 and preclinical development for other potential product candidates. Our business is dependent on our ability to successfully complete development of, and obtain regulatory approval for, our product candidates in a timely manner. We may face unforeseen challenges in our product candidate development strategy, and we can provide no assurances that (i) our product candidates will prove to be effective, (ii) we will be able to take advantage of

abbreviated regulatory pathways for any of our product candidates or (iii) we will ultimately be successful in our ongoing and future clinical trials.

Our ability to generate product revenues, which we do not expect to occur for several years, if ever, will depend on the successful development and eventual commercialization of the product candidates we develop, which may never occur. All of our product candidates, and any future product candidates we develop, will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other jurisdictions, demonstrating cost effectiveness to pricing and reimbursement authorities in various jurisdictions, obtaining and securing sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization, and substantial investment and significant marketing efforts before we generate any revenues from any future product sales.

Our ability to successfully complete clinical development and obtain regulatory approval from the FDA, EMA or comparable regulatory authority for our product candidates will depend on several factors, including the following:

- successful and timely completion of our current clinical trials;
- initiation and successful patient enrollment and completion of additional clinical trials on a timely basis;
- receipt of safety, tolerability and efficacy profiles that are satisfactory to the FDA, EMA or any comparable regulatory authority for marketing approval;
- agreement by regulatory authorities with our interpretation of data from our preclinical studies or clinical trials;
- the adequacy of record keeping or the record keeping of our clinical trial sites or investigators;
- approval by regulatory authorities of our manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies or our own manufacturing facility;
- timely receipt of marketing approvals for our lead product candidates from applicable regulatory authorities;
- the performance of our current and future collaborators; and
- the extent of any required post-marketing approval commitments to applicable regulatory authorities.

We do not have control over these factors and any of them could impact or prevent our ability to obtain regulatory approval, in which event, our business will be harmed.

Additionally, our Phase 1/2a clinical trial for LAVA-1207 involves studying a relatively small patient population, which makes it difficult to predict whether the results observed in such clinical trials will be repeated in larger and more advanced clinical trials. We may experience numerous unforeseen events prior to, during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including the following:

- delays in reaching a consensus with regulatory authorities on the design, location or implementation of our clinical trial for LAVA-1207 and other potential product candidates;
- delays or setbacks in patient identification, qualification and enrollment;
- clinical trials of our product candidates may produce negative or inconclusive results;
- redesigning our study protocols and need to conduct additional studies as may be required by a regulator;
- changes in regulation or policy relating to the development and commercialization of our product candidate by the FDA, EMA or other comparable foreign regulatory authorities;

- delay or failure in obtaining the necessary approvals from regulators or institutional review boards (IRBs), in order to commence a clinical trial at a prospective trial site, or their suspension or termination of a clinical trial once commenced;
- the number of patients required for clinical trials for our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or may be lower than we anticipate due to challenges in recruiting, qualifying and enrolling suitable patients that meet the study criteria, participants may drop out of these clinical trials at a higher rate than we anticipate or the duration of these clinical trials may be longer than we anticipate;
- imposition of a clinical hold by regulatory authorities as a result of, among other reasons, a serious adverse event or a failed inspection of our clinical trial operations, trial sites or manufacturing facilities;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; and
- need to conduct additional clinical trials or abandon product development programs.

Furthermore, any inability to successfully complete preclinical and clinical development could result in additional costs or impair our ability to generate revenue from future product sales or other sources. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring competing products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

Success in preclinical studies or early-stage clinical trials may not be indicative of results in future clinical trials.

Results from preclinical studies or early-stage clinical trials are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. Our product candidate, LAVA-1207 is still in the early stages of development in a Phase 1/2a clinical trials and may fail to show the desired safety and efficacy in clinical development despite demonstrating positive results in preclinical studies or having successfully advanced through initial clinical trials.

Furthermore, we have limited safety and clinical efficacy data for the use of LAVA-1207 in humans. There can be no assurance that the results seen in preclinical studies for any of our product candidates ultimately will result in success in clinical trials. In addition, there can be no assurance that we will be able to achieve the same or similar success in our preclinical studies and clinical trials of our other product candidates.

There is a high failure rate for drugs and biologic products proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. The design of a clinical trial may also affect its ability to support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval.

If we do not observe favorable results in the clinical trials of our product candidates that would support regulatory approval, we may decide to delay or abandon clinical development of such product candidates. Similarly, data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including due to changes in regulatory policy during the period of our product candidate development. Any such delays could materially and adversely affect our business, financial condition, results of operations and prospects.

We may be unable to expand our discovery and development pipeline, which could limit our growth and revenue potential.

Our business is focused on developing our proprietary Gammabody platform of bispecific gamma delta ($\gamma\delta$) T cell engagers to transform the treatment of cancer. In this regard, we have invested substantial technical, financial and human resources toward drug discovery activities with the goal of identifying new potential product candidates to advance into clinical trials. Notwithstanding this investment, many programs that initially show promise will ultimately fail to yield product candidates for multiple reasons. For example, product candidates may, on further study, be shown to have inadequate efficacy, harmful side effects, suboptimal pharmaceutical profiles or other characteristics suggesting that they are unlikely to be commercially viable products.

Apart from our drug discovery efforts, our strategy to expand our development pipeline is also dependent on our ability to successfully identify and acquire or in-license relevant investigational assets and technologies to support the treatment of cancer. However, the in-licensing and acquisition of investigational oncology assets and technologies is a highly competitive area, and many other companies are pursuing the same or similar investigational oncology assets and technologies to those that we may consider attractive. In particular, larger companies with more capital resources and more extensive clinical development and commercialization capabilities may have a competitive advantage over us. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We may also be unable to in-license or acquire additional investigational oncology assets and technologies on acceptable terms that would allow us to realize an appropriate return on our investment. Even if we succeed in our efforts to obtain rights to suitable investigational oncology assets and technologies, the competitive business environment may result in higher acquisition or licensing costs, and our investment in these potential product candidates and technologies will remain subject to the inherent risks associated with the development and commercialization of new drugs. In certain circumstances, we may also be reliant on licensors for the continued development of any product candidates and/or technologies that we have in-licensed and such licensors' efforts to safeguard their underlying intellectual property.

With respect to acquisitions, we may not be able to integrate the target company successfully into our existing business, maintain the key business relationships of the target company, or retain key personnel of the acquired business. Furthermore, we could assume unknown or contingent liabilities or otherwise incur unanticipated expenses. Any acquisitions or investments made by us also could result in our spending significant amounts of resources, issuing dilutive securities, assuming or incurring significant debt obligations and contingent liabilities, incurring large one-time expenses, and acquiring intangible assets that could result in significant future amortization expense and significant write-offs, any of which could harm our financial condition and results of operations. If our drug discovery efforts, including research collaborations, in-licensing arrangements and other business development activities, do not result in suitable product candidates, our business and prospects for growth could suffer.

We have in the past, and in the future may enter into collaborations with third parties to conduct, supervise and monitor our preclinical studies and clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business and delay or impair our ability to obtain regulatory approval or otherwise commercialize our product candidates.

We rely upon, and intend to rely on for the foreseeable future, clinical research organizations (CROs) and academic institutions to monitor and manage data for our preclinical programs and ongoing clinical programs, including our clinical trial for LAVA-1207 and our preclinical programs for hematologic malignancies and other undisclosed targets. We control only certain aspects of the activities of our third-party service providers, including investigators and CROs. Nevertheless, we will be responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities.

We and these CROs are required to comply with good clinical practices (GCPs) which are regulations and guidelines enforced by the FDA and comparable regulatory authorities for any of our product candidates that are in preclinical and clinical development. The regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on CROs to conduct GCP-compliant clinical trials, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed

unreliable, and the FDA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. If our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Further, these investigators, academic institutions and CROs are not our employees, and we will not be able to control, other than by contract, the number of resources, including time, which they devote to our product candidates and clinical trials. Use of third-party service providers may require us to disclose our proprietary or confidential information to these parties, which could increase the risk that this information will be misappropriated.

Our reliance on third parties to conduct clinical trials will result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with CROs and other third parties can be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Such parties may:

- have staffing difficulties or experience management or ownership changes;
- fail to comply with contractual obligations, including with respect to confidentiality;
- experience regulatory compliance issues;
- undergo changes in priorities; or
- become financially distressed.

These factors may adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If our CROs, or hospitals where we conduct our clinical trials, do not successfully carry out their contractual duties or obligations with us or regulatory agencies, fail to meet necessary safety measures and protocols or meet expected deadlines, or fail to comply with regulatory and/or independent institutional review board (IRB) requirements, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develop. Consequently, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If our relationships with any CROs or hospitals where we conduct our current clinical trials terminate, we may not be able to enter into arrangements with alternative CROs and other third parties or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. While we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business, financial condition and prospects.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the regulatory authorities, which may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. Such regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the applicable regulatory authority and may ultimately lead to the denial of marketing approval of our product candidates.

Additionally, the FDA, EMA or an IRB may also suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a clinical trial in accordance with regulatory requirements, that we are

exposing participants to unacceptable health risks, or they find deficiencies in our investigational new drug applications (INDs) or the conduct of these clinical trials. Failures of our CROs to comply with regulations could also cause damage to our reputation and to public perception about our product candidates and technology. Consequently, if we experience delays in our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be negatively impacted, and our ability to generate revenues from our product candidates may be delayed.

Disruptions at the FDA and other government agencies caused by funding shortages, market conditions or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being advanced, developed, cleared or approved or commercialized in a timely manner or at all, which could negatively impact our business.

Disruptions at the FDA and other agencies, including government budget and funding levels, statutory, regulatory, and policy changes, their ability to hire and retain key personnel as well as impacts resulting from broader market conditions may affect the FDA's ability to perform routine functions thereby extending the time necessary for new biologics or modifications to be cleared, or approved biologics to be reviewed and approved by necessary government agencies. If a prolonged government shutdown occurs, government funding levels are significantly reduced, or current or future global health concerns prevent the FDA or other regulatory authorities from conducting regulator inspections, reviews or other activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Regulatory authorities may require concurrent approval of a companion diagnostic device with our product candidates, which could be time consuming and costly and may delay our ability to commercialize such product candidate.

Under the U.S. Federal Food, Drug, and Cosmetic Act, companion diagnostics are regulated as medical devices, and the FDA generally requires pre-market approval (PMA) for companion diagnostics at the same time as the related product candidate. The PMA application process, including the gathering of analytical and prospective clinical data and the submission to and review by the FDA, is rigorous and requires the applicant to provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, performance, good manufacturing practices, and labeling. A PMA is not guaranteed and may take considerable time, and the FDA may ultimately respond to a PMA submission with a "not approvable" determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval.

For our product candidate and future product candidates, we do not believe it will be necessary to use FDA-cleared or Conformite Europeenne (CE) marked or FDA-approved diagnostic tests to diagnose patients or to assure the safe and effective use of product candidates in clinical trial patients. The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express the specific marker that the companion diagnostic was developed to detect.

If a regulatory authority requires approval of a companion diagnostic for any of our product candidates, whether before or after it obtains marketing approval, we, and future collaborators, may encounter difficulties in developing and obtaining approval for such product candidate. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval or continued marketing of such product candidate.

Development of a product candidate intended for use in combination with an already approved therapy may present increased complexity and more or different challenges than development of a product candidate for use as a single agent or monotherapy.

We are developing LAVA-1207 and may develop other product candidates for use in combination with approved therapies. We have not studied the benefits and potential challenges or side effects of combination therapies with our product candidates. The FDA, EMA or other comparable regulatory authority may require us to use more complex clinical trial designs to evaluate the contribution of each product and product

candidate to any observed effects. It is possible that the results of these clinical trials could show that most or any positive results are attributable to the already approved product. Moreover, following product approval, the FDA, EMA or other comparable regulatory authority may require that products used in conjunction with each other be cross labeled. To the extent that we do not have rights to already approved products, this may require us to work with another company to satisfy such a requirement. Further, developments related to the already approved therapies may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the approved therapy's safety or efficacy profile, changes to the availability of the approved therapy, and changes to the standard of care.

If we encounter difficulties in enrolling, qualifying or retaining patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in part depends on patient enrollment, and as such, identifying and qualifying patients to participate in our LAVA-1207 clinical trial and future clinical trials is critical to our success. We may encounter difficulties in enrolling enough eligible patients to participate in our clinical trials, thereby delaying or preventing development and approval of our product candidates. Even once enrolled, we may be unable to retain enough patients to complete any of our clinical trials.

We may experience difficulties in patient enrollment for our trials for LAVA-1207. Because our focus includes diseases with limited patient populations, there may be limited patient pools from which to draw to complete our clinical trials in a timely and cost-effective manner. If any such patient enrolled in any of our clinical trials must drop out due to pre-existing or unrelated health issues or due to a serious adverse effect, or dies, and we are not able to recruit additional patients in a timely manner, or at all, our clinical trials could be delayed or otherwise halted. Consequently, despite diligent planning of our clinical trials and analysis of their feasibility regarding patient recruitment, we may experience difficulties, delays or inability in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the severity and incidence of the disease under investigation;
- the design of the trial and the complexity for patients and clinical sites;
- the general health condition of the patient and their immune cells broadly;
- the risk that patients' general health conditions do not allow the conduct of certain study/screening procedures, the manufacture of therapeutic product or application of the appropriate standard-of-care treatment;
- the ability to consistently manufacture Gammabody product candidates in sufficient quantities at sufficient activity to provide a suitable therapeutic dose;
- competing clinical trials in similar indications for other new therapeutics, new combination treatments, or new medicinal products;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved or become standard of care for the indications we are investigating;
- the ability to obtain and maintain patients' consents due to various reasons;
- the risk that enrolled subjects will drop out or die before completion of the trial;
- the ability to develop and provide appropriate screening, product characterization and release assays;
- patients failing to complete a clinical trial or returning for post-treatment follow-up;
- our ability to manufacture the requisite materials for a patient and clinical trial; and
- inability of clinical sites to enroll patients as healthcare capacities are required to cope with natural disasters, epidemics or other health system emergencies.

Our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. Any negative results we may report in our LAVA-1207 clinical trial may make it difficult or impossible to recruit and retain patients in future clinical trials. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible.

Serious adverse events (SAEs) or undesirable or unexpected side effects of LAVA-1207 or future product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their physician. Often, it is not possible to determine whether the product candidate being studied caused these conditions. Regulatory authorities may draw different conclusions or require additional testing to confirm these determinations if they occur. Many times, side effects are only detectable after investigational drugs are tested in large-scale pivotal trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our product candidates have unacceptable side effects or cause serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would harm our business, prospects, operating results and financial condition.

Undesirable side effects caused by our current and future product candidates, delivery methods or dosage levels could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or other comparable regulatory authority. As a result of safety or toxicity issues that we may experience in our clinical trials, we may be placed on clinical hold and not receive approval to market any product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our clinical trial could reveal an unacceptably high severity and incidence of side effects, or side effects outweighing the benefits of our product candidates. In such an event, our studies could be delayed, suspended or terminated and the FDA, EMA or comparable regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The treatment-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the clinical trial or result in potential product liability claims.

To date, we have only tested the Gammabody platform, including LAVA-1207 in a limited number of patients with cancer and these clinical trial participants have only been observed for a limited period after dosing. There were no CRS events greater than grade 2 observed in the LAVA-051 trial at the dose levels studied. No CRS events greater than grade 2 have been observed in the monotherapy arm of the LAVA-1207 trial. A single dose limiting toxicity (DLT) of subdural hematoma was reported in cohort 6, the only DLT in the LAVA-1207 monotherapy arm of the trial. As of the date of this annual report, there have been no similar DLT in the monotherapy arm of the trial. Three DLTs were reported in patients receiving multiple doses of LDIL-2 in addition to LAVA-1207, two of which were transaminase increases that were clearly immune-related. Since we initiated step dosing and amended the DLT criteria for the duration of transaminase increases, no CRS has been reported and DLTs have been reported in the LDIL-2 arms of the trial. The safety results of preclinical studies and early clinical trials, as well as data from interim analysis of ongoing clinical trials, may not be predictive of the results of ongoing or future clinical trials.

As we continue developing LAVA-1207 and initiate clinical trials of our additional product candidates, unacceptable toxicities, SAEs, undesirable or potentially fatal side effects, high-grade CRS, viral infections, relapse of disease or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, and inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or

death. Should we observe unacceptable toxicities in our clinical trials or identify undesirable side effects or other unexpected findings, our trials could be delayed or even terminated, and our development programs may be halted entirely.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, several potentially significant negative consequences could result.

Consequently, such events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidates, which could have a material adverse effect on our business.

There may be potential unforeseen business disruptions or market fluctuations that delay our business operations, product development, supply chain or clinical trials and increase our costs or expenses, such as business or operational disruptions, delays, or system failures due to malware, general economic and market conditions, overall fluctuations in the United States and international equity markets, including deteriorating market conditions, unauthorized access, terrorism, war, natural disasters, strikes, geopolitical conflicts, restrictions on trade, import or export restrictions, or public health crises, such as pandemics.

Public health crises could have an adverse effect our business. Effects of a pandemic that may delay or otherwise adversely affect our ongoing and planned preclinical activities, our planned clinical trials as well as our business generally, include:

- delays related to disruptions at CROs and contract manufacturers, or in the supply chain;
- delays in receiving approval from regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff who, as healthcare providers, may have heightened exposure;
- delays or difficulties in enrolling and retaining patients in clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our planned clinical trials;
- difficulties interpreting data from clinical trials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as clinical trial sites and hospital staff supporting the conduct of clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others; and
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines; and interruptions, difficulties or delays arising in our existing operations and company culture as a result of many of our employees working remotely.

Any of these effects, and other effects of a pandemic, could have a material adverse effect on our business, financial condition, results of operations and prospects. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United States, Europe and other economies, which could impact our ability to raise the necessary capital needed to develop and commercialize our programs and current and future product candidates.

Interim, "top-line" and preliminary data from current or future clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, "top-line" or preliminary data from our clinical trial for LAVA-1207 or future clinical trials. Interim, "top-line" or preliminary data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim, "top-line" and preliminary data also remain subject to audit and verification

procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, “top-line,” and preliminary data should be viewed with caution until the final data are available. Differences between interim, “top-line” and preliminary data and final data could significantly harm our business prospects and may cause the trading price of our common shares to fluctuate significantly.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, “top-line,” or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize current and future product candidates, our business, operating results, prospects or financial condition may be harmed.

We face significant competition, and many of our competitors have substantially greater experience and resources than we have. Our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully market or commercialize our product candidates.

The clinical and commercial landscape in the indications we are targeting, as well as in the field of immuno-oncology, is highly competitive. We face potential competition with respect to our current product candidates and may face competition with respect to any other product candidates that we may seek to develop or commercialize in the future from pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research institutions.

Many of our current or potential competitors, alone or with their strategic partners, have greater financial resources, larger research and development staffs, and more experience in researching, developing and testing products than we do. They may have more experience in conducting clinical trials, obtaining FDA and other regulatory approvals, and manufacturing, marketing and distributing therapeutic products. Smaller companies like us may successfully compete by establishing collaborative relationships with larger pharmaceutical companies or academic institutions. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors.

Our competitors in the field of $\gamma\delta$ T cell therapy include Adicet Bio, Inc., Clade Therapeutics, Editas Medicine, Inc., Eureka Therapeutics, Inc., ImCheck Therapeutics, Immatics N.V., IN8bio, Inc., Leucid Bio Ltd, PhosphoGam Inc., Shattuck Labs Inc., Sandhill Therapeutics, Inc., and TC BioPharm Limited. Our $\gamma\delta$ T cell product candidates may also compete with other T cell and NK cell engaging therapies as well as NK cell-engaging therapies.

There are many other companies that have commercialized or are developing immuno-oncology therapies for cancer including large biotechnology and pharmaceutical companies, such as Amgen, AstraZeneca, BMS, Eli Lilly and Company, EMS Serono, Genentech, a subsidiary of Roche, Merck & Co., Merck KGa, EMD, Serono, Novartis, Pfizer, Sanofi and Takeda Pharmaceutical Company Ltd. Many companies, not limited to those above, are attempting to combine immuno-oncology antibody therapies to modulate two cancer pathways simultaneously. Others have developed bispecific antibodies or bispecific fusion proteins to leverage the effect of a combination of single-target traditional monoclonal antibodies, which we refer to as traditional antibodies, in a single molecule.

Many of our potential competitors, alone or with their strategic partners, compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our

commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of cancer and other diseases. Our competitors may succeed in developing, obtaining patent protection for, or commercializing their products more rapidly than us, which could result in our competitors establishing a strong market position before we are able to enter the market. Consequently, we may not be successful in marketing any product candidates we may develop against competitors.

2.5.3 Risks related to manufacturing and reliance on third parties

The manufacture of biotechnology products is complex, and manufacturers often encounter difficulties in production, which could negatively affect our ability to develop or commercialize current and future product candidates.

The manufacture of biotechnology products is complex and requires significant expertise and capital investment. We and our contract manufacturers must comply with cGMP regulations and guidelines for clinical trial product manufacture and for commercial product manufacture. We may encounter difficulties in production of LAVA-1207 or future product candidates, particularly in scaling up, addressing product quality, product comparability, validating production processes and mitigating potential sources of contamination. These difficulties include:

- challenges procuring raw materials;
- maintaining quality control for our products, including stability of products, quality assurance testing, issues arising from operator error;
- retaining qualified personnel for manufacturing processes;
- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- reliance on third-party suppliers and manufacturers;
- compliance with cGMP requirements and other inspections by the FDA, EMA or other comparable regulatory authorities.
- the cost and timing of establishing, expanding and scaling manufacturing capabilities;
- inability to manufacture, or obtain from third parties, sufficient quantities of qualified materials under cGMPs, for the completion in pre-clinical and clinical studies; and
- problems with biopharmaceutical product candidate storage, stability and distribution resulting from global supply chain disruptions.

In addition, if microbial, viral or other contaminations are discovered in therapeutic products or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Any adverse developments affecting manufacturing operations for LAVA-1207 and future product candidates may result in lot failures, inventory shortages, shipment delays, product withdrawals, recalls or other interruptions in the supply of our drug product, which could prevent the administration to patients and delay the development of our product candidates. We may also have to write off inventory, incur other charges and expenses for supply of drug product that fails to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. In such event, it would negatively impact our ability to generate revenue, harm our reputation, and could have an adverse effect on our business and financial condition.

We rely on a single-source supplier for bulk drug substance (BDS) and drug manufacturing. The loss of this supplier or its failure to supply us with BDS on a timely basis could impair our ability to develop our product candidate or otherwise delay the development process, which could adversely affect our business.

We currently depend on one single-source supplier for BDS for LAVA-1207. In the event we lose our single-source supplier, our ability to develop LAVA-1207 will likely be adversely impacted and delayed, which could adversely affect our business. There are no immediate plans to select a second BDS supplier for LAVA-1207.

Although we believe that we have a substantial reserve of BDS to support our current clinical trial program, there can be no assurance that our supply of BDS will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. Additionally, we do not have any control over the process or timing of the acquisition or manufacture of materials by our supplier and cannot ensure that it will deliver to us the BDS we order on time, or at all. The loss of BDS provided by this supplier could require us to change the design of our product candidate development process based on the functions, limitations, features and specifications of the replacement.

In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Our reliance on this single-source supplier exposes us to certain risks, including:

- our supplier may cease or reduce production or deliveries, raise prices or renegotiate terms;
- we may be unable to locate a suitable replacement on acceptable terms or on a timely basis, if at all; and
- if there is a disruption to our single-source supplier's operations, and if we are unable to enter into arrangements with alternative suppliers, we may need to halt our clinical trial program;

The manufacturing of our product candidate and future product candidates may also be affected by the growth in the costs and expenses of components or raw materials for such product candidates. Likewise, supply sources could be interrupted from time to time and, if interrupted, there is no guarantee that supplies could be resumed (whether in part or in whole) within a reasonable timeframe and at an acceptable cost or at all. Furthermore, subsequent orders of the same supplies may be according to different specifications, which could cause delays in our manufacturing process.

Any adverse developments affecting manufacturing operations for our product candidate or future product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, cost increases or other interruptions in the supply of our product candidates, which could delay our clinical trial and materially impact our business and operations.

We currently store our Gammabody product candidate at specialized external storage facilities operating under established rules and regulations, and any damage or loss to storage freezers if not detected and remediated in time, would cause delays in replacement, and our business could suffer.

Our Gammabody product candidate and future product candidates are or will be manufactured from a vial of a master cell bank or a working cell bank of that antibody's production cell line. We have or intend to have one master cell bank for each Gammabody bispecific T cell engager that was or will be produced and tested in accordance with cGMP and applicable regulations. Any adverse developments affecting manufacturing operations for our product candidates or future product candidates while they are undergoing clinical trials could delay the timeline on which such trials are being conducted.

Our master and working cell banks are stored at multiple specialized external storage facilities operating under established rules and regulations. If these cells are damaged, including by the loss or malfunction of liquid nitrogen filled Dewar vessels or freezers, or back-up power systems, as well as by damage from fire, power loss or other natural disasters, we would need to establish replacement cell banks, which could impact clinical supply and could delay our clinical trial or future clinical trials. We would also need another supplier with a good manufacturing process (GMP) facility. If we or our third-party contractors are unable to establish

replacement cell banks, as applicable, we could incur significant additional expenses and liability, our development programs could be delayed or terminated, and our business could suffer.

If we cannot manufacture our product candidate or the product candidates of our collaborations reliably or in sufficient amounts utilizing Contract Development Manufacturing Organizations (CDMOs) or ourselves, at acceptable costs and on a timely basis, we may be unable to supply sufficient product candidates for nonclinical studies or clinical trials or to support commercialization of our product candidate, if approved.

We do not own or operate manufacturing facilities and have no plans to build our own clinical or commercial-scale manufacturing capabilities. We cannot ensure that our suppliers will remain in business, have sufficient capacity or supply to meet our needs, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. If we cannot establish sufficient supply through alternative third-party CDMOs or in our own facilities, should we develop these, our ability to conduct the planned and future clinical trials and our plans for commercialization would be materially adversely affected.

In addition, we currently rely on a small number of CDMOs to produce our product candidate, development candidates and collaborator candidates, and as a result, we face certain additional risks relating to our manufacturing operations. A single significant disruptive event at the manufacturing operations of one of our CDMOs can have a material adverse effect on our business, prospects, financial condition and results of operations. Business interruption insurance may not adequately compensate us for any losses that may occur and we would have to bear the additional cost of any disruption. For instance, if we were to experience an unexpected loss of supply, or if our CDMOs are unable to meet our demand for their services, we could experience delays in our research and development activities, planned clinical trials or commercialization of approved products. Finding alternative CDMOs or suppliers of acceptable quality who can deliver appropriate volumes at acceptable cost may require additional time and resources. Moreover, the transition periods involved in the change of CDMOs and suppliers, if necessary, could significantly delay our clinical trials and the commercialization of our product candidate or future product candidates, if approved.

Manufacturers of drug and biological products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel, as well as compliance with strictly enforced federal, state and non-U.S. regulations. Furthermore, if contaminants are discovered in the supply of our drug product or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our product candidate, collaborator candidates or development candidates will not occur in the future. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

We will need to work with CDMOs that can meet all applicable FDA and other regulatory authority requirements on an ongoing basis. If the manufacturing process is changed during product development, the FDA or other regulatory authorities could require us to repeat some or all previously conducted trials or conduct additional trials to obtain bridging data, which could delay or impede our ability to obtain marketing approval. If we or our CDMOs are unable to reliably produce and release our product candidate, development candidates or collaborator candidates to specifications acceptable to FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to further develop, conduct clinical trials for, and commercialize such product candidates. Similarly, approval of our product candidates could be delayed or denied if the intended manufacturing site fails to pass the required preapproval inspection. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CDMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require clinical trials to obtain bridging data or the repetition of one or more clinical trials, increase clinical trial

costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods, and have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Future clinical trials that we conduct, as well as any potential commercialization of our product candidate if approved, will depend on the reliability, safety and efficacy of our manufacturing methodology. Our efforts to scale up production of our bispecific $\gamma\delta$ T cell engager antibodies in anticipation of future clinical trials or commercialization may reveal defects in our methodology, an inability to overcome biology or may otherwise encounter challenges, including scrutiny from regulatory authorities. To the extent we encounter any such difficulties, our ability to conduct additional clinical trials or to scale for commercialization will be hindered or prevented, which would have an adverse effect on our business.

2.5.4 Risks related to our intellectual property

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If we are unable to obtain or protect rights relating to our technology and current and future product candidates, or if our intellectual property rights are inadequate, we might not be able to compete effectively.

We have entered into license agreements and agreements where we have received a contingent assignment to certain patent rights with third parties and we expect to enter into additional such agreements in the future to advance our research or allow commercialization of LAVA-1207 or any future product candidates we may develop. These license agreements impose financial and other obligations that are relevant to our business and financial operations, and if we fail to comply with our obligations under these agreements, we could lose our rights, or face further liability, under such license agreements. For example, if we fail to meet our obligations under the Amsterdam UMC Agreement in any material respect and fail to cure such breach in a timely fashion, Amsterdam UMC may terminate the agreement, and we would be obligated to transfer back to Amsterdam UMC the assigned patent rights. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the agreement, we may not be able to do so in a timely manner, at an acceptable cost or at all. For more information on the Amsterdam UMC Agreement, see *"Item 4: Information on the Company."* If these agreements are terminated, we could lose intellectual property rights that are important to our business, be liable for damages to such licensors or be prevented from developing and commercializing our product candidates. Termination of these agreements or reduction or elimination of our rights under these agreements may also result in our being required to negotiate new or reinstated agreements with less favorable terms, and it is possible that we may be unable to obtain any such additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis.

License agreements we enter into in the future may not provide exclusive rights to use intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all our licenses.

Disputes may arise between us and our current or future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense, transfer or assign patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could significantly harm our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could significantly harm our competitive position, business, financial condition, results of operations and prospects.

If we are unable to obtain and maintain patent and other intellectual property protection for current and future product candidates and technology, or if the scope of protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and technology may be adversely affected.

Our success depends in part on our ability to obtain and maintain protection for our owned and in-licensed intellectual property rights and proprietary technology. We rely on patents and other forms of intellectual property rights, including in-licenses of intellectual property rights and biologic materials of others, to protect our current or future discovery platform, product candidates, methods used to manufacture our future product candidates, and methods for treating patients using our future product candidates.

We and our licensors have sought, and intend to seek, to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and our technology that are important to our business including LAVA-1207. We may also seek to protect our proprietary position by acquiring or in-licensing additional issued patents or pending patent applications from third parties.

As of December 31, 2023, we own, co-own or exclusively license four (4) issued U.S. patents, twenty (20) pending U.S. patent applications, thirteen (13) pending European regional-phase patent applications, six (6) pending Patent Cooperation Treaty (PCT) patent applications, twenty (20) issued patents in other territories and more than eighty (80) pending patent applications in other territories, which are important to the development of our business. For more information relating to our patent portfolio, see *"Item 4: Information on the Company."* If we or our licensors are unable to obtain and maintain intellectual property protection with respect to inventions and technology important to our business, our competitive position, financial condition, results of operations and prospects may be significantly harmed.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. Since patent applications in the United States and most other countries are confidential for a period after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file a patent application relating to any particular aspect of a product candidate or technology. As a result of these and other factors, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may also diminish the value of our patents or narrow the scope of our patent protection.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents have been issued from such applications, and then only to the extent the issued claims cover the technology. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and

development activities, any of these parties may breach the agreements and disclose such activities before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Moreover, we may be subject to a third-party pre-issuance submission of prior art or become involved in opposition, derivation, reexamination, inter partes review, post-grant review, interference or other similar proceedings, or litigation, challenging our patent rights or the patent rights of our licensors. The costs of defending our patents or enforcing our proprietary rights in such administrative proceedings or litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates or could embolden competitors to launch products or take other steps that could disadvantage us in the marketplace or draw us into additional expensive and time-consuming disputes.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

We or our licensors have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our product candidates in every country or territory in which we may sell our products, if approved. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from infringing our patents in all countries outside the United States, or from selling or importing products that infringe our patents in and into the United States or other jurisdictions.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if the patent applications we license or own do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates.

Furthermore, we may develop, acquire or license intellectual property rights that have been generated through the use of Dutch or U.S. government funding. As a result, the Dutch or U.S. government may have certain rights, or march-in rights, to such patent rights and technology. Typically, the government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In certain circumstances, the government may also have the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the country. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

We may also be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. It is possible that we do not perfect our ownership of all patents, patent applications and other intellectual property, including that we do not identify all inventors, or identify incorrect inventors, which

may lead to claims disputing inventorship or ownership of our patents, patent applications or other intellectual property by former employees or other third parties or that we do not establish an unbroken chain of title from inventors to us. Errors in inventorship or ownership can sometimes also impact priority claims. If we were to lose ability to claim priority for certain patent filings, intervening art or other events may preclude us from issuing patents. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership.

Obtaining and maintaining our patent rights depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or patent applications will have to be paid to the United States Patent and Trademark Office (USPTO) and various government patent agencies outside the United States over the lifetime of our owned and licensed patents and/or applications and any patent rights we may own or license in the future. We rely on our outside counsel or our licensing partners and other professionals to help us comply with these requirements and pay these fees when due, and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, nonpayment of fees and failure to properly legalize and submit formal documents. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

Patent terms may be inadequate to protect the competitive position of our current and future product candidates for an adequate amount of time.

Depending upon the timing, duration and specifics of FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for a limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years beyond the normal expiration of the patent as compensation for patent term lost during product development and the FDA regulatory review process. However, the extension cannot extend the total patent term beyond 14 years from the date of product approval and is limited to the approved indication (or any additional indications approved during the period of extension). Furthermore, only one patent per approved product can be extended and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. Similar provisions are available in Europe, Japan and other jurisdictions to extend the term of a patent that covers an approved drug; however, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevancy patents or otherwise failing to satisfy applicable requirements, or may grant more limited extensions than we request. If this occurs, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. Additionally, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, any of which could harm our competitive position, business, financial condition, results of operations and prospects.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property or other proprietary rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability and the ability of others with whom we may collaborate to develop, manufacture, market and sell our current and any future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights.

We, or our licensors, or any future strategic partners may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future product candidates and technology, including oppositions, interference proceedings, reexaminations, post grant review, inter partes review or derivation proceedings before the USPTO in the United States, or any equivalent regulatory authority in other countries. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. These proceedings can be expensive and time-consuming, and many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions. Even if we believe such claims are without merit, there is no assurance that a court would find in our favor on questions of validity, enforceability, priority or non-infringement. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future product candidates. To successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this is a high burden and requires us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent.

Intellectual property rights of third parties could adversely affect our ability to commercialize our current or future technologies or product candidates, and we might be required to litigate or obtain licenses from third parties to develop or market our current or future technologies or product candidates, which may not be available on commercially reasonable terms or at all.

Given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Other companies and research institutions have filed, and may file in the future, patent applications related to gamma delta T cell immunotherapy. Some of these patent applications have already been allowed or issued, and others may issue in the future. While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes that our product candidate infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the drug or product candidate that is the subject of the actual or threatened suit.

If we are found to infringe, misappropriate or otherwise violate a third party's valid and enforceable intellectual property or other proprietary rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidate(s) and technology. Under any such license, we would most likely be required to pay various types of fees, milestones, royalties or other amounts. Moreover, we may not be able to obtain any required license on commercially reasonable terms or at all. We

could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidate. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. We may also be required to indemnify collaborators or contractors against such claims. A finding of infringement, misappropriation or other violation of third-party intellectual property could prevent us from manufacturing and commercializing our current or any future product candidates or force us to cease some or all our business operations, which could harm our business.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have an adverse effect on our business, financial condition, results of operations and prospects. Furthermore, even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees, consultants and advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals, or we, have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims, regardless of their merit, and we cannot predict whether we would prevail in any such actions. Our failure in defending any such claims, in addition to paying monetary damages, may cause us to lose valuable intellectual property rights or personnel and may prevent or delay our development and commercialization efforts, which could significantly harm our business, financial condition, results of operation and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and may cause negative publicity.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications because of work they performed on our behalf. We may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, for which we may not have an adequate remedy, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have an adverse effect on our business, financial condition, results of operations and prospects.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property or proprietary rights, which could be expensive, time-consuming and unsuccessful.

Competitors or other third parties may infringe, misappropriate or otherwise violate our patents, the patents of our licensors or our other intellectual property or proprietary rights. To counter infringement, misappropriation or unauthorized use, we may be required to file infringement or other intellectual property claims, which can be expensive and time-consuming and are likely to divert significant resources from our core business,

including distracting our technical and management personnel from their normal responsibilities. In addition, in a patent infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable, and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our owned or licensed patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our owned or licensed patents at risk of being invalidated or interpreted narrowly and could put our owned or licensed patent applications at risk of not issuing. Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technology or platform, or any product candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is or will be no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates.

We may not be able to prevent, alone or with our licensors, infringement, misappropriation or other violations of our intellectual property and proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property and proprietary rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios.

Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or otherwise violating or from successfully challenging our intellectual property and proprietary rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our current and any future product candidates.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Under the Leahy-Smith America Invents Act, or the America Invents Act, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also allows third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business, financial condition, results of operations, and prospects.

In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty about our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we own, have licensed or might obtain in the future. Changes in patent law and regulation in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our

ability to obtain new patents or to enforce patents that we own or have licensed or that we may obtain in the future.

In Europe in June 2023, a new unitary patent system was introduced, which will significantly impact European patents, including those granted before the introduction of the system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a European patent with unitary effect, or a Unitary Patent. Each Unitary Patent is subject to the jurisdiction of the Unitary Patent Court, or UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents under the jurisdiction of the UPC could be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with any certainty the long-term effects of the new unitary patent system.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents covering our current and any future product candidates in all countries throughout the world would be prohibitively expensive, and our and our licensors' intellectual property rights in some countries outside the United States may be less extensive than those in the United States. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents, and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our or our licensors' patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our licensors at risk of being invalidated or interpreted narrowly, could put our patent applications or the patent applications of our licensors at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Reliance on third parties requires us to share our know-how or trade secrets, which increases the possibility that a competitor will discover them or that our know-how or trade secrets will be misappropriated or disclosed.

Since we rely on third parties to help us discover, develop, and manufacture our current and any future product candidates, or if we collaborate with third parties for the development, manufacturing or commercialization of our current or any future product candidates, we must, at times, share know-how or trade secrets with them. We may also conduct joint research and development programs that may require us to share know-how or trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our

advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our know-how or trade secrets. Despite the contractual provisions employed when working with third parties, the need to share know-how or trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations. In addition, from time to time, we may hire scientists or other employees or consultants who originate from jurisdictions, including China, which have a history of engaging in misappropriation or theft of trade secrets or other acts of trade secret espionage. If any such individuals are found to be engaging in such illegal behavior, it could have a material adverse effect on our ability to protect our intellectual property and our business prospects more generally.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors, and consultants to publish data potentially relating to our know-how or trade secrets. Despite our efforts to protect our know-how and trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors, and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third-party illegally or unlawfully obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

If we are unable to protect the confidentiality of our know-how or trade secrets, our business and competitive position would be harmed.

Our competitors may independently develop knowledge, methods, and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or third party, we would have no right to prevent them, or those to whom they communicate such trade secrets, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us.

If our trademarks are not adequately protected, then we may not be able to build name recognition in our markets of interest, resulting in harm to our business.

We have registered trademarks and pending trademark applications in the United States and various foreign jurisdictions for our marks related to our business. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for any of our current or future product candidates. Whether allowed or registered, our trademarks and trade names may be challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, or adopt trademarks similar to ours, and there may be trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks, and we may not have adequate resources to enforce our rights in such trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks, then we may not be able to compete effectively, and our competitive position, business, financial condition, results of operations and prospects may be significantly harmed.

In addition, any proprietary name we propose to use with our current or any other product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Intellectual property rights do not necessarily address all potential threats to the competitive advantages maintained by our business.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make compounds or formulations that are similar to any current or future product candidates but that are not covered by the claims of any patents, should they issue, that we own or license;
- we or our licensors might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or license;
- we or our licensors might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- we or our licensors may not be able to detect infringement of issued patents we own or license;
- it is possible that pending patent applications we own or in-license will not lead to issued patents;
- issued patents that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- issued patents that we own or license may not have sufficient term or geographic scope to provide meaningful protection;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive drugs for sale in our major commercial markets;

- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent to maintain certain trade secrets, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, it could significantly harm our business, financial condition, results of operation and prospects.

2.5.5 Risks related to our business operations, employee matters and managing growth

We are highly dependent on the services of our senior management team and if we are not able to retain our current management team or recruit and retain additional management, clinical and scientific personnel, our business will be harmed.

We are highly dependent on our senior management team. Each of them may currently terminate their employment with us at any time. The loss of the services of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining other senior executives, qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of our senior management or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing senior managers and key employees may be difficult and may take an extended period because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully lead, develop, gain regulatory approval of and commercialize our product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired senior employees into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations. Additionally, we do not maintain “key person” life insurance for any of our executive officers.

We plan to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2023, we had 35 full-time employees. As the clinical development of our product candidates progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, drug development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. In addition, our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We are and expect to continue to be reliant on third parties for key aspects of our business and operations, including our existing and future research, manufacturing and supply. If such parties fail to adequately perform or we are not able to maintain our current relationships or enter new strategic relationships which such third parties, our business, financial condition, commercialization prospects and results of operations may be adversely affected.

We are reliant on third parties for key aspects of our business and operations, including the development our existing and future research programs and product candidates, implementation and management of our clinical trials, and manufacturing and supply of our products and product candidates. Reliance on third parties exposes us to additional risks and uncertainties that may not exist if we were able to manage such aspects of our business ourselves.

We are currently party to multiple collaborations for the potential discovery and development of multi-specific antibody products that are directed to specified targets in all fields of use. We also intend to explore other strategic partnerships to broaden our Gammabody platform. Because we do not own any facility that may be used as our clinical or commercial-scale manufacturing and processing facility, we expect to rely on third parties for at least a portion of our manufacturing process, including for clinical and commercial supply of LAVA-1207. Reliance on such third parties and other manufacturers and suppliers for our current product candidate and collaborations may pose several risks, including that such third parties:

- may not have sufficient resources or devote the necessary resources to our relationship due to internal constraints such as budget limitations, lack of human resources, or a change in strategic focus;
- may believe our intellectual property is not valid or is unenforceable, or that the product candidates subject to the arrangement infringes, misappropriates or otherwise violates the intellectual property rights of others;
- may dispute their responsibility to conduct development and commercialization activities, including the payment of related costs or the division of any revenues;
- may decide to pursue a competitive product developed outside of the collaboration arrangement;
- may not be able to obtain, or believe they cannot obtain, the necessary regulatory approvals or certifications or comply with cGMP requirements;
- may experience challenges in manufacturing to our specifications and in compliance with regulatory requirements; or
- may delay the development or commercialization of our product candidates in favor of developing or commercializing another party's product candidate.

In addition, we may not be able to negotiate commercial arrangements with any of such parties, including the negotiation of a commercial supply agreement for the manufacture of LAVA-1207 with a global contract manufacturer on acceptable terms, if at all. Our ability to reach a definitive agreement for a collaboration, clinical development, manufacturing or supply will depend, among other things, upon our assessment of the third-party's resources and expertise, the terms and conditions of the proposed commercial relationship and the proposed third-party's evaluation of a number of factors. If we are unable to reach agreements with suitable third parties on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all.

We are unable to predict when, if ever, we will enter into any such relationships because of the numerous risks and uncertainties associated with establishing them, including:

- expenditure of substantial operational, financial and management resources;
- dilutive issuances of our securities to such third parties;

- substantial actual or contingent liabilities; and
- termination or expiration of the arrangement, which would delay the development and may increase the cost of developing our product candidates.

We may also be subject to further risks if our third-party providers do not properly maintain, enforce or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation, any of which could adversely affect our business, financial position and operations.

All the risks relating to product development, regulatory approval and commercialization applicable to us, including those described in this "Risk Factors" section, also apply to the activities of our program collaborators. Additionally, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination, the collaborator may deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If our collaborator terminates its agreement with us, we may find it more difficult to attract new collaborators, which could negatively impact our ability to develop or commercialize such product candidate.

If any of our current collaborations are delayed or terminated, or if any of our collaboration partners materially breach its obligations thereunder, it could cause significant delays in the development efforts of the Gammabody platform.

We are currently party to multiple collaboration agreements, including with Pfizer (formerly Seagen, acquired by Pfizer in 2023) to develop EGFRd2 (PF-8046052), an investigational candidate targeting epidermal growth factor receptor (EGFR) (the Pfizer Agreement), the collaboration with Janssen for the discovery and development of novel bispecific antibody based gamma delta T cell engagers for the treatment of cancer (the Janssen Agreement) and the collaboration with Merck to evaluate its anti-PD-1 therapy Keytruda (pembrolizumab) in combination with LAVA-1207 (the Merck Agreement). Our financial performance may be significantly harmed if any of these collaborations are delayed or terminated, or if any of our collaborators material breach their obligations to us under these agreements.

Under the Pfizer Agreement, Pfizer paid us a non-refundable upfront payment of $50.0 million and has the option to obtain exclusive rights to two (2) additional targets, subject to an option payment for each product candidate. If Pfizer exercises its option on a given product candidate, we will develop such target candidate. We also have an option to elect to co-fund EGFRd2 (PF-8046052), at a certain opt-in price at a designated time pursuant to the Pfizer Agreement. Additionally, we will be entitled to royalties on any future sales of such products by Pfizer. It is difficult to predict how Pfizer's business strategy will change over time; as of now we have no indication that they will abandon the program, and in March 2024, Pfizer paid us $7 million for achieving a clinical development milestone, but changes in strategy by Pfizer would effectively end our contract and future milestones. We continue to hold regular governance and team meetings, and Pfizer continues to be engaged in the EGFRd2 (PF-8046052) collaboration.

In addition, under the Janssen Agreement, we granted Janssen an exclusive, sublicensable, worldwide license under certain of our patents, materials, and know-how, including certain rights assigned to us pursuant to the Amsterdam UMC Agreement, to exploit multi-specific antibody products which have variable domains specific to the licensed target or products which are directed to the licensed target, in all fields of use. In May 2023, within the framework of the Janssen Agreement, Janssen selected a lead bispecific antibody utilizing the Gammabody platform for an undisclosed tumor associated antigen for development and we received a financial milestone payment. Efforts are underway by Janssen to advance the candidate towards the clinic. As part of the Janssen Agreement, we received a non-refundable upfront payment of $8.0 million, and we are entitled to additional milestone payments from Janssen if the lead candidate progress through certain clinical and regulatory milestones. We are also eligible to receive up to an aggregate of $195 million upon the achievement of certain development and commercial milestones and tiered royalties based on commercial sales levels. Following each research stage, the Janssen Agreement will automatically terminate if the parties decide not to proceed with the subsequent research stage or, following the completion of all research stages, if Janssen decides not to bring a candidate forward into further development.

Further, under the Merck Agreement, we will be provided with pembrolizumab for the dose escalation and expansion phases of LAVA's ongoing Phase 1/2a study of LAVA-1207, with the combination arm expected to be initiated in the first half of 2024. Enrollment and dose escalation will also continue in the LAVA-1207 monotherapy and interleukin-2 arms of the study.

If any of our collaborators were to terminate these collaboration agreements, or deprioritize our collaboration programs, we may not have the resources or skills to replace those of our collaborators, which could require us to seek additional funding or another collaboration that might not be available on favorable terms or at all, and could cause significant delays in development and/or commercialization efforts, including delays in validating our Gammabody platform, and result in substantial additional costs to us. Termination of such collaboration agreements or the loss of rights provided to us under such agreement may create substantial new and additional risks to the successful development and commercialization of our products and could materially harm our reputation, financial condition and operating results.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards, which could adversely affect the development of current and future product candidates and our business.

We are exposed to the risk of fraud or other misconduct by our employees, collaborators, principal investigators, consultants, commercial partners and outside actors. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commissions, customer incentive programs, and other business arrangements. Such misconduct also could involve the improper use of information obtained during clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

We may be classified as a passive foreign investment company (PFIC) for U.S. federal income tax purposes, which could result in adverse U.S. federal income tax consequences to U.S. investors in our common shares.

Based on the estimated composition of our income, assets and operations, we do not believe that we were classified as a PFIC for U.S. federal income tax purposes for the taxable year ended December 31, 2023. A non-U.S. company will be considered a PFIC for any taxable year if (i) at least 75% of its gross income is passive income (including interest income), or (ii) at least 50% of the value of its assets (generally based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income. Passive income generally includes dividends, interest, rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets and received directly its proportionate share of the income of such other corporation. The value of our assets generally is determined by reference to the market price of our common shares, which may fluctuate considerably. In addition, the composition of our income and assets is affected by how, and how quickly, we spend the cash we raise. If we were to be treated as a PFIC for any taxable year during which a U.S. Holder (as defined in the section entitled "Material U.S. Federal Income Tax Considerations for U.S. Holders" hereof) held our common shares, certain adverse U.S. federal

income tax consequences could apply to such U.S. Holder, including (1) the treatment of all or a portion of any gain on disposition of a common share as ordinary income, (2) the application of an interest charge with respect to such gain and certain distributions and (3) compliance with certain reporting requirements. See the section titled “Material U.S. Federal Income Tax Considerations for U.S. Holders.”

***There are risks inherent in our business that may subject us to potential product liability suits and other claims, which may require us to engage in expensive and time-consuming litigation or pay substantial damages and may harm our reputation,* which could negatively impact our business.**

Our business exposes us to product liability risks, which are inherent in the testing, clinical development, manufacturing, marketing and sale of biopharmaceutical products. For example, we may be sued if any current or future product candidate we develop allegedly causes, or is perceived to cause injury or is found to be otherwise unsuitable during product testing, clinical development, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach or violation of warranties and/or trademarks. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our current and future product candidates. Even a successful defense would require significant financial and management resources.

Regardless of merit or eventual outcome, product liability or other claims may, among other things, result in:

- decreased demand for any approved products;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or cancellation of clinical trials;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- exhaustion of any available insurance and our capital resources;
- loss of revenue;
- a potential decrease in our share price; and
- the inability to commercialize any products we develop.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of current or future product candidates. We obtained product liability insurance covering our clinical trial and will obtain insurance for future clinical trials with policy limits that we believe are customary for similarly situated companies and adequate to provide us with coverage for foreseeable risks. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If we determine that it is prudent to increase our product liability coverage due to the commercial launch of any approved product, we may be unable to obtain such increased coverage on acceptable terms, or at all. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental, health and safety laws and regulations, which can be expensive and restrict or interrupt our business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the generation, storage, use and disposal of hazardous materials, including the components of our product candidates, such as genetically modified cells, and other hazardous compounds and wastes. We and our manufacturers and suppliers are subject to environmental, health and safety laws and regulations governing, among other matters, the use, manufacture, generation, storage, handling, transportation, discharge and disposal of these hazardous materials and wastes and worker health and safety. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination or injury, which could result in an interruption of our commercialization efforts, research and development efforts and business operations, damages and significant cleanup costs and liabilities under applicable environmental, health and safety laws and regulations. We also cannot guarantee that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials and wastes generally comply with the standards prescribed by these laws and regulations. We may be held liable for any resulting damages costs or liabilities, which could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations.

Furthermore, environmental, health and safety laws and regulations are complex, change frequently and have tended to become more stringent and enforcement is prioritized. We cannot predict the impact of such changes and cannot be certain of our future compliance. We may be required to incur substantial expenses in connection with current and future environmental, health and/ or safety compliance, in which case, our production and development efforts may be interrupted or delayed and our financial condition and results of operations may be materially adversely affected. Failure to comply with these environmental, health and safety laws and regulations may result in substantial fines, penalties or other sanctions. We do not currently carry hazardous waste insurance coverage.

2.5.6 Risks related to regulatory compliance

The regulatory approval process of the FDA, EMA and other comparable foreign regulatory authorities are lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of current or future product candidates.

Of the large number of products in development, only a small percentage successfully complete the FDA, EMA or comparable regulatory authorities' approval processes and are commercialized. The lengthy approval or marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval or marketing authorization to market LAVA-1207 or future product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

We may face unforeseen challenges in our product candidate development strategy, and we can provide no assurances that our product candidates or clinical trial design will prove to be effective, that we will be able to take advantage of expedited regulatory pathways for any of our product candidates, or that we will ultimately be successful in current or future clinical trials. We may request regulatory approval of LAVA-1207 or future product candidates by target, regardless of cancer type or origin, which the FDA or other regulatory authorities may have difficulty accepting if our clinical trials only involved cancers of certain origins. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

We currently anticipate initially seeking regulatory approvals in the United States and Europe but may in the future submit applications for the regulatory approval of LAVA-1207 or our future product candidates to additional regulatory authorities. It is possible that neither our current product candidate, collaboration candidates nor any future product candidates we may seek to develop in the future will obtain regulatory approval. Neither we nor any of our partners are permitted to market any of our product candidates in the United States or abroad until we receive regulatory approval from the FDA, EMA or the applicable regulatory agency.

We could also encounter delays if our clinical trial investigators encounter unresolved ethical issues associated with enrolling participants in clinical trials of current or future product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

If we are successful in obtaining regulatory approvals for LAVA-1207 or other product candidates, we will be subject to ongoing regulatory oversight.

Our current and future product candidates, if approved, could be contingent on the performance of costly additional clinical trials, including post-market clinical trials, for a more limited indication or patient population than we originally request, and may not be approved or authorized with the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate, which would adversely impact our business and prospects.

We will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record keeping, submission of safety and other post-market information and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirement if LAVA-1207 or future product candidates are approved. Any regulatory approvals that we receive for our product candidates may also be subject to a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of treatment with such product candidates outweigh the risks for each potential patient, which may include, among other things, a communication plan to healthcare practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry, We or our collaborators may also be required to engage in similar action such as patient education, certification of healthcare professionals or specific monitoring. A REMS may also be required to limit the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or may contain requirements for potentially costly post-marketing testing, including Phase 4 trials, and for surveillance to monitor the quality, safety and efficacy of the product candidate. Such regulatory requirements may differ from country to country depending on where we have received regulatory approval. Compliance with such ongoing regulatory requirements is costly and requires the implementation and maintenance of extensive controls, procedures, and time commitments by our personnel.

If we, or a regulatory authority, discover previously unknown problems with a current or future product candidate, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product candidate is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that product candidate, a regulatory authority may impose restrictions relative to that product candidate, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the product candidate from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of our product candidates, a regulatory authority may, among other things, issue warning letters or untitled letters, mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners, or require other restrictions on the labeling or marketing of such products, require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance, seek an injunction or impose administrative, civil or criminal penalties or monetary fines, suspend or modify any ongoing clinical trials, or suspend, modify withdraw regulatory approval or restrict the marketing or manufacturing of the product candidate. If any of the foregoing actions occurs, it would negatively affect our business, financial condition and results of operations.

Moreover, the FDA and other regulatory authorities strictly regulate the promotional claims that may be made about biologic products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

Even if a product candidate receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

Even if any product candidate receives marketing approval, it may fail to gain market acceptance by physicians, patients, third-party payors and others in the medical community. If any such product candidate does not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on several factors, including but not limited to:

- the cost, efficacy, safety profile, convenience, ease of administration and other potential advantages compared to alternative treatments and therapies;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of our relationships with patient communities;
- the availability of third-party coverage and adequate reimbursement and patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of the product candidate together with other medications.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our product candidates may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. Because we expect sales of current and future product candidates, if approved, to generate substantially all our revenues for the foreseeable future, the failure of such product candidates to find market acceptance would harm our business.

We may seek orphan drug designation for some or all of our current or future product candidates and may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for supplemental market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs or biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug in the United States will be recovered from sales in the United States for that drug. The criteria for designating an "orphan medicinal product" in the European Union are similar in principle to those in the United States. Regulation (EC) No. 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment.

Orphan medicinal product status in the European Union can provide up to 10 years of marketing exclusivity, meaning that another application for marketing authorization of a later similar medicinal product for the same therapeutic indication will generally not be approved in the European Union. Although we may have drug candidates that may obtain orphan drug exclusivity in Europe, the orphan approval and associated exclusivity

period may be modified for several reasons, including a significant change to the orphan medicinal product designations or approval criteria after-market authorization of the orphan product (e.g., product profitability exceeds the criteria for orphan drug designation), problems with the production or supply of the orphan drug or a competitor drug, although similar, is safer, more effective or otherwise clinically superior than the initial orphan drug.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product may be entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a Biologics License Application (BLA), to market the same product for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other products that have a different active ingredient for use in treating the same indication or disease. Further, the FDA can waive orphan exclusivity if we cannot manufacture a sufficient supply of our product.

We may seek orphan drug designation for current or future product candidates. Even when we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we, through our manufacturer, are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we intend to seek orphan drug designation for other product candidates, we may never receive these designations.

We may not elect or be able to take advantage of any expedited development or regulatory review and approval processes available to product candidates granted breakthrough therapy or fast track designation by the FDA.

We intend to evaluate and engage in discussions with regulatory authorities, including the FDA, on regulatory strategies that could enable us to take advantage of expedited development pathways for our current product candidates or future product candidates, although we cannot be certain that any such products will qualify for any expedited development pathways or that regulatory authorities will grant, or allow us to maintain, the relevant qualifying designations. Potential expedited development pathways that we could pursue include breakthrough therapy and fast track designation as well as other pathways that may become available.

Breakthrough therapy designation is intended to expedite the development and review of products that treat serious or life-threatening diseases when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation of a product candidate as a breakthrough therapy provides potential benefits that include intensive guidance on an efficient drug development program, beginning as early as Phase 1, organizational commitment involving senior managers; and eligibility for rolling review and priority review. Breakthrough therapy designation does not change the standards for product approval. There can be no assurance that we will receive breakthrough therapy designation for any product candidate or any particular indication.

We may also seek fast track designation. If a drug or biologic candidate is intended for the treatment of a serious or life-threatening condition or disease and the drug demonstrates the potential to address unmet medical needs for the condition, the sponsor may apply for fast-track designation. Even if we do apply for and receive fast track designation, we may not experience a faster development, review or approval process compared to conventional FDA procedures. The FDA may rescind fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

Additionally, we may also seek accelerated approval under the FDA’s accelerated approval programs. The FDA may approve a drug or biologic for a serious or life-threatening disease or condition that generally provides meaningful advantages over available treatments and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured

earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

Seeking and obtaining these designations depends on the results of our clinical program, and we cannot guarantee whether and when we may have the data from our clinical programs to support an application to obtain any such designation. The FDA and comparable foreign regulatory agencies have broad discretion whether to grant any of these or similar designations, so even if we believe a particular product candidate is eligible for one or more of these designations, we cannot assure you that the applicable regulatory authority would decide to grant it. Even if we do receive the designations we may apply for, we may not experience a faster development process, review or approval compared to conventional procedures, as applicable. The FDA or other regulatory agencies may also rescind any granted designations if it believes that the data from our clinical trial no longer support the designation.

We expect the product candidates we develop will be regulated as biologics, and may be subject to competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when processes intended to implement BPCIA may be fully adopted by the FDA, any of these processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In addition, the approval of a biologic product biosimilar to one of our products could have a material adverse impact on our business as it may be significantly less costly to bring to market and may be priced significantly lower than our products.

Our relationships with customers, physicians, and third-party payors will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, including anti-kickback and false claims laws, transparency laws, local and foreign environmental and safety laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, including physicians, and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws, health data privacy laws, transparency laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations. For additional information on the healthcare laws and regulations that we may be subject to, see section titled “Information about the Company—Government Regulation.”

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians, some of whom are compensated with a stipend or share options for services performed for us, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Coverage and adequate reimbursement may not be available for our product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. While no uniform policy for coverage and reimbursement exists in the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Therefore, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Additionally, we or our collaborators may develop companion diagnostic tests for use with our product candidates. We or our collaborators will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our other product candidates, once approved.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, legislative and regulatory changes to the healthcare delivery and reimbursement system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. There have been and continue to be several federal and state initiatives in the United States that seek to reduce healthcare costs and improve the quality of healthcare.

For example, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the ACA, substantially changed the way healthcare is financed by both governmental and private payors in the United States and increased access to healthcare coverage for individuals. Since its enactment, there have been executive, judicial and Congressional challenges to the ACA. Most of the ACA survived such challenges but further healthcare reform measures of the Biden administration may impact the ACA or our business. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. Under the IRA and starting in 2023, Medicare can negotiate prices with pharmaceutical companies for certain high-cost drugs covered under Part B and Part D (prescription drugs like our potential product candidates). The negotiation process started in 2023 and negotiated prices are planned to take effect in 2026 and we will continue to evaluate the impact on our business. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although they may be the Medicare drug price negotiation

program is currently subject to legal challenges. We continue to evaluate the effect that health reforms may have on our business. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015. It is unclear how the payment adjustments under the Medicare quality payment program will impact overall physician reimbursement.

We expect that additional U.S. federal healthcare reform measures to be adopted in the future, could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our current or any future product candidates or additional pricing pressures. If we or any third parties we may engage are slow or unable to adapt to changes in existing or new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our current or any future product candidates we may develop may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Further, any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Implementing cost containment measures or other healthcare reforms may prevent us from generating revenue, attaining profitability or commercializing our products. For additional information on healthcare reform, see the section titled “Information about the Company—Government Regulation and Product Approval.”

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize current or any future product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, U.S. federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

European drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European member states.

We intend to seek approval to market our product candidate in the United States as well as select foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in Europe, the pricing of biologics is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidate. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidate will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidate and may be affected by existing and future healthcare reform measures.

Much like the Anti-Kickback Statue prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in Europe. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of European Union member states. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician’s employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union member states. These requirements are provided in the national laws, industry

codes or professional codes of conduct, applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in most foreign countries, including in Europe, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of our product candidate to other available therapies to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for our product. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our strategic partners and the potential profitability of our product candidate in those countries would be negatively affected.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our product candidates are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts for any of our current and future product candidates that receive approval. Social media practices in the biotechnology and pharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities and heightened scrutiny by the FDA, the SEC and other regulators. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. If such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. In addition, we may encounter attacks on social media regarding our company, management, product candidates or products. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

If our information technology systems or those third parties upon which we rely or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we and the third parties upon which we rely, collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets. Our internal computer systems, cloud-based computing services and those of our current and any future vendors, clinical investigators, CROs, collaborators, contractors, or consultants, are vulnerable to damage or interruption from natural disasters, fire, power loss, telecommunications failures, server malfunction, software or hardware failures. In addition, we and the third

parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), traditional computer "hackers," malicious code (such as viruses and worms), employee theft or misuse, denial-of-service attacks, adware, malware installation, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, sophisticated nation-state and nation-state supported actors and attacks enhanced or facilitated by AI, and other similar threats. Cyberattacks and other malicious internet-based activity continue to increase in frequency, sophistication and intensity, and are becoming increasingly difficult to detect.

We have conducted information security audits or evaluations on our internal computer systems, but we cannot guarantee that our or our vendors', clinical investigators', CROs', collaborators', contractors', or consultants' security measures will be sufficient to protect against unauthorized access to, or other compromise of, our systems and our confidential, financial or proprietary data, including personal information, which is stored in or otherwise processed by such systems. Many of our employees work remotely on a part-time basis, which may pose additional data security risks. While we have security measures in place designed to protect our confidential and proprietary information and prevent data loss and other security breaches, there can be no assurance that our security measures or those of our third-party service providers that store or otherwise process certain of our confidential, financial or proprietary data on our behalf will be effective in protecting against unauthorized access to our platform or such data, particularly given that our ability to monitor our third-party service providers' data security is limited. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in deploying remedial measures and patches designed to address identified vulnerabilities.

The techniques used to sabotage or to obtain unauthorized access to our or our third-party service providers' platform, systems, networks and/or physical facilities in which data is stored or through which data is transmitted change frequently, may not be recognized until launched, and can originate from a wide variety of sources, and we and our third-party services providers may be unable to implement adequate preventative measures or stop security breaches while they are occurring. The recovery systems, security protocols, network protection mechanisms and other security measures that we have integrated into our platform, systems, networks and physical facilities, which are designed to protect against, detect and minimize security breaches, may not be adequate to prevent or detect service interruption, system failure or data loss. Our platform, systems, networks, and physical facilities could be breached, or confidential or proprietary information could be otherwise compromised due to employee error or malfeasance, third parties may also exploit vulnerabilities in, or obtain unauthorized access to, platforms, systems, networks and/or physical facilities utilized by our third-party service providers.

If a cyberattack or other security incident were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other confidential or proprietary information or other similar disruptions. For example, the loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. The costs to respond to a security breach and/or to mitigate any security vulnerabilities that may be identified could be significant, our efforts to address these issues may not be successful, and these issues could result in interruptions, delays, cessation of service, negative publicity, loss of public trust, delays in the development and commercialization of our product candidates. Any security breach may also result in regulatory inquiries or action, litigation, or other investigations, fines, penalties, and damages, any of which can affect our financial and operational condition.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. Many jurisdictions have enacted laws requiring companies to notify individuals, regulatory authorities, and others of security breaches involving certain types of data. In addition, our agreements with certain counterparties and partners may require us to notify them in the event of a security breach. Such mandatory disclosures are costly, could lead to negative publicity, may cause the public to lose confidence in the effectiveness of our security measures and require us to expend significant

capital and other resources to respond to and/or alleviate problems caused by an actual or perceived security breach.

Further, security compromises experienced by our collaborators, business partners, patients or employees with respect to data hosted on our platform, internal computer systems, and/or cloud-based computing services, even if caused by third-party misuse or negligence, may lead to loss, unauthorized access, or public disclosures of such data, which could harm our reputation, erode confidence in the effectiveness of our security measures, negatively impact our ability to attract new collaborators or other business relationships, or cause existing contractual counterparties to elect not to renew their agreements with us. Any data breach by service providers that are acting as data processors and processing personal information on our behalf could also mean that we are subject to these fines and must comply with the notification obligations set out above.

Unauthorized access to our platform, systems, networks, or physical facilities could result in litigation with or liabilities to our contractual counterparties or other relevant stakeholders, which may adversely affect our business. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. While we maintain cybersecurity insurance, we could still be required to spend money in defense or settlement, divert management's time or attention, fundamentally change our business activities and practices or modify our products and/or platform capabilities, which could have an adverse effect on our business. Litigation could also increase our costs of doing business or adversely affect our reputation.

Our risks are likely to increase as we continue to expand, and process, store, and transmit increasingly large amounts of proprietary and sensitive data and we may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. In addition, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data, as well as regulatory compliance obligations and risks.

Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. Our employees and personnel may use generative artificial intelligence ("AI") technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us. Providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

To the extent we and our vendors incorporate artificial intelligence technologies into our business processes, we may face new and uncertain regulatory risks and compliance costs relating to the use of such technologies. For example, the European Union's proposed Artificial Intelligence Act may, once passed, require us to undertake costly compliance obligations, including detailed risk assessments, to implement or use artificial intelligence technologies, with the risk of significant administrative penalties and potential claims in the event of non-compliance. In the United States and elsewhere, legislators and regulators are

considering or imposing new requirements on the use of artificial intelligence. For example, in October 2023 President Biden signed an executive order to manage the risks presented by AI. These emerging standards may require us to modify our business practices and implement new policies, processes and procedures to comply. We may also face fines, claims, or other enforcement under uncertain legislative and regulatory standards as best practices for the use of artificial intelligence technologies continue to evolve.

We, our CROs, CMOs, clinical trial sites and other consultants or contractors on which we rely, are subject to stringent and changing laws, regulations and standards, contractual obligations, industry standards, policies and other obligations related to data privacy and security. The actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims); fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences for our business, results of operations, and financial condition.

In the ordinary course of business, we process personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, and data we collect about trial participants in connection with clinical trials. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security. Data privacy and security have become a significant focus in the United States and abroad. The regulatory framework for privacy issues is rapidly evolving and is likely to remain uncertain for the foreseeable future. Many government bodies and agencies have adopted or are considering adopting laws and regulations regarding the collection, use, processing, storage, transmission, destruction, and disclosure of personal information and breach notification procedures. We are also required to comply with laws, rules and regulations relating to data security. Interpretation of these laws, rules and regulations in applicable jurisdictions is ongoing and cannot be fully determined at this time.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws and video privacy protection laws). In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data, and allow for statutory fines for noncompliance. As we expand our operations, these laws which vary from jurisdiction to jurisdiction, may increase our compliance costs and potential liability.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms to ensure compliance with these and new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations.

Outside the United States, an increasing number of laws, regulations and industry standards govern data privacy and security. For example, European Union's the General Data Protection Regulation (GDPR), and the United Kingdom's GDPR (UK GDPR) also impose significant privacy and security compliance obligations, as well as restrictions on the transfer of personal information from Europe to the United States and most other non-European Economic Area countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the

interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups.

As a result of our clinical development, we, our clinical investigators, CROs and consultants may have access to sensitive data regarding the patients enrolled in our clinical trials, and our current and future product candidates will rely on the use of patient and donor data and material. This data will contain information that is personal in nature, and the maintenance of this data is subject to certain privacy-related laws, such as GDPR, the U.S. Health Insurance Portability and Accountability Act (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act and U.S. state privacy laws. These rules inter alia require that written authorizations from patients are obtained, and that policies, procedures and reasonable and appropriate security measures are implemented that protect individually identifiable health and other information we receive and to ensure that such information is used only as authorized by the patient. If the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we will not be allowed access to the patient's information and our research efforts can be substantially delayed. Also, any violations of these rules by us could subject us to civil and criminal penalties and adverse publicity and could harm our ability to initiate and complete clinical trials.

Complying with the GDPR and other related foreign privacy laws and regulations may cause us to incur substantial operational costs or require us to change our business practices. Despite our efforts to bring our practices into compliance with these laws and regulations, we may not be successful in our efforts to achieve compliance either due to internal or external factors such as resource allocation limitations or a lack of vendor cooperation. Any inability to adequately address privacy concerns, even if unfounded, or comply with applicable privacy or data protection laws, regulations and policies, could result in additional cost and liability to us, damage our reputation, inhibit sales and adversely affect our business, results of operations and financial condition. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the GDPR or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended (FCPA) the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, other state and U.S. national and foreign anti-bribery and anti-money laundering laws in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We interact with officials and employees of U.S. and foreign government agencies and government-affiliated hospitals, universities and other organizations. In addition, we may engage third-party intermediaries to promote our clinical research activities in the U.S. Europe, or other foreign countries to obtain necessary permits, licenses and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

We adopted a Code of Business Conduct and Ethics and implemented policies and procedures to ensure compliance with such code. The Code of Business Conduct and Ethics mandates compliance with the FCPA and other comparable anti-corruption laws applicable to our business throughout the world. However, we cannot be assured that our employees and third-party intermediaries will comply with this code or such anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions,

disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas, investigations or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

2.5.7 Risks related to ownership of our common shares

The market price of our common shares has been, and may continue to be volatile and fluctuate substantially, and you could lose all or part of your investment and may subject us to securities litigation suits.

The market price of our common shares is volatile. The stock market in general and the market for biopharmaceutical and pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, holders of our common shares may lose all or part of their investment. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this annual report, the market price for our common shares may be influenced by, among others, the following:

- the enrollment or results of our clinical trials for LAVA-1207 and the commencement of enrollment or results of our other or future product candidates, collaboration partners or those of our competitors;
- the success of competitive products or therapies or announcements by potential competitors of their product development efforts;
- regulatory or legal developments in the United States, the Netherlands, Europe more broadly and other jurisdictions;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or shareholder litigation;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our common shares;
- announcement or expectation of additional financing efforts or sales by our shareholders;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States, Europe and elsewhere;
- changes in the structure of healthcare payment systems; and
- investors' general perception of us and our business.

In addition, some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming and could divert our management's attention and our resources. Furthermore, during litigation, there could be

negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common shares.

Investors may have difficulty enforcing civil liabilities against us or the members of our board of directors and our officers (functionarissen).

We are organized and existing under the laws of the Netherlands. As such, under Dutch private international law, the rights and obligations of our shareholders vis-à-vis the Company originating from Dutch corporate law and our articles of association, as well as the civil liability of our officers (*functionarissen*) (including our directors and executive officers) are governed in certain respects by the laws of the Netherlands.

We are not a resident of the United States and our officers may also not all be residents of the United States. As a result, depending on the subject matter of the action brought against us and/or our officers, United States courts may not have jurisdiction. If a Dutch court has jurisdiction with respect to such action, that court will apply Dutch procedural law and Dutch private international law to determine the law applicable to that action. Depending on the subject matter of the relevant action, a competent Dutch court may apply another law than the laws of the United States.

Also, service of process against non-residents of the United States can in principle (absent, for example, a valid choice of domicile) not be effected in the United States.

Furthermore, substantially all of our assets are located outside the United States. On the date of this annual report, (i) there is no treaty in force between the United States and the Netherlands for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters and (ii) both the Hague Convention on Choice of Court Agreements (2005) and the Hague Judgments Convention (2019) have entered into force for the Netherlands, but have not entered into force for the United States. Consequently, a judgment rendered by a court in the United States will not automatically be recognized and enforced by the competent Dutch courts. However, if a person has obtained a judgment rendered by a court in the United States that is enforceable under the laws of the United States and files a claim with the competent Dutch court, the Dutch court will in principle give binding effect to that United States judgment if (i) the jurisdiction of the United States court was based on a ground of jurisdiction that is generally acceptable according to international standards, (ii) the judgment by the United States court was rendered in legal proceedings that comply with the Dutch standards of proper administration of justice including sufficient safeguards (*behoorlijke rechtspleging*), (iii) binding effect of such United States judgment is not contrary to Dutch public order (*openbare orde*) and (iv) the judgment by the United States court is not incompatible with a decision rendered between the same parties by a Dutch court, or with a previous decision rendered between the same parties by a foreign court in a dispute that concerns the same subject and is based on the same cause, provided that the previous decision qualifies for recognition in the Netherlands. Even if such a United States judgment is given binding effect, a claim based thereon may, however, still be rejected if the United States judgment is not or no longer formally enforceable. Moreover, if the United States judgment is not final (for instance when appeal is possible or pending) a competent Dutch court may postpone recognition until the United States judgment will have become final, refuse recognition under the understanding that recognition can be asked again once the United States judgment will have become final, or impose as a condition for recognition that security is posted.

A competent Dutch court may deny the recognition and enforcement of punitive damages or other awards. Moreover, a competent Dutch court may reduce the amount of damages granted by a United States court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Thus, United States investors may not be able, or experience difficulty, to enforce a judgment obtained in a United States court against us or our officers.

Provisions of our articles of association or Dutch corporate law might deter acquisition bids for us that might be considered favorable and prevent, delay or frustrate any attempt to replace or dismiss directors.

Under Dutch law, various protective measures are possible and permissible within the boundaries set by Dutch law and Dutch case law.

In this respect, our general meeting authorized our board of directors to grant a call option during a period of five years following the closing of this offering to an independent foundation under Dutch law (if and when incorporated), or protective foundation, to acquire preferred shares pursuant to a call option agreement, or the call option agreement, that may be entered into between us and such protective foundation after the closing of this offering. This call option, if and when granted, shall be continuous in nature and can be exercised repeatedly on multiple occasions. If the protective foundation, if and when incorporated, would exercise such call option, if and when granted, a number of preferred shares up to 100% of our issued share capital held by others than the protective foundation, minus one share, will be issued to the protective foundation. These preferred shares would then be issued to the protective foundation under the obligation to pay up 25% of their nominal value. In order for the protective foundation to finance the issue price in relation to the preferred shares, the protective foundation may enter into a finance arrangement with a bank or other financial institution. As an alternative to securing this external financing, subject to applicable restrictions under Dutch law, the call option agreement, if and when entered into, may provide that the protective foundation may request us to provide, or cause our subsidiaries to provide, sufficient funding to the protective foundation to enable it to satisfy the payment obligation (or part thereof) in cash and/or to charge an amount equal to the payment obligation (or part thereof) against our profits and/or reserves in satisfaction of such payment obligation. The articles of association of the protective foundation, if and when incorporated, will provide that it will promote and protect the interests of our company, the business connected with it and our stakeholders from time to time, and repressing possible influences which could threaten the strategy, continuity, independence and/or identity of our company or the business connected with it, to such an extent that this could be considered to be damaging to the aforementioned interests. These influences may include a third party acquiring a significant percentage of our common shares, the announcement of an unsolicited public offer for our common shares, shareholder activism, other concentration of control over our common shares or any other form of undue pressure on us to alter our strategic policies. The protective foundation, if and when incorporated, shall be structured to operate independently of us. The voting rights of our shares are based on nominal value and, as we expect our common shares to trade substantially in excess of their nominal value, preferred shares issued at 25% of their nominal value can carry significant voting power for a substantially reduced price compared to the price of our common shares and thus can be used as a defensive measure. These preferred shares, if and when issued, will have both a liquidation and dividend preference over our common shares and will accrue cash dividends at a fixed rate calculated over the amount paid-up on those preferred shares pro rata tempore for the period during which they were outstanding. The protective foundation would be expected to require us to cancel its preferred shares, if and when issued to the protective foundation, once the perceived threat to our company, its business and its stakeholders has been removed or sufficiently mitigated or neutralized. However, subject to the same limitations described above, the protective foundation would, in that case, continue to have the right to exercise the call option in the future in response to a new threat to the interests of our company, our business and our stakeholders from time to time.

Also certain provisions of our articles of association may make it more difficult for a third-party to acquire control of us or effect a change in the composition of our board of directors. These include:

- a provision that our directors can only be appointed on the basis of a binding nomination prepared by our board of directors which can only be overruled by a two-thirds majority of votes cast representing more than half of our issued share capital;
- a provision that our directors can only be dismissed by the general meeting by a two-thirds majority of votes cast representing more than half of our issued share capital, unless the dismissal is proposed by our board of directors in which latter case a simple majority of the votes cast would be sufficient;
- a provision allowing, among other matters, the former chairperson of our board of directors or our former Chief Executive Officer to manage our affairs if all of our directors are dismissed and to appoint others to be charged with our affairs, including the preparation of a binding nomination for our directors as discussed above, until new directors are appointed by the general meeting on the basis of such binding nomination; and
- a requirement that certain matters, including an amendment of our articles of association, may only be resolved upon by our general meeting if proposed by our board of directors.

Dutch law also allows for staggered multi-year terms of our directors, as a result of which only part of our directors may be subject to appointment or re-appointment in any given year.

Furthermore, in accordance with the Dutch Corporate Governance Code, or DCGC, shareholders who have the right to put an item on the agenda for our general meeting or to request the convening of a general meeting shall not exercise such rights until after they have consulted our board of directors. If exercising such rights may result in a change in our strategy (for example, through the dismissal of one or more of our directors), our board of directors must be given the opportunity to invoke a reasonable period of up to 180 days to respond to the shareholders' intentions. If invoked, our board of directors must use such response period for further deliberation and constructive consultation, in any event with the shareholder(s) concerned and exploring alternatives. At the end of the response time, our board of directors shall report on this consultation and the exploration of alternatives to our general meeting. The response period may be invoked only once for any given general meeting and shall not apply (i) in respect of a matter for which either a response period or a statutory cooling-off period (as discussed below) has been previously invoked or (ii) in situations where a shareholder holds at least 75% of our issued share capital as a consequence of a successful public bid.

Moreover, our board of directors can invoke a cooling-off period of up to 250 days when shareholders, using their right to have items added to the agenda for a general meeting or their right to request a general meeting, propose an agenda item for our general meeting to dismiss, suspend or appoint one or more directors (or to amend any provision in our articles of association dealing with those matters) or when a public offer for our company is made or announced without our support, provided, in each case, that our board of directors believes that such proposal or offer materially conflicts with the interests of our company and its business. During a cooling-off period, our general meeting cannot dismiss, suspend or appoint directors (or amend the provisions in our articles of association dealing with those matters) except at the proposal of our board of directors. During a cooling-off period, our board of directors must gather all relevant information necessary for a careful decision-making process and at least consult with shareholders representing 3% or more of our issued share capital at the time the cooling-off period was invoked, as well as with our Dutch works council (if we or, under certain circumstances, any of our subsidiaries would have one). Formal statements expressed by these stakeholders during such consultations must be published on our website to the extent these stakeholders have approved that publication. Ultimately one week following the last day of the cooling-off period, our board of directors must publish a report on its policy and conduct of affairs on our website. This report must remain available for inspection by shareholders and others with meeting rights under Dutch law at our office and must be tabled for discussion at the next general meeting. Shareholders representing at least 3% of our issued share capital may request the Enterprise Chamber of the Amsterdam Court of Appeal, or the Enterprise Chamber (*Ondernemingskamer*), for early termination of the cooling-off period. The Enterprise Chamber must rule in favor of the request if the shareholders can demonstrate that:

- our board of directors, in light of the circumstances at hand when the cooling-off period was invoked, could not reasonably have concluded that the relevant proposal or hostile offer constituted a material conflict with the interests of our company and its business;
- our board of directors cannot reasonably believe that a continuation of the cooling-off period would contribute to careful policy-making; or
- other defensive measures, having the same purpose, nature and scope as the cooling-off period, have been activated during the cooling-off period and have not since been terminated or suspended within a reasonable period at the relevant shareholders' request (i.e., no 'stacking' of defensive measures).

Shareholders may not be able to exercise pre-emption rights and, as a result, may experience substantial dilution upon future issuances of common shares or grants of rights to subscribe for shares.

In the event of an issuance of common shares or a grant of rights to subscribe for common shares, subject to certain exceptions, each shareholder will have a pro rata pre-emption right in proportion to the aggregate nominal value of such holder's common shares. These pre-emption rights may be restricted or excluded by a resolution of the general meeting or by another corporate body designated by the general meeting. Our board of directors has been authorized until March 2026 to issue shares or grant rights to subscribe for shares up to

our authorized share capital from time to time and to limit or exclude pre-emption rights, the issuance of common shares or other equity securities could cause existing shareholders to experience substantial dilution.

Concentration of ownership of our common shares among our existing executive officers, directors and principal shareholders may prevent new investors from influencing significant corporate decisions.

Our executive officers, directors and shareholders who own more than 5% of our outstanding common shares as of February 28, 2024, in the aggregate, beneficially own shares representing approximately 71.5% of our outstanding common shares. If our executive officers, directors and shareholders who own more than 5% of our outstanding common shares acted together, they may be able to significantly influence all matters requiring shareholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. The concentration of voting power and transfer restrictions could delay or prevent an acquisition of our company on terms that other shareholders may desire or result in the management of our company in ways with which other shareholders disagree.

We will need to raise additional capital, which may not be available on acceptable terms, or at all. Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We do not have any committed external source of funds. To the extent that we raise additional capital, if available, through the sale of equity or convertible debt securities, your ownership interest in our company may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing shareholders. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common shares to decline and existing stockholders may not agree with our financing plans or the terms of such financings. Adequate additional financing may not be available to us on acceptable terms, or at all.

If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us, if at all. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product candidate development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

Modifications will involve additional costs. In addition, we would lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to FPIs.

2.5.8. Risks related to financial reporting

We incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

We are an emerging growth company (EGC), as defined in the Jumpstart Our Business Startups Act of 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act; and to the extent that we no longer qualify as a foreign private issuer, (a) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and (b) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation, including golden parachute compensation. We cannot predict whether investors will find our common shares less attractive if we rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be reduced or more volatile.

As a public company, and particularly after we are no longer an EGC, if we choose in the future to file on domestic forms to take advantage of certain exemptions for smaller reporting companies, or are no longer eligible to elect to be treated as a smaller reporting company, we may incur additional legal, accounting and other expenses. The Sarbanes-Oxley Act, and rules subsequently implemented by the U.S. Securities and Exchange Commission (SEC), the Nasdaq Stock Market LLC (Nasdaq), the Dutch Civil Code (DCC) and the Dutch Corporate Governance Code (DCGC) impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. In addition, our management and other personnel need to devote a substantial amount of time to comply with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies.

We are subject to Section 404 of the Sarbanes-Oxley Act (Section 404) and are required to furnish a report by our management on our internal control over financial reporting. Once we are no longer an EGC, we will also be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We would cease to be an EGC upon the earliest to occur of (i) the last day of the fiscal year in which we have more than $1.235 billion in annual gross revenues; (ii) the date we qualify as a “large accelerated filer,” with at least $700.0 million of equity securities held by non-affiliates; (iii) the issuance, in any three-year period, by our Company of more than $1.0 billion in nonconvertible debt securities held by non-affiliates; and (iv) December 31, 2026. To ensure compliance with Section 404(a) of the Sarbanes-Oxley Act, we have engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, hire additional qualified accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm once we are subject to Section 404(b) of the Sarbanes-Oxley Act, will be able to conclude that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Pursuant to the DCC, Dutch limited liability companies may qualify as a so-called structure company (*structuurvennootschap*) to which the large company regime (*structuurregime*) is applicable. Currently, the requirements to qualify as such are that a company has filed a statement with the trade register of the Dutch Chamber of Commerce, for a consecutive period of three years, stating that it meets the following criteria (i) according to our balance sheet with explanatory notes, our issued share capital together with our reserves amounts to at least Euro (EUR) 16 million, (ii) we, or any of our dependent companies (as defined by Dutch law), has established a Dutch works council pursuant to statutory requirements under Dutch law and (iii) we and our dependent companies (as defined by Dutch law) together regularly employ at least 100 employees in the Netherlands. The qualification as a structure company may affect the governance structure of our company. Among other things, our executive directors would then be appointed by our non-executive directors (instead of the general meeting) and certain nomination rights (including for the Dutch works council) would apply to the appointment of our non-executive directors. We have never filed a statement that we meet the criteria of the structure regime and do not expect to qualify as a structure company for at least the next three years.

We have identified material weaknesses in our internal control over financial reporting. If we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common shares.

Although we are not yet subject to the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act, we are responsible for designing, establishing and maintaining internal control over our financial reporting. In connection with the preparation of our financial statements as of and for the year ended December 31, 2023, we identified control deficiencies that we concluded represented material weaknesses in our internal control over financial reporting across the principles for certain components of the Committee of Sponsoring Organizations of the Treadway Commission (COSO) 2013 framework at the entity level (*i.e.* monitoring, information & communication and control activities) and accordingly, across our business and IT processes. The material weaknesses that we identified related to:

(a) inadequate general controls over information technology, among which are the lack of change management and software development Life cycle (SDLC) procedures and insufficient level of user access controls to key financial systems, and
(b) our ability to design and maintain appropriate segregation of duties.

We have taken measures during the year ended December 31, 2023 to remediate these material weaknesses and to further enhance our internal control over financial reporting for the year ended December 31, 2023. However, the weaknesses discussed above will not be considered remediated until the appliable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. As such, we cannot consider these material weaknesses as remediated as of December 31, 2023.

We may discover additional weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are unable to maintain proper and effective internal controls over financial reporting, or identify any material weakness, we may not be able to produce timely and accurate financial statements which could result in material misstatements in our financial statements and potentially require us to restate our financial

statements. If we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, when required, our investors could lose confidence in the accuracy and completeness of our reported financial information, the market price of our shares could be materially adversely affected, we could face restricted access to the capital markets, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

While we have been taking measures and plan to continue to take measures to design and implement an effective control environment, we cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to prevent future material weaknesses.

These material weaknesses could result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected. However, the previously identified material weaknesses did not result in a misstatement to the annual consolidated financial statements previously filed or included in this Annual Report on Form 20-F.

See "*Item 8. Controls and Procedures"* for additional information regarding these material weaknesses.

As a foreign private issuer, we are permitted to, and do, follow certain home country corporate governance practices instead of otherwise applicable Nasdaq requirements, and we will not be subject to certain U.S. securities laws including, but not limited to, U.S. proxy rules and the filing of certain Exchange Act reports. If we lose our status as a foreign private issuer, additional reporting obligations may apply.

As a foreign private issuer (FPI) we are permitted to, and do, follow certain home country corporate governance practices instead of those otherwise required by Nasdaq for domestic U.S. issuers, including with respect to shareholder approval of certain security issuances. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on Nasdaq may provide less protection to you than what is accorded to investors under the listing rules of Nasdaq applicable to domestic U.S. issuers.

As an FPI, we are exempt from the rules and regulations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, related to the furnishing and content of proxy statements, including the applicable compensation disclosure requirements. Our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act and we are exempt from filing quarterly reports with the SEC under the Exchange Act. Moreover, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information, although we have voluntarily adopted a corporate disclosure policy substantially similar to Regulation FD. These exemptions and leniencies reduce the frequency and scope of information and protections you may otherwise have been eligible in relation to a U.S. domestic issuer.

We would lose our foreign private issuer status if a majority of our shares are owned by U.S. residents and a majority of our directors or executive officers are U.S. citizens or residents or we fail to meet additional requirements necessary to avoid loss of foreign private issuer status. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly higher, including filing more detailed and extensive periodic reports and registration statements on U.S. domestic issuer forms with the SEC, convert to accounting principles generally accepted in the U.S. (U.S. GAAP) and modify certain of our policies to comply with accepted governance practices associated with U.S. domestic issuers. Such conversion and modifications will involve additional costs. In addition, we would lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to FPIs.

2.5.9. General Risk Factors

Further downgrades of the U.S. credit rating, automatic spending cuts, or another government shutdown could negatively impact our liquidity, financial condition and earnings.

U.S. debt ceiling and budget deficit concerns have increased the possibility of additional credit-rating downgrades and economic slowdowns, or a recession in the United States. Although U.S. lawmakers have previously passed legislation to raise the federal debt ceiling on multiple occasions, ratings agencies have lowered or threatened to lower the long-term sovereign credit rating on the United States. The impact of this or any further downgrades to the U.S. government's sovereign credit rating or its perceived creditworthiness could adversely affect the U.S. and global financial markets and economic conditions. Moreover, absent further quantitative easing by the Federal Reserve, these developments could cause interest rates and borrowing costs to rise, which may negatively impact our ability to access the U.S. debt markets on favorable terms. In addition, disagreement over the federal budget has caused the U.S. federal government to shut down for periods of time. Continued adverse political and economic conditions could have a material adverse effect on our business, financial condition and results of operations.

3 LEGAL PROCEEDINGS

From time to time, the Company is involved in legal proceedings and adjudications generally incidental to its normal business activities, none of which has had, individually or in the aggregate, a material adverse impact on the Company. The Company accrues for loss contingencies when a present obligation (legal or constructive) has arisen as a result of a past event, payment is probable, and the amount can be estimated reliably. These estimates are based on an analysis made by internal and external legal counsel considering information known at the time. Legal costs in connection with loss contingencies are expensed as incurred. The Company believes that the resolution of any current legal matters will not have a material adverse impact on its financial position or results of operations.

4 OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion of our financial condition and results of operations in conjunction with the consolidated financial statements included in the "Consolidated financial statements" and the Notes included elsewhere in this report. The following discussion contains forward-looking statements that involve certain risks and uncertainties. Our actual results could differ materially from those discussed in these statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report, particularly under the "Risk factors" and "Cautionary Note Regarding Forward-Looking Statements" sections.

Our audited consolidated financial statements are included elsewhere in this report.

4.1 Operating Results

Global Conditions

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 the Russian invasion of Ukraine and the Israel-Hamas war.

Components of operating results

Revenue from research and license agreements

To date, we have not generated any revenue from product sales, and we do not expect to generate any revenue from the sale of products in the near future. Our success depends primarily on the successful development and regulatory approval of our product candidate, development candidates and collaborator candidates and our ability to finance operations. If our development efforts result in clinical success and regulatory approval for our product candidate, development candidates or collaborator candidates, or we

enter into collaboration agreements with third parties for additional product candidates, we may generate revenue from those product candidates.

In September 2022, we entered an agreement with Seagen (acquired by Pfizer in December 2023 (Pfizer Agreement)) to develop, manufacture and commercialize PF-8046052 (formerly LAVA-1223), an advanced preclinical asset that utilizes our proprietary Gammabody technology to target EGFR-expressing solid tumors. Under the Pfizer Agreement, we received a $50 million nonrefundable upfront payment in October 2022 and are eligible to receive up to approximately $650 million upon the achievement of development, regulatory and commercial milestones, as well as royalties ranging from the single digits to the mid-teens on future sales. The Pfizer Agreement also provides Pfizer with the opportunity to exclusively negotiate rights to apply our proprietary Gammabody platform on up to two additional tumor targets until mid-year 2024, which could result in additional payments to us. In March 2024, Pfizer paid us $7 million for achieving a clinical development milestone.

Pfizer has also granted us a one-time option to obtain increased royalties if we exercise a buy up option within a certain amount of time from certain key early clinical data becoming available for the first licensed product. Following notice, we have a specified period to exercise the buy-up option to pay Pfizer a one-time $35 million fee, the (buy-up fee). In the event we exercise the buy-up option and pay the buy-up fee, we are entitled to receive tiered royalties based on commercial sales levels from low teen to high teen percentages of net sales of licensed products.

Royalties are payable on a licensed product-by-licensed product and country-by-country basis beginning with the first commercial sale of such licensed product in such country of sale and expiring ten years after such sale, subject to specified and capped reductions for the market entry of biosimilar products, loss of patent coverage of licensed products, and for payments owed to third parties for additional rights necessary to commercialize licensed products in the territory. For additional information, see “License Agreements – Pfizer Agreement” and Note 4 to the consolidated financial statements.

In May 2020, we entered into the Janssen Agreement. As part of the Janssen Agreement, we received a non-refundable upfront payment of $8.0 million. As of December 31, 2023, there was no unearned income related to this payment. The revenue related to the upfront payment was recognized as revenue on a straight-line basis over the term of the research activities under the Janssen Agreement, as this method approximated the underlying research and development activities over time. In December 2020, we achieved the first Research Milestone, as defined in the Janssen Agreement, triggering a milestone payment of $1.0 million. In 2021, we achieved the second Research Milestone, triggering a milestone payment of $1.0 million. In May 2023, within the framework of the Janssen Agreement, Janssen selected a lead bispecific antibody utilizing the Gammabody platform for an undisclosed tumor associated antigen to progress into development, and we received a $2.5 million milestone payment. Efforts are underway to advance the candidate towards the clinic. Each milestone payment was recorded as revenue when achieved, as each was linked to the completion of specific and separable research and development deliverables, rather than recorded over time like the upfront payment.

We are entitled to receive tiered royalties based on commercial sales levels from low to mid-single digit percentages of net sales of licensed products. Royalties are payable on a licensed product-by-licensed product and country-by-country basis beginning with the first commercial sale of such licensed product in such country of sale and expiring ten years after such sale, subject to specified and capped reductions for the market entry of biosimilar products, loss of patent coverage of licensed products, and for payments owed to third parties for additional rights necessary to commercialize licensed products in the territory. For additional information, see “License Agreements – Janssen Agreement” and Note 4 to the consolidated financial statements.

Operating expenses

Our primary categories of operating expenses are research and development expenses and general and administrative expenses.

Research and development expenses consist primarily of the costs incurred in performing research and development activities and conducting preclinical studies and clinical trial activities. Our research and development expenses consist of:

- personnel-related expenses such as salaries, employee benefits and share-based compensation for employees engaged in research and development;
- expenses incurred under agreements with contract manufacturing organizations (CMOs), contract research organizations (CROs), and consultants that conduct and support preclinical studies and clinical trial activities;
- expenses incurred in connection with the master research services agreement with the Amsterdam UMC;
- costs associated with obtaining and maintaining patents and other intellectual property; and
- expenses including laboratory supplies and research materials, facility expenses, and depreciation of research and development fixed assets.

We expense research and development costs as incurred. We do not allocate employee-related costs, costs associated with our discovery efforts, laboratory supplies, depreciation, facility expenses or other indirect costs to specific product development programs because these costs are deployed across multiple programs, and as such, are not separately classified.

Although our research and development expenses decreased in 2023 as compared to 2022 in connection with the discontinuation of the LAVA-051 development program, we expect that our research and development expenses will increase substantially in connection with our ongoing and planned preclinical and clinical development activities in the near term and in the future.

General and administrative expenses consist of personnel-related expenses for employees involved in general corporate functions, including accounting, finance, insurance, tax, legal and human relations, costs associated with outside professional fees such as legal counsel and auditors, costs associated with use by these functions of facilities and equipment, such as facility expenses, depreciation expenses, other operating costs not included in research and development, and general corporate expenses. General and administrative expenses are expensed as incurred.

Although our general and administrative expenses decreased in 2023 as compared to 2022 in connection with cost cutting initiatives, we expect general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development activities.

Income tax

We are subject to income taxes in the Netherlands and the United States.

A tax charge was recognized during the year ended December 31, 2023 due to the U.S. profitable position as a result of a cost plus intercompany remuneration. As of December 31, 2023, we had Dutch tax loss carryforwards of $70.3 million. Furthermore, an amount of $72.1 million of IP development costs was capitalized for tax purposes as of December 31, 2023. This amount can be amortized and offset against future income derived from this IP.

The 2023 taxable amount is not final as the 2023 Dutch corporate income tax return is still in draft. The 2021 and 2022 Dutch corporate income tax returns are final and have been filed in time.

On the basis of the 2023 annual accounts, there are accounting-to-tax differences of $9.7 million. These differences primarily relate to the amortization of IP development costs capitalized for Dutch corporate income tax purposes in preceding years, the capitalization of IP development expenses incurred in 2023 for Dutch corporate income tax purposes and IFRS 16 lease amounts. Other differences relate to non-deductible share-based payment expenses, expenses which were treated as non-deductible for Dutch corporate income tax purposes and other non-deductible mixed expenses.

For further information on tax loss carryforwards under Dutch corporate income tax law, please refer to Note 9 of the consolidated financial statements.

Comparison of the Years Ended December 31, 2023 and 2022:

Revenue from contracts with customers

Our revenue from contracts with customers was $6.8 million and $19.4 million for the years ended December 31, 2023 and 2022, respectively.

In connection with the Pfizer Agreement we entered into in September 2022, we recognized $4.3 in revenue for the year ended December 31, 2023. Of that amount, $3.7 million primarily relates to the initial supply and manufacturing technology transfer related stability studies and $0.6 million relates to reimbursement of additional services. For the year ended December 31, 2022 we recognized $17.9 million in revenue in connection with the Pfizer Agreement. Of that amount, $15.2 million related to the nonrefundable upfront payment and $2.7 million related to reimbursement for manufacturing technology transfer and research activities. We determined that the one-time buy-up fee of $35.0 million represents variable consideration, for which we have deferred revenue recognition until such time we choose to exercise the option or allow it to expire.

Additionally, we had revenue from contracts with customers of $2.5 million and $1.5 million for the years ended December 31, 2023 and 2022, respectively, attributable to our Janssen Agreement. The revenue for the year ended December 31, 2023 related to a $2.5 million milestone that was triggered under the Janssen Agreement following the selection of a lead bispecific antibody utilizing the Gammabody platform for an undisclosed tumor associated antigen. In connection with this collaboration, we received a non-refundable upfront payment of $8.0 million in 2020 that was recognized on a straight-line basis over the two-year term of the research activities under the Janssen Agreement, as this method approximated the underlying research and development activities over time. The revenue for the year ended December 31, 2022 only related to the straight-line recognition of the upfront payment. As of December 31, 2023 and 2022, we had no remaining unearned income related to this upfront payment.

Cost of sales of goods and providing services

Our cost of sales of goods and providing services was $3.5 million and zero for the years ended December 31, 2023 and 2022, respectively, related to the cost of the initial supply delivery and related stability studies under the Pfizer Agreement. For the year ended December 31, 2023, $2.6 million related to costs of product materials and $0.9 million related to costs of services related to stability studies for the product materials.

Research and development expenses

Below are our research and development expenses for the years ended December 31, 2023 and 2022:

	For the Year Ended December 31,		
(in thousands)	2023	2022	Variance
Pre-clinical and clinical trial expenses	$ 20,421	$ 28,178	$ (7,757)
Personnel-related expenses	6,629	6,150	479
Research and development activities expenses	2,680	2,241	439
Facilities and other research and development expenses	2,356	1,546	810
Share-based compensation expense	1,728	1,975	(247)
Amsterdam UMC and other license expenses	—	15	(15)
	$ 33,814	**$ 40,105**	**$ (6,291)**

Research and development expenses were $33.8 million for the year ended December 31, 2023, compared to $40.1 million for the year ended December 31, 2022. Pre-clinical and clinical trial expenses decreased by $7.8 million primarily due to reduced manufacturing scale-up costs, negotiated reduction in contract manufacturing invoices, and reduced clinical trial activities due to the discontinuation of our LAVA-051 clinical trial, announced in June 2023. Personnel-related expenses increased by $0.5 million primarily due to increased research and development headcount during 2023, compared to 2022, and the severance costs as a result of research and development headcount reductions in the second half of 2023. Research and

development activity expenses increased by $0.4 million primarily due to increased patent renewal fees. Facilities and other research and development expenses increased by $0.8 million due to increased office and laboratory leases, costs related to move into our new facilities and increased travel costs. Non-cash share-based compensation expenses decreased by $0.2 million primarily due to the reversal of expenses associated with research and development headcount reductions.

General and administrative expenses

Below are our general and administrative expenses for the years ended December 31, 2023 and 2022:

	For the Year Ended December 31,		
(in thousands)	**2023**	**2022**	**Variance**
Personnel-related expenses	$ 3,812	$ 5,010	$ (1,198)
Professional and consultant fees	2,869	3,954	(1,085)
Insurance, facilities, fees and other related costs	2,734	3,022	(288)
Share-based compensation expense	3,311	2,138	1,173
	$ 12,726	**$ 14,124**	**$ (1,398)**

General and administrative expenses were $12.7 million for the year ended December 31, 2023, compared to $14.1 million for the year ended December 31, 2022. Personnel-related expenses decreased $1.2 million due to reduction in general and administrative headcount for the year ended December 31, 2023, as compared to the year ended December 31, 2022. Professional and consultant fees decreased by $1.1 million due to reduced recruitment, legal and financing advice cost. Insurance, facilities, fees and other related costs decreased by $0.3 million primarily due to decreases in directors' and officers' insurance costs partly offset by increased costs of leased office space. The increase of $1.2 million in share-based compensation expense was primarily due to the reversal of expenses associated with stock option forfeitures due to the departure of our former chief financial officer in 2022.

Interest income (expense), net

Interest income, net increased $2.7 million, from income of $0.3 million for the year ended December 31, 2022, to $3.0 million for the year ended December 31, 2023. Interest income, net includes interest income from cash equivalents and investments, net of interest on borrowings associated with our Innovation Credit from *Rijksdienst voor Ondernemend Nederland*, lease interest and negative interest on cash deposits held at financial institutions in 2022.

Foreign currency exchange gain (loss), net

Our foreign currency exchange gain decreased $4.3 million, from a gain of $2.9 million for the year ended December 31, 2022, to a loss of $1.4 million for the year ended December 31, 2023. This decrease was due to the impact of the fluctuation of the USD currency rate compared to the Euro on transaction gains and losses on cash and investments and other transactions denominated in USD held and occurring in the Euro functional currency entity.

Comparison of the Years Ended December 31, 2022 and 2021

For discussion of the year ended December 31, 2022, compared to 2021, refer to Item 4 in our December 31, 2022 Annual Report.

4.2 Liquidity and Capital Resources

As of December 31, 2023, we had cash, cash equivalents and investments totaling $95.6 million, compared to cash and cash equivalents of $132.9 million as of December 31, 2022. We hold our cash and cash equivalents in both USD and Euros. We have historically funded our operations primarily through issuance of preference shares prior to our IPO, from the sale of common shares in our IPO and more recently through

research and licensing revenue and receipt of milestone payments under our collaboration agreements. Our expenditures are primarily related to research and development activities and general and administrative activities to support business operations.

In October 2022, we received a nonrefundable up-front payment of $50.0 million in connection with entering into the Pfizer Agreement.

In 2019, we received a $5.5 million Innovation Credit from *Rijksdienst voor Ondernemend Nederland (RVO)* for the LAVA-051 program. Borrowings under the Innovation Credit, which bear interest at 10.0%, were received in quarterly installments. As of December 31, 2023, we had $5.3 million in borrowings under the Innovation Credit, including accrued interest. The initial repayment of principal and accrued interest is due on September 30, 2025. In June 2023, the Company announced the discontinuance of the LAVA-051 program. This discontinuance ended the receipt of future installments. We are currently preparing the required Project Settlement Report because of the discontinuance of LAVA-051 and expect RVO to make their decision on repayment of the Innovation Credit in the second half of 2024. As a result, the Company has classified the Innovation Credit as a current liability.

In March 2021, we completed our IPO and received net proceeds from the IPO of approximately $89.0 million after deducting underwriting discounts and commissions of $7.0 million and offering costs of $4.5 million. In April 2021, we received additional net proceeds from the IPO of $5.9 million from the exercise of the overallotment option by the underwriters. In addition, in September 2020 and March 2021, we received $56.6 million in net proceeds from our Series C financing, net of repurchasing Series A Preferred and common shares.

Cash and cash equivalents, and short-term marketable securities are financial instruments that potentially subject us to concentrations of credit risk. As of December 31, 2023 and 2022, cash consists of cash deposited with three financial institutions and account balances exceeded federally insured limits.

Management believes that we are not exposed to significant credit risk due to the financial strength of these financial institutions.

Based on our current operating plan, we believe that our existing cash, cash equivalents and investments as of December 31, 2023 are sufficient to meet our projected cash requirements for at least 12 months from the date of this annual report. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including, but not limited to, our ability to:

- continue the ongoing and planned development of our product candidate, LAVA-1207;
- initiate, conduct and complete any ongoing, anticipated or future preclinical studies and clinical trials for our current and future product candidates;
- develop processes and scale manufacturing production for our current and future product candidates in accordance with cGMP;
- seek regulatory and marketing approvals for LAVA-1207 and any of our other development candidates that successfully complete clinical trials;
- discover and develop additional bispecific $\gamma\delta$ engagers and make further investments in our Gammabody platform to identify additional product candidates;
- maintain, protect and expand our intellectual property portfolio; including costs associated with opposing and invalidating competitor patents and licensing other technologies for our product candidates;
- establish a sales, marketing, manufacturing and distribution, supply chain and other commercial infrastructure in the future to commercialize any current or future product candidate for which we may obtain marketing approval;
- expand our operations in the United States and Europe;

- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- acquire or in-license additional product candidates and technologies;
- develop a potential companion diagnostic;
- incur additional legal, accounting and other expenses associated with operating as a public company;
- address any events outside of our control, including, but not limited to, outbreaks of infectious diseases; and
- face general economic and market conditions and overall fluctuations in the United States and international equity markets, such as deteriorating conditions due to investor concerns regarding inflation and the Russian invasion of Ukraine, the Israel-Hamas war and other geopolitical conditions.

Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our operations through equity offerings, debt financings or other capital sources, which may include strategic collaborations or other arrangements with third parties. Additional funds may not be available to us on acceptable terms or at all. If we raise additional funds by issuing equity or convertible debt securities, our shareholders will suffer dilution and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common shareholders. Debt financing, if available, may involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities receive any distribution of our corporate assets. If we raise funds through collaborations or other similar arrangements with third parties, we may have to relinquish valuable rights to technologies, future revenue streams, product candidates or research programs or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common shares. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, scale back or cease our research and development activities, preclinical studies and clinical trials for our product candidates and our establishment and maintenance of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

The following table summarizes our cash flows for each of the years ended December 31, 2023, 2022 and 2021 (in thousands):

	For the Year Ended December 31,		
(in thousands)	**2023**	**2022**	**2021**
Net cash (used in) provided by operating activities	$ (38,972)	$ 4,043	$ (28,647)
Net cash (used in) provided by investing activities	(17,635)	9,346	(43,545)
Net cash (used in) provided by financing activities	(571)	283	151,160
Net (decrease) increase in cash and cash equivalents	**$ (57,178)**	**$ 13,672**	**$ 78,968**

Cash Flows (Used in) Provided by Operating Activities

Net cash used in operating activities for the year ended December 31, 2023 was $39.0 million, compared to net cash provided by operating activities of $4.0 million for the year ended December 31, 2022. The decrease in 2023 was primarily due to a reduction in deferred revenue of $33.5 million and an increase in loss before income tax of $10 million. The changes were the result of the 2022 receipt of a $50.0 million nonrefundable up-front payment received in connection with our Pfizer Agreement.

Net cash provided by operating activities for the year ended December 31, 2022 was $4.0 million, compared to net cash used in operating activities of $28.6 million for the year ended December 31, 2021. The increase in 2022 was primarily due to an increase in deferred revenue of $38.2 million and a decrease in loss before

income tax of $10.5 million. The changes were the result of the 2022 receipt of the $50.0 million nonrefundable up-front payment received in connection with our Pfizer Agreement. This increase was offset by $14.9 million net decreases in changes in other working capital.

Cash Flows (Used in) Provided By Investing Activities

Cash flows used in investing activities for the year ended December 31, 2023 was $17.6 million compared to net cash provided by investing activities of $9.3 million for the year ended December 31, 2022. During the year ended December 31, 2023, we received $73.2 million from the maturities of investments, offset by investment purchases of $90.1 million and equipment purchases of $0.7 million. During the year ended December 31, 2022, we purchased $70.9 million in investments and $0.6 million in equipment, offset by proceeds from maturities of investments of $80.8 million.

Cash flows provided by investing activities for the year ended December 31, 2022 was $9.3 million compared to net cash used in investing activities of $43.5 million for the year ended December 31, 2021. During the year ended December 31, 2022, we received $80.8 million from the maturities of investments, offset by investment purchases of $70.9 million and equipment purchases of $0.6 million. During the year ended December 31, 2021, we purchased $45.3 million in investments and $0.8 million in equipment, offset by proceeds from maturities of investments of $2.5 million.

Cash Flows (Used in) Provided by Financing Activities

Cash flows used in financing activities for the year ended December 31, 2023 of $0.6 million was primarily comprised of principal payments on lease liabilities of $1.0 million, partially offset by proceeds from borrowings of $0.5 million

Cash flows provided by financing activities for the year ended December 31, 2022 of $0.3 million was primarily comprised of proceeds from borrowings of $0.6 million, partially offset by principal payments on lease liabilities of $0.3 million.

Cash flows provided by financing activities for the year ended December 31, 2021 of $151.2 million was primarily comprised of net proceeds of $94.2 million from our IPO, including the exercise of the underwriters' over-allotment option, net proceeds from the Series C financing of $61.8 million and proceeds from borrowings of $0.7 million, partially offset by payments of $5.2 million for Series A preferred share and common share repurchases and $0.3 million in repayments of lease liabilities.

4.3 Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements or any holdings in variable interest entities.

4.4 Research and development, patents and licenses etc.

Please refer to 4.1 Operating Results and 4.2 Liquidity and Capital Resources and 2.2 Business overview – Intellectual Property" elsewhere in this annual report.

4.5 Trend information

Please refer to 4.1 Operating Results in this annual report.

4.6 Critical accounting policies and material judgments, estimates and assumptions

We prepare our financial statements in accordance with IFRS Accounting Standards as issued by the IASB, which requires us to make judgments, estimates and assumptions that affect the reported amounts of our assets and liabilities and the disclosure of our contingent assets and liabilities at the end of each fiscal period and the reported amounts of revenue and expenses during each fiscal period. Critical accounting policies are defined as those policies that are reflective of material judgments, estimates and uncertainties, which would potentially result in materially different results under different assumptions and conditions. Based on this definition, we have identified the critical accounting policies and material judgments addressed below. We also have other accounting policies, which involve the use of estimates, judgments and assumptions that are significant to understanding our results, but the impact of these estimates, judgments and assumptions on our

financial condition or operating performance is not considered material. Please see these policies in the notes to our audited consolidated financial statements included elsewhere in this annual report.

We regularly evaluate these judgments and estimates based on our own historical experience, knowledge and assessment of current business and other conditions and our expectations regarding the future based on available information and assumptions that we believe to be reasonable, which together form our basis for making judgments about matters that are not readily apparent from other sources. We believe the following accounting policies involve the most significant judgments, estimates and assumptions used in the preparation of our financial statements.

Clinical trial expenses

As part of the process of preparing our financial statements, we are required to estimate our clinical trial expenses. Our clinical trial accrual process seeks to account for expenses resulting from our obligations under contracts with vendors, consultants and CROs and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our objective is to reflect the appropriate clinical trial expenses in our financial statements by matching the appropriate expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of the trial as measured by subject progression and the timing of various aspects of the trial.

We determine accrual estimates based on estimates of the services received and efforts expended that take into account discussion with applicable personnel and outside service providers as to the progress or state of completion of trials. During a clinical trial, we adjust our clinical expense recognition if actual results differ from our estimates. We make estimates of our accrued expenses and prepaid assets as of each balance sheet date in our financial statements based on the facts and circumstances known to us at that time. Our clinical trial accrual and prepaid assets are dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Although we do not expect our estimates to differ materially from amounts we actually incur, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low for any particular period. Historically we have had no material adjustments to our estimates.

Deferred tax assets

We are subject to income taxes in the Netherlands and the U.S. Significant judgment is required in determining the use of net operating loss carryforwards and taxation of upfront and milestone payments for income tax purposes. There are many transactions and calculations for which the ultimate tax determination is uncertain. Where the final tax outcome of these matters is different from the amounts that were initially recorded, such differences will impact the current and deferred income tax assets and liabilities in the period in which such determination is made.

A tax charge was recognized during the reporting periods due to the U.S. profitable position. We have tax loss carryforwards of $70.3 million and capitalized IP development costs of $72.1 million as of December 31, 2023. As a result of the Dutch corporate income tax law, tax loss carryforwards are not subject to a time limitation and remain available for utilization with taxable income indefinitely. Actual utilization of these losses is however limited to 50% of the taxable amount that exceeds EUR 1 million.

Deferred income tax assets are recognized for tax losses and other temporary differences to the extent that the realization of the related tax benefit through future taxable profits is probable. We recognize deferred tax assets arising from unused tax losses or tax credits only to the extent we have sufficient taxable temporary differences or if there is convincing other evidence that sufficient taxable profit will be available against which the unused tax losses, deduction of capitalized IP development costs or unused tax credits can be utilized by us. Our judgment is that sufficient convincing other evidence is not available and therefore, a deferred tax asset is not recognized.

In order to promote innovative technology development activities and investments in new technologies, a corporate income tax incentive has been introduced in Dutch tax law called the “Innovation Box.” Profits from

self-developed qualifying intangible assets are effectively subject to a 9% income tax rate for 2021 and future years, instead of the general headline rate of 25.8% as of 2022. We believe we qualify for the Innovation Box and are currently in the process of obtaining advance certainty from the Dutch tax authorities. For further information, please refer to Note 9 in our consolidated financial statements.

5 DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

5.1 Non-Executive Directors

The following table lists the composition of the non-executive directors currently serving and those who served in 2023 but are no longer on the board of directors, including the ages of the directors, their current terms of service and year of expiry of their term, and their position.

Name	Age	Nationality	Gender	Term served	Year in which term expires	Position	Attendance rate at Board meetings
Kapil Dhingra	64	US	M	February 2021 - Present	2024	Chairperson and Non-Executive Director	100%
Jay Backstrom	69	US	M	June 2022 - Present	2025	Non-Executive Director	100%
Peter A. Kiener	71	UK	M	January 2023 - Present	2026	Non-Executive Director	100%
James Noble	65	UK	M	June 2022 - Present	2025	Non-Executive Director	100%
Christy Oliger	54	US	F	March 2023 - Present	2026	Non-Executive Director	100%
Mary E. Wadlinger	64	US	F	January 2023 - Present	2026	Non-Executive Director	100%
Karen J. Wilson	61	US	F	March 2021 - Present	2024	Non-Executive Director	100%
Stefan Luzi	40	CH	M	January 2018 – March 2023	N.A.	Non-Executive Director	100%

The following is a brief summary of the business experience of our current non-executive board members. Unless otherwise indicated, the current business address for each director is the same as our business address: Yalelaan 62, 3584 CM Utrecht, the Netherlands.

Kapil Dhingra, M.B.B.S. has served as Chairperson of our board and as a non-executive director since February 2021. He has served as Managing Member of KAPital Consulting, LLC, which he also co-founded, since 2008. Dr. Dhingra currently serves on the boards of directors of several publicly traded and privately held companies, including Black Diamond Therapeutics, Inc. since January 2021, Replimune Group since July 2017, Median Technologies since June 2017, Kirilys Therapeutics since March 2021, Mariana Oncology since January 2017 and Servier since January 2022. He also served on the board of directors of Autolus Therapeutics from August 2014 to December 2023 and Five Prime Therapeutics from December 2015 to April 2021. Dr. Dhingra previously served as Vice President, Head of the Oncology Disease Biology Leadership Team and Head of Oncology Clinical Development at Hoffman-La Roche from May 1999 to August 2008. He received a M.B.B.S. from the All India Institute of Medical Sciences. We believe that Dr. Dhingra is qualified to serve on our board of directors because of his extensive experience in executive positions with several pharmaceutical companies and in the clinical development of pharmaceuticals in several therapeutic areas, including in oncology, and his experience serving on the boards of several publicly traded life science companies.

Jay Thomas Backstrom, M.D., M.P.H. has served as a non-executive director since June 2022. Dr. Backstrom is currently Chief Executive Officer of Scholar Rock, a biopharmaceutical company focused on discovery and development of novel therapies targeting the TGF-beta superfamily of growth factors, a position he assumed in October 2022. Prior to Scholar Rock, he served as executive vice president, research and development, at Acceleron Pharma, from December 2019 through completion of the Merck acquisition in 2021. He previously served as Chief Medical Officer for the Celgene Corporation from April 2016 through December 2019. Dr. Backstrom joined Celgene in March 2008 as vice president of clinical research and development for the MDS and AML therapeutic area. He subsequently served as senior vice president of clinical research and development for the hematology and oncology and the head of global regulatory affairs before being appointed the Chief Medical Officer, a position he held up through the completion of the Bristol Myers Squibb-Celgene merger in December 2019. After earning his medical degree at the Lewis Katz School of Medicine at Temple University in Philadelphia, he completed his medical training including serving as Chief

Medical Resident in the Department of Medicine at Temple University Hospital. Dr. Backstrom has served as a non-executive board director of Autolus Therapeutics from August 2020 (including chair of the R&D Committee) through February 2023, Be Biopharma since 2021 and Disc Medicine from January 2022 through June 2023. Dr. Backstrom received his M.D. and completed medical training at the Lewis Katz School of Medicine at Temple University, and he received a Master's in public health from the Saint Louis University School of Public Health. We believe Dr. Backstrom is qualified to serve on our board of directors because of his extensive experience as a pharmaceutical executive and in clinical development and regulation of pharmaceuticals.

Peter A. Kiener, DPhil has served as a non-executive director since January 2023. He has served as a founding member of BioKien LLC since 2018 and is a consultant and part-time partner at Bridge Valley Ventures/IGC Life Sciences. From 2019 through 2021, Dr. Kiener served as interim chief executive officer at Cereius. From 2014 through 2018, he served as chief scientific officer and head of research and development at Sucampo Pharmaceuticals, which was acquired by Mallinckrodt. From 2013 to 2015, Dr. Kiener served as chief scientific officer of Ambrx Inc., a clinical-stage biopharmaceutical company focused on the development of antibody-drug conjugates (ADCs), from 2009 to 2013, Dr. Kiener served as president and co-founder of Zyngenia Inc. an early-stage biopharmaceutical company and from 2001 to 2009, he served as executive vice president and global head of biologics research and development at MedImmune LLC, the global biologics arm of AstraZeneca. He received a Bachelor of Science from Lancaster University in Lancaster, UK and his DPhil from Oxford University, Sir William Dunn School of Pathology. We believe that Dr. Kiener is qualified to serve on our board of directors due to his extensive experience leadership experience in biotechnology companies and in the clinical development of pharmaceuticals in several therapeutic areas.

James J. Noble, M.A. has served as a non-executive director since June 2022. From 2008 to 2019, Mr. Noble served as chief executive officer and co-founder of Adaptimmune Therapeutics. From July 2008 until March 2014, Mr. Noble was chief executive officer of Immunocore, which he also co-founded. Mr. Noble currently serves on the boards of directors of several publicly traded and privately held companies, including Orexo AB, where he is also chairman since 2020, Sutura Therapeutics where he is also chairman since 2020 and Celleron Therapeutics (now renamed Ingenox Therapeutics) since 2019 and Pneumagen, where he is also chairman since 2023. Mr. Noble has also served as a non-executive board director for publicly traded life science companies, including as deputy chairman of GW Pharmaceuticals until its acquisition by Jazz Pharmaceuticals in 2021. Mr. Noble received an M.A. from the University of Oxford. We believe that Mr. Noble is qualified to serve on our board of directors due to his extensive experience leading biotechnology companies.

Christy J. Oliger has served as a non-executive director since March 2023. She has over 30 years of experience in the biopharmaceutical industry and is recognized for building productive teams and improving operational effectiveness. From 2000 to 2020, Ms. Oliger served in several commercial leadership roles at Roche/Genentech, most recently as senior vice president, BioOncology business unit. She also led Roche's global portfolio management function comprised of a late-stage development portfolio of greater than 300 projects in therapeutic areas including oncology, neurology, rare disease, respiratory, dermatology and immunology. Prior to Genentech, Ms. Oliger held several management roles at Schering-Plough. Ms. Oliger serves on the board of directors of several publicly traded companies, including Karyopharm Therapeutics since August 2020, Reata Pharmaceuticals since April 2021, Replimune Group since September 2021, Rayze Oncology since September 2023 and previously served on the board of directors of Sierra Oncology from June 2021 to July 2022. Ms. Oliger received a Bachelor of Arts in Economics from the University of California at Santa Barbara. We believe Ms. Oliger is qualified to serve on our board of directors because of her strategic, operational and commercial experience in the biotechnology industry, including oncology.

Mary E. Wadlinger has served as a non-executive director since January 2023. Ms. Wadlinger most recently served as senior vice president, Corporate Affairs & Chief Human Resources Officer at Forma Therapeutics from 2014 to 2022, where she led the organization and people strategy through critical growth and reorganization as the company transformed from drug discovery to a fully-integrated drug development and commercial readiness company. She remained with the company as a consultant through the acquisition by Novo Nordisk. Prior to Forma, she served as vice president, human resources at Millennium Pharmaceuticals, a subsidiary of Takeda Pharmaceuticals from 2003 through 2014, where she served as a

key leader in numerous corporate transformations, growth initiatives, M&A activity, and overall integration within Takeda. Ms. Wadlinger earned a Bachelor of Science degree in Finance from the University of Maine Business School. We believe Ms. Wadlinger is qualified to serve on our board of directors due to her extensive experience in corporate organization and people strategy.

Karen J. Wilson has served as a non-executive director since March 2021. She currently serves on the board of directors of Elicio Therapeutics (formerly Angion Biomedica) since March 2020 and Connect Biopharma since December 2020, and previously served on the board of directors of Vaxart, Inc. from August 2020 to August 2022. Ms. Wilson served as Senior Vice President of Finance at Jazz Pharmaceuticals plc until September 2020 after serving as Vice President of Finance and Principal Accounting Officer. Prior to joining Jazz Pharmaceuticals in February 2011, Ms. Wilson served as Vice President of Finance and Principal Accounting Officer at PDL BioPharma, Inc. She also previously served as a Principal at the consulting firm of Wilson Crisler LLC, Chief Financial Officer of ViroLogic, Inc., Chief Financial Officer and Vice President of Operations for Novare Surgical Systems, Inc., and as a consultant and auditor for Deloitte & Touche LLP. Ms. Wilson is a Certified Public Accountant and received a B.S. in Business from the University of California, Berkeley. We believe that Ms. Wilson is qualified to serve on our board of directors due to her extensive background in financial and accounting matters for public companies and her leadership experience in the life sciences industry.

5.2 Senior Management

The following table presents information about our current executive director (who is also a member of our board of directors) and executive officers, including their ages as of the date of this annual report:

Name	Age	Year in which term expires	Position
Stephen Hurly	56	2024	Executive Management Director and Chief Executive Officer
Ton Adang	63	—	Chief Development Officer
Amy Garabedian	48	—	General Counsel and Corporate Secretary
Charles Morris (1)	58	—	Chief Medical Officer
Fred Powell	63	—	Chief Financial Officer
Hans van der Vliet	51	—	Chief Scientific Officer

(1) Charles Morris was appointed Chief Medical Officer effective February 6, 2023.

The following is a brief summary of the business experience of certain of our executive directors and executive officers.

Stephen Hurly has served as our President, Chief Executive Officer and as an executive director since June 2019. Prior to joining LAVA Therapeutics, he served as President and Chief Executive Officer of Sesen Bio, a Nasdaq listed late-stage oncology firm, from September 2016 to August 2018. From August 2015 to September 2016, he served as the President and Chief Executive Officer of Viventia Bio Inc., a specialty pharmaceutical company acquired by Sesen Bio Inc in September 2016. He has served on the board of directors of PHusis Therapeutics Inc., a private targeted small molecule therapeutics company, since May 2011. Previously, he was the Chief Executive Officer of Burrill & Co.'s Merchant Banking Division, a finance business for life science companies, from June 2011 to August 2015. From June 2008 to June 2011, he was also the head of the Life Sciences Investment Banking Practice at Boenning & Scattergood, a securities asset management and investment banking firm. He graduated from Swarthmore College with a B.A. degree in Engineering and earned an M.B.A. from the University of Chicago.

Ton Adang, Ph.D., has served as our Chief Development Officer since July 2017, initially as a consultant through his management consultancy company, PMC Biopartners B.V., and then full-time beginning in August 2019. Prior to joining Lava Therapeutics, he served as Chief Operating Officer at EnCare Biotech from August 2014 to December 2017, as Chief Operating Officer at Fast Forward Pharmaceuticals from October 2012 to October 2017, as Project Director at AM-Pharma from August 2014 to September 2016 and as Chief Operating Officer at SimiBio BV from July 2011 to June 2014. Dr. Adang also previously served in various roles at Merck, including as Site Scientific Operations Lead from March 2010 to July 2011 and as

Senior Director of Project & Pipeline Management from November 2009 to March 2010. He received his PhD in Bioorganic Chemistry and Biopharmaceutical Sciences from the University of Leiden at the Divisions of Bio-Pharmaceutical Sciences and Bio-Organic Chemistry, and his MSc in Life Sciences from Wageningen University.

Amy Garabedian has served as our General Counsel and Corporate Secretary since July 2021. She has advised pharmaceutical & biotech companies from start-ups to multi-national public companies on the complex legal issues for almost twenty years. From 2015 to 2021, Ms. Garabedian served as associate general counsel of Spark Therapeutics (Roche), where she served as a strategic and innovative advisor, playing an instrumental role in the successful U.S. launch of the first gene therapy for a genetic disease, led key business development transactions, and enabled pre-clinical, clinical and commercial product development. Earlier in her career, Ms. Garabedian held positions of increasing responsibility at Sandoz (Novartis) and as a business and finance attorney at Ballard Spahr LLP. She holds a B.S. in genetics and developmental biology from Penn State University, a M.S. in regulatory affairs from Temple University and a J.D. from Widener University Delaware School of Law.

Charles Morris, MBChB, MRCP, has served as our Chief Medical Officer since February 2023. Dr. Morris is a medical oncologist with over 25 years of oncology drug development experience in the international biotech and pharmaceutical industry. From April 2021 until January 2023, Dr. Morris was chief medical officer for Celyad Oncology, a CAR-T focused cell therapy company. Prior to Celyad, he served as CMO at Radius Health from 2018 to 2020 and held senior leadership positions with PsiOxus Therapeutics from 2016 to September 2018. He also worked as chief development officer at ImmunoGen from 2012 to 2016. Dr. Morris also worked at Allos Therapeutics and Cephalon Inc., where he contributed to all phases of development for several novel programs targeting solid and hematological tumor indications. While at Cephalon, he served as vice president of worldwide clinical research during the approval of TREANDA® (bendamustine) for the treatment of indolent non-Hodgkin lymphoma and chronic lymphocytopenia. Dr. Morris began his career at AstraZeneca where he held roles of increasing responsibility including global medical lead for Faslodex® (fulvestrant) through its approval for breast cancer. He received a Bachelor of Medicine, Bachelor of Surgery and Bachelor of Medical Science in Clinical Pharmacology and Therapeutics degree from Sheffield University Medical School and is a Member of the Royal College of Physicians of London.

Fred Powell has served as our Chief Financial Officer since November 2022. From 2016 to 2022, Mr. Powell served as the executive vice president and chief financial officer of Antares Pharma, which was acquired by Halozyme Therapeutics in May 2022. Prior to that, from 2012 until 2016, Mr. Powell served as Chief Financial Officer at Celator Pharmaceuticals (acquired by Jazz Pharmaceuticals), OraPharma, Inc. from 2011 until 2012 (acquired by Valeant Pharmaceuticals International) and BMP Sunstone Corporation from 2005 until 2011 (acquired by Sanofi-Aventis). Mr. Powell also held various positions of increasing responsibility at KPMG LLP. Mr. Powell is the chairman of the Advisory Board for Penn State Scranton. He holds a B.S. in accounting from Penn State University.

Hans van der Vliet, M.D., Ph.D., has served as our Chief Scientific Officer since 2017. Since December 2019, he has served as a professor of medical oncology at the Amsterdam UMC, where he has also served as a Medical Oncologist since September 2008. From January 2005 to January 2006, Dr. van der Vliet performed post-doctoral research at the Division of Hematology and Oncology, Beth Israel Deaconess Medical Center, Harvard Medical School. He received his MD from the University of Amsterdam and his PhD from the VU University in Amsterdam and performed his internal medicine and medical oncology specialization in the VU University Medical Center in Amsterdam.

There are no family relationships among any of our directors or senior management. There are no arrangements or understanding with major shareholders, customers, suppliers or others, pursuant to which any person was selected to serve as a director or member of senior management.

5.3 Compensation

Pursuant to Art. 2:135 sub 1 DCC, our general meeting of shareholders has adopted a remuneration policy. Our remuneration policy is designed to (i) attract, retain and motivate directors with the leadership qualities, skills and experience needed to support and promote the growth and sustainable success of the Company and its business, (ii) drive strong business performance, promote accountability and incentivize our directors to achieve short and long-term performance targets with the objective of increasing the Company's equity value and contributing to the Company's strategy for sustainable long-term value creation, (iii) assure that the interests of our directors are closely aligned to those of the Company, its business and its stakeholders, and (iv) ensure the overall market competitiveness of the compensation packages which may be granted to our directors, while providing our board of directors sufficient flexibility to tailor the Company's compensation practices on a case-by-case basis, depending on the market conditions from time to time. We believe that this approach and philosophy benefits the realization of the Company's sustainable long-term objectives while keeping with the Company's risk profile.

Dutch law does not provide for limitations with respect to the aggregate annual compensation paid to our directors, provided that such compensation is consistent with our compensation policy.

Our compensation policy authorizes our Board to determine the amount, level and structure of the compensation packages of our directors at the recommendation of our compensation committee. These compensation packages may consist of a mix of fixed and variable compensation components, including base salary, short-term incentives, long-term incentives, fringe benefits, severance pay and pension arrangements, as determined by our Board.

The aggregate compensation, including benefits in kind, accrued or paid to members of our Board and Senior Management with respect to the year ended December 31, 2023 for services in all capacities was approximately $7.6 million.

The following table sets forth the compensation paid or accrued, including benefits in kind, to members of our Board for the year ended December 31, 2023:

	Total compensation
Stephen Hurly	$ 814,399
Kapil Dhingra	$ 82,625
Karen J. Wilson	$ 55,000
James Noble	$ 52,500
Jay Backstrom	$ 47,000
Peter A. Kiener	$ 39,000
Christy J. Oliger	$ 37,846
Mary E. Wadlinger	$ 40,000

The following table sets forth the number of stock options granted to members of our Board during the year ended December 31, 2023:

	Number of Options	Exercise Price	Expiration date
Jay Backstrom	20,000	$ 3.60	1/2/2033
James Noble	20,000	$ 3.60	1/2/2033
Peter A. Kiener	20,000	$ 2.10	3/8/2033
Christy J. Oliger	20,000	$ 2.10	3/8/2033
Mary E. Wadlinger	20,000	$ 2.10	3/8/2033

The following table sets forth the share ownership of our Board and Senior Management as of December 31, 2023:

	Number of Common Shares	Percentage of Shares Outstanding	Voting Rights
Stephen Hurly	5,000	(1)	(2)
Hans van der Vliet	77,350	(1)	(2)
Ton Adang	800	(1)	(2)
Fred Powell	65,000	(1)	(2)
Amy Garabedian	8,850	(1)	(2)
Charles Morris	—	(1)	(2)
Kapil Dhingra	30,000	(1)	(2)
Karen J. Wilson	10,000	(1)	(2)
Peter A. Kiener	—	(1)	(2)
Jay Backstrom	—	(1)	(2)
James Noble	—	(1)	(2)
Christy J. Oliger	—	(1)	(2)
Mary E. Wadlinger	—	(1)	(2)

(1) Represents less than 1% of our shares outstanding.
(2) Each common share carries one vote per share.

The following table sets forth the stock option ownership of our Board and Senior Management as of December 31, 2023:

	Number of Options	Exercise Price	Percentage of Shares Outstanding	Expiration date
Stephen Hurly	232,934	$ 2.76	0.9 %	2/11/2030
Stephen Hurly	494,819	$ 2.76	1.9 %	12/16/2030
Stephen Hurly	310,000	$ 5.10	1.2 %	12/20/2031
Stephen Hurly	800,000	$ 3.64	3.0 %	12/21/2032
Fred Powell	195,000	$ 4.38	0.7 %	11/1/2032
Ton Adang	7,072	$ —	— %	n.a.
Ton Adang	24,310	$ —	0.1 %	n.a.
Ton Adang	6,630	$ —	— %	n.a.
Ton Adang	8,619	$ —	— %	n.a.
Ton Adang	99,008	$ —	0.4 %	n.a.
Ton Adang	60,000	$ 5.10	0.2 %	12/20/2031
Ton Adang	120,000	$ 3.64	0.5 %	12/21/2032
Amy Garabedian	125,000	$ 10.33	0.5 %	7/8/2031
Amy Garabedian	35,000	$ 4.79	0.1 %	3/17/2032
Amy Garabedian	160,000	$ 3.64	0.6 %	12/21/2032
Hans van der Vliet	68,289	$ —	0.3 %	n.a.
Hans van der Vliet	125,000	$ 5.10	0.5 %	12/20/2031
Hans van der Vliet	160,000	$ 3.64	0.6 %	12/21/2032
Charles Morris	210,000	$ 3.86	0.8 %	2/5/2033
Kapil Dhingra	207,740	$ 9.50	0.8 %	3/2/2031
Kapil Dhingra	20,000	$ 5.10	0.1 %	12/20/2031
Kapil Dhingra	20,000	$ 3.64	0.1 %	12/21/2032
Karen J. Wilson	24,261	$ 15.00	0.1 %	3/24/2031
Karen J. Wilson	20,000	$ 5.10	0.1 %	12/20/2031
Karen J. Wilson	20,000	$ 3.64	0.1 %	12/21/2032
Jay Backstrom	20,000	$ 3.64	0.1 %	12/21/2032
Jay Backstrom	20,000	$ 3.60	0.1 %	1/2/2033
James Noble	20,000	$ 3.64	0.1 %	12/21/2032
James Noble	20,000	$ 3.60	0.1 %	1/2/2033
Peter A. Kiener	20,000	$ 2.10	0.1 %	3/8/2033
Christy J. Oliger	20,000	$ 2.10	0.1 %	3/8/2033
Mary E. Wadlinger	20,000	$ 2.10	0.1 %	3/8/2033

Equity Incentive Plans

In 2018, we established a share option plan (2018 Stock Option Plan) that entitles employees, directors, and consultants providing services to purchase depository receipts for our common shares. Under this plan, holders of vested options are entitled to purchase common shares at the exercise price determined at the date of the grant.

In 2020, we established a U.S. share option plan (2020 U.S. Stock Option Plan) that entitles employees, directors and consultants providing services to give the right to acquire a number of common shares. Under this plan, holders of vested options are entitled to purchase common shares at the exercise price determined at the date of the grant.

In 2021, we established the 2021 Long-term Incentive Option Plan, as an incentive for all our employees, members of our board of directors and select external consultants. As of March 25, 2021, the 2018 Stock Option Plan and the 2020 U.S. Stock Option Plan ceased to have any future shares available.

Under the option plans, the options granted generally have a maximum term of 10 years and can generally have the following vesting schemes:

- 25% of the options vest on the first anniversary of the vesting commencement date, and the remaining 75% of the options vest in 36 monthly installments for each full month of continuous service provided by the option holder thereafter, such that 100% of the options shall become vested on the fourth anniversary of the vesting commencement date.
- the options vest in 48 monthly installments for each full month of continuous service provided by the option holder thereafter, such that 100% of the options shall become vested on the fourth anniversary of the vesting commencement date.
- the options vest in 12 monthly installments for each full month of continuous service provided by the option holder thereafter, such that 100% of the options shall become vested on the first anniversary of the vesting commencement date.
- the options vest 100% on the first anniversary of the vesting commencement date.

During the year ended December 31, 2023, none of the granted stock options under these Equity Incentive Plans have been exercised.

See Note 36 (*Directors' remuneration*) to the Company Financial Statements for further information concerning the implementation of our remuneration policy in the fiscal year to which this report relates. In determining the level and structure of the compensation of the directors in the fiscal year to which this report relates relevant scenario analyses carried out in advance have been considered as follows: LAVA uses a multi-step approach for compensation that relies on personal objectives that incorporate both corporate objectives and personal objectives that must align with LAVA's values. These objectives are developed early in the year and are evaluated regularly to provide end of year feedback and throughout the year. The evaluations are discussed with the Compensation Committee and compensation is awarded in line with calibrated performance.

5.4 Pay ratio

The DCGC recommends that the Company provide a ratio comparing the compensation of our executive directors and that of a "representative reference group" determined by the Company and to describe any changes (if any) to such ratio in comparison with the ratio provided in the five previous fiscal years. We have chosen to compare the cash compensation of our Chief Executive Officer to that of an average full-time employee. We have used the aggregate cash compensation over the fiscal year concerned as a reference amount (i.e., excluding the value of equity incentive awards and other non-cash compensation components). To calculate the ratio, we have annualized the salaries of employees who had worked with us for less than a year as of December 31, 2023. Based on this methodology, the ratio between the cash compensation of our Chief Executive Officer and an average full-time employee for the fiscal year to which this report relates is 5 to 1 (rounded to the nearest integer). This pay ratio has developed as follows over the past two years: the pay ratio was 4 to 1 (rounded to the nearest integer) as of December 31, 2022 and 4 to 1 (rounded to the nearest integer) as of December 31, 2021.

5.5 Board Practices

Board Structure

In connection with our IPO, we transitioned from a two-tier board structure to a one-tier board structure consisting of executive and non-executive directors. The board shall be composed in such a way to ensure a degree of diversity appropriate to the Company with regard to expertise, experience, competencies, other personal qualities, sex or gender identity, age, nationality and cultural or other background. The current chair of the board is Kapil Dhingra.

The board is responsible for the continuity of the Company and its business and for sustainable long-term value creation by the Company and its business. The board takes into account the impact the actions of the Company and its business have on people and the environment and to that end weighs the relevant

stakeholder interests. The board shall adopt values for the Company and the Company's business that contribute to a culture focused on sustainable long-term value creation.

The board shall encourage behavior that is in keeping with the values and propagate these values through leading by example. Attention shall be paid to the following, among other things:

(a) the strategy and the business model;

(b) the environment in which the enterprise operates;

(c) the existing culture within the enterprise, and whether it is desirable to implement any changes in this; and

(d) the social safety within the enterprise and the ability to discuss and report actual or suspected misconduct or irregularities.

Board of Directors Composition

Our board of directors is composed of eight members, comprised of one executive director, Stephen Hurly, our Chief Executive Officer, and seven non-executive directors. Members of our board serve for staggered three year terms as follows:

- Kapil Dhingra, Stephen Hurly and Karen J. Wilson with terms expiring at the annual general meeting of shareholders in 2024;
- Jay T. Backstrom and James J. Noble with terms expiring at the annual general meeting of shareholders in 2025; and
- Peter A. Kiener, Mary Wadlinger and Christy J. Oliger with terms expiring at the annual general meeting of shareholders in 2026.

As a result of the staggered board, only one class of directors will be elected at each annual general meeting of shareholders, with the other classes continuing for the remainder of their respective terms. Each of our directors will hold office for the term set forth above, except in the case of his or her earlier death, resignation or dismissal. Our directors do not have a retirement age requirement under our articles of association. We do not have any board service agreements with any of the members of our board of directors.

Board Committees

The board of directors has established a standing Audit Committee, Compensation Committee and Nomination and Corporate Governance Committee.

Audit Committee

The Audit Committee consists of Karen J. Wilson, Christy J. Oliger and James J. Noble. The Audit Committee assists the board of directors in overseeing our accounting and financial reporting processes and the audits of our financial statements. Ms. Wilson serves as chairperson. Kapil Dhingra served on the Audit Committee until Christy Oliger was appointed in March 2023.

In addition, the Audit Committee is responsible for the appointment, compensation, retention and oversight of the work of our independent registered public accounting firm. The audit committee is governed by a charter that complies with applicable Nasdaq rules, which charter is posted on our website.

Compensation Committee

The Compensation Committee consists of Mary Wadlinger, Karen J. Wilson and James Noble. The Compensation Committee assists the board of directors in determining compensation for our executive officers and our directors. Mr. Noble serves as chairperson. The Compensation Committee is governed by a charter that is posted on our website.

Nomination and Corporate Governance Committee

The Nomination and Corporate Governance Committee consists of Kapil Dhingra, Jay Backstrom and Christy Oliger. The Nomination and Corporate Governance Committee assists our board of directors in identifying

individuals qualified to become our directors consistent with criteria established by us and in developing our code of business conduct and ethics. During the year ended December 31, 2023, Dr. Dhingra served as chairperson until Christy Oliger was appointed as chairperson and Mary Wadlinger was nominated as a member in March 2024. The Nomination and Corporate Governance Committee is governed by a charter which is posted on our website.

As of December 31, 2023, the attendance rates for our committees was as follows:

Name		Audit Committee	Compensation Committee	Nomination and Corporate Governance Committee
Kapil Dhingra		100% attendance	—	100% attendance
Karen Wilson		100% attendance	100% attendance	—
Jay Backstrom		—	—	100% attendance
James Noble		100% attendance	100% attendance	—
Mary Wadlinger	(1)	—	100% attendance	—
Christy Oliger	(2)	100% attendance	—	100% attendance

(1) Mary Wadlinger joined the board of directors in January 2023
(2) Christy Oliger joined the board of directors in March 2023

During the fiscal year to which this report relates, our audit committee met four times in order to carry out its responsibilities. The main items discussed at those meetings included review and approval of our quarterly and annual consolidated financial statements and related SEC filings, required communications from our independent auditors and overall risk assessments.

During the fiscal year to which this report relates, our compensation committee met three times in order to carry out its responsibilities. The main items discussed at those meetings included overall compensation philosophy in conjunction with a third-party compensation expert and review and approval of executive management and board of director compensation.

During the fiscal year to which this report relates, our nomination and corporate governance committee met two times in order to carry out its responsibilities. The main items discussed at those meetings included approval and appointment of key executive officers and board members and succession planning.

5.6 Employees

As of December 31, 2023, we had 37 employees. In Europe, 23 of our employees work in research and development and 4 work in general and administrative areas. In the United States, 5 of our employees work in research and development and 5 work in general and administrative areas. None of our employees are subject to a collective bargaining agreement or represented by a trade or labor union. All of our employees are eligible for participation in our 2021 Long-term Incentive Option Plan and are granted equity awards as deemed appropriate by our board of directors or senior management, typically in the form of stock options.

In August 2023, we finalized a reduction in workforce of approximately 36% in the U.S. and the Netherlands to better align our resources with our focus on LAVA-1207 and redesigned focus on research and development.

For 2024, we do not expect substantial changes in our workforce.

6 MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

6.1 Major Shareholders

The following table presents information relating to the beneficial ownership of our common shares as of December 31, 2023 by: (i) each person, entity or group of affiliated persons, known by us to own beneficially 5% or more of our outstanding common shares; (ii) each member of our Board and Senior Management; and (iii) our Board and Senior Management as a group. As of June 30, 2023, the measurement date for determining FPI status, less than 50% of our common shares were held by U.S. holders.

We are not owned or controlled, directly or indirectly, by any other corporation, by any foreign government or by any other natural or legal persons. To our knowledge, there is no arrangement, the operations of which may at a subsequent date result in a change in control.

The number of common shares beneficially owned by each person, entity, or group of affiliated persons is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any common shares over which the person, entity, or group of affiliated persons has sole or shared voting power or investment power as well as any common shares that the person, entity, or group of affiliated persons has the right to acquire within 60 days of December 31, 2023 through the exercise of any option, warrant or other right.

This information in the table relating to 5% or greater shareholders is based upon information from Schedules 13D and 13G filed with the SEC and our Senior Management's understanding of each person, entity or group of affiliated persons beneficial ownership. The percentage of outstanding common shares is computed on the basis of 26,289,087 common shares outstanding as of December 31, 2023. All major shareholders listed below have the same voting rights. Unless otherwise indicated below, the address for each beneficial owner listed is c/o LAVA Therapeutics, at Yalelaan 62, 3584 CM Utrecht, the Netherlands.

	As of December 31, 2023	
Name of beneficial owner	**Number of shares**	**Percentage of class**
5% or greater shareholders		
Cooperative Gilde Healthcare IV UA (1)	5,421,170	20.6 %
Versant Ventures (2)	4,587,837	17,5 %
Redmile Group, LLC (3)	2,074,372	7,9 %
Sanofi Foreign Participations B.V. (4)	1,919,455	7,3 %
Novo Holdings A/S (5)	1,878,194	7,1 %
Board and Senior Management		
Stephen Hurly (6)	1,008,388	3.8 %
Hans van der Vliet (7)	241,519	*
Kapil Dhingra (8)	227,987	*
Ton Adang (9)	188,809	*
Amy Garabedian (10)	153,017	*
Fred Powell (11)	125,938	*
Karen J. Wilson (12)	73,587	*
Charles Morris (13)	52,500	*
James Noble (14)	40,000	*
Jay Backstrom (14)	40,000	*
Peter A. Kiener (15)	20,000	*
Mary E. Wadlinger (15)	20,000	*
Christy J.Oliger	-	*
All board members and senior management as a group (13 persons) (16)	2,191,745	8.3 %

* Represents less than 1% of our shares outstanding.

(1) This information has been obtained from a Schedule 13D filed on March 31, 2021 by entities and individuals associated with Cooperative Gilde Healthcare IV U.A. ("Gilde Healthcare"). All shares are held of record by Gilde Healthcare, Gilde Healthcare IV Management B.V. is the manager of Gilde Healthcare and may be deemed to have voting, investment and dispositive power with respect to these securities. Gilde Healthcare IV Management B.V. is fully owned by Gilde Healthcare Holding B.V. The managing partners of Gilde Healthcare Holding B.V. are Edwin de Graaf, Marc Olivier Perret and Martemanshurk B.V. The address for Gilde is Newtonlaan 91, 3584 BP Utrecht, the Netherlands.

(2) This information has been obtained from a Schedule 13D filed on April 8, 2021 by entities associated with Versant Venture Capital VI, L.P. ("Versant VI"), Versant Ventures VI GP, L.P. ("GP VI"), Versant Ventures VI GP-GP, LLC ("LLC VI"), Versant Vantage I, L.P. ("Vantage LP"), Versant Vantage I GP, L.P. ("Vantage GP") and Versant Vantage I GP-GP, LLC ("Vantage LLC" and, with Versant VI, GP VI, LLC VI, Vantage LP and Vantage GP, collectively, the "Reporting Persons"). LLC VI is the general partner of GP VI, which is the general partner of Versant VI. Each of LLC VI and GP VI share voting and dispositive power over the shares held by Versant VI. Vantage LLC is the general partner of Vantage GP, which is the general partner of Vantage LP. Each of Vantage LLC and Vantage GP share voting and dispositive power over the shares held by Vantage LP. These shares are held by Versant VI. LLC VI is the general partner of GP VI, which is the general partner of Versant VI. Each of LLC VI and GP VI share voting and dispositive power over the shares held by Versant VI and as a result may be deemed to have beneficial ownership over such securities. The address for the Reporting Persons is One Sansome Street, Suite 3630, San Francisco, CA 94104.

(3) This information has been obtained from a Schedule 13G filed on February 14, 2024 by entities and individuals associated with Redmile Group, LLC. Redmile Group LLC's beneficial ownership is comprised of shares owned by certain private investment vehicles managed by Redmile Group, LLC, including Redmile Biopharma Investments II, L.P., which shares may be deemed beneficially owned by Redmile Group, LLC as investment manager of such private investment vehicles. The shares may also be deemed beneficially owned by Jeremy C. Green as the principal of Redmile Group, LLC. Redmile Group, LLC and Mr. Green each disclaim beneficial ownership of these shares, except to the extent of its or his pecuniary interest in such shares, if any. The address for each of the above person and entities is One Letterman Drive, Building D, Suite D3-300, San Francisco, California 94129.

(4) This information has been obtained from a Schedule 13G filed on March 31, 2021 by Sanofi. The shares are held of record by Sanofi Foreign Participations B.V., a wholly owned subsidiary of Sanofi. Sanofi has the ability to exercise voting and dispositive power over the shares held by Sanofi Foreign Participations B.V. The address for Sanofi Foreign Participations B.V. is Paasheuvelweg 25, 1105BP Amsterdam, the Netherlands.

(5) This information has been obtained from a Schedule 13D filed on November 9, 2023 by entities associated with Novo Holdings A/S. Novo Holdings A/S is a Danish limited liability company that is wholly owned by Novo Nordisk Foundation (the "Foundation"), a Danish commercial foundation. Novo Holdings A/S is the holding company in the group of Novo companies (currently comprised of Novo Nordisk A/S and Novozymes A/S) and is responsible for managing the Foundation's assets, including its financial assets. Based on the governance structure of Novo Holdings A/S and the Foundation, the Foundation is not deemed to have any beneficial ownership of the securities held by Novo Holdings A/S. The address for Novo is Tuborg Havnevej 19, DK-2900 Hellerup, Denmark. On March 7, 2024, Novo Holdings filed Form SC 13D/A which stated that they sold all 1,878,199 shares which they held at February 28, 2024.

(6) Consists of 5,000 common shares and 1,003,388 common shares underlying options exercisable within 60 days of December 31, 2023.

(7) Consists of 77,350 common shares and 164,169 common shares underlying options exercisable within 60 days of December 31, 2023.

(8) Consists of 30,000 common shares and 197,987 common shares underlying options exercisable within 60 days of December 31, 2023.

(9) Consists of 800 common shares and 188,009 common shares underlying options exercisable within 60 days of December 31, 2023.

(10) Consists of 8,850 common shares and 144,167 common shares underlying options exercisable within 60 days of December 31, 2023.

(11) Consists of 65,000 common shares and 60,938 common shares underlying options exercisable within 60 days of December 31, 2023.

(12) Consists of 10,000 common shares and 63,587 common shares underlying options exercisable within 60 days of December 31, 2023.

(13) Consists of 52,500 common shares underlying options exercisable within 60 days of December 31, 2023.

(14) Consists of 40,000 common shares underlying options exercisable within 60 days of December 31, 2023.

(15) Consists of 20,000 common shares underlying options exercisable within 60 days of December 31, 2023.

(16) Consists of 197,000 common shares and 1,994,745 common shares underlying options exercisable within 60 days of December 31, 2023.

6.2 Related Party Transactions

Under our related party transaction policy, related person transactions (as defined by the policy) must be reviewed by, and are subject to the approval or ratification of, our board of directors or a designated committee thereof consisting solely of independent directors, including the audit committee. Our articles of association require us to indemnify our current and former directors to the fullest extent permitted by law, subject to certain exceptions, and we have entered into indemnification agreements with all of our directors.

Each of our executive officers has entered into an employment agreement with us for an indefinite period. The employment agreements generally provide for base salary, sign-on bonuses, discretionary annual bonuses based on a percentage of base salary and eligibility to receive equity awards and to participate in the Company's benefits plans.

Please refer to "*Item 5: Directors, Senior Management and Employees"* for additional information on our board of directors and senior management. We did not have any material related party transactions during 2023.

For further information on related party transactions, see Note 21 (*Related Parties*) to the Consolidated Financial Statements.

Where applicable, best practice provisions 2.7.3, 2.7.4 and 2.7.5 of the DCGC have been observed with respect to the transactions referenced above in chapter 6.2.

7 QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to a variety of risks in the ordinary course of our business, including, but not limited to, foreign currency risk and interest rate risk. We regularly assess each of these risks to minimize any adverse effects on our business as a result of those factors. For a detailed discussion, see Note 22 of the consolidated financial statements for the years ended December 31, 2023 and 2022 included elsewhere in this annual report.

8 CONTROLS AND PROCEDURES

a. Risk management and control systems

Although we are not yet subject to the certification or attestation requirement of Section 404 of the Sarbanes-Oxley Act, in connection with the preparation of our financial statements as of and for the year ended December 31, 2023, we identified control deficiencies that we concluded represented material weaknesses in our internal control over financial reporting across the principles for certain components of the Committee of Sponsoring Organizations of the Treadway Commission (COSO) 2013 framework at the entity level (*i.e.* monitoring, information & communication and control activities) and accordingly, across our business and IT processes. The material weaknesses that we identified related to:

(a) inadequate general controls over information technology, among which are the lack of change management and software development Life cycle (SDLC) procedures and insufficient level of user access controls to key financial systems, and

(b) our ability to design and maintain appropriate segregation of duties.

We are committed to maintaining a strong internal control environment, and management believes that the actions below will remediate the material weaknesses identified and strengthen our overall financial control environment.

During the year ended December 31, 2023, management, under the oversight of the Audit Committee, has continued the process of executing our remediation plan. Management has executed on the following measures in its remediation plan:

- hired additional external accounting resources, including third-party internal control advisors and technical accounting advisors;
- enhanced and maintained formal accounting policies, procedures and controls over the fair presentation of our financial statements; performed a detailed risk assessment to identify and scope significant accounts, systems and processes;
- redesigned and documented significant processes and internal controls over financial reporting;
- enhanced proper segregation of duties and management review and approvals across all key business processes;
- enhanced entity level and IT general controls; and
- performed testing and assessment of internal controls to evaluate the design and operating effectiveness of key controls.

Management believes that these actions, once fully implemented and operating, will remediate the material weaknesses discussed above. However, these material weaknesses will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. As such, we cannot consider these material weaknesses as remediated as of December 31, 2023.

Other than with respect to the remediation efforts noted above, there have been no significant changes in the Company's internal control over financial reporting that have occurred during the period covered by this Annual Report that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

We may discover additional weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 in a timely manner, when required, or if we are unable to maintain proper and effective internal controls over financial reporting, or identify any material weakness, we may not be able to produce timely and accurate financial statements which could result in material misstatements in our financial statements and potentially require us to restate our financial statements. If we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, when required, our investors could lose confidence in the accuracy and completeness of our reported financial information, the market price of our shares could be materially adversely affected, we could face restricted access to the capital markets, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

While we have been taking measures and plan to continue to take measures to design and implement an effective control environment, we cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate or prevent future material weaknesses.

b. In control statement

On the basis of reports and information provided to our board of directors, our board of directors is of the opinion that:

- this report provides sufficient insight into any failings in the effectiveness of the Company's risk management and control systems;
- notwithstanding the material weaknesses identified and described above, the Company's risk management and control systems provide reasonable assurance that the Company's financial reporting does not contain material inaccuracies;
- based on the Company's state of affairs as at the date of this report, it is justified that the Company's financial reporting is prepared on a going concern basis;
- this report states those material risks and uncertainties that are relevant to the expectation of the Company's continuity for a period of twelve months after the date of this report; and
- adequate alternative measures have been taken in the absence of an internal audit department through the use of a third party to operate in such capacity.

Any material failings in, material changes to, and/or material improvements of the Company's risk management and control systems which have been observed, made and/or planned, respectively, during the fiscal year to which this report relates, have been discussed with our audit committee and with our non-executive directors.

Furthermore, our board of directors confirms that:

- to the best of its knowledge, the statutory annual accounts included in this report give a true and fair view of assets, liabilities, financial position and loss of the Company and its consolidated subsidiary taken as a whole; and
- this report includes a fair review concerning the position, on the balance sheet date, and the development and performance of the business of the Company and its consolidated subsidiary taken as a whole, together with a description of the principal risks and uncertainties that they face.

9 CORPORATE GOVERNANCE

9.1 Dutch Corporate Governance Code

For the fiscal year to which this report relates, the Dutch Corporate Governance Code 2022 (DCGC) applied to the Company. The text of the DCGC can be accessed at http://www.mccg.nl. 2

Except as set out below, during the fiscal year to which this report relates, the Company complied with the principles and best practice provisions of the DCGC, to the extent that these are directed at our board of directors. To ensure compliance with the code of business conduct and ethics, we review the code of business conduct and ethics with our employees, directors and officers and we have not identified any compliance issues with our code of business conduct and ethics.

Risk management and internal audit function (best practice provisions 1.2.2, 1.3.1, 1.3.2, 1.3.3, 1.3.4 and 1.3.5)

The Company has not established an internal audit department. Our board of directors is of the opinion that adequate alternative measures have been taken in the form of the Company's risk management and control systems, as outlined elsewhere in this report, and that it is presently not necessary to establish an internal audit department through use of a third party to operate in this capacity.

Majority requirements for dismissal and setting-aside binding nominations (best practice provision 4.3.3)

Our directors are appointed by the general meeting on the basis of a binding nomination prepared by our board of directors. This means that the nominee will be appointed to the board of directors, unless the general meeting removes the binding nature of the nomination (in which case a new nomination will be prepared by our board of directors for a subsequent general meeting). Our articles of association provide that the general meeting can only pass such a resolution by at least a two-thirds majority of the votes cast, representing more than half of the issued share capital. However, the DCGC recommends that the general meeting can pass such a resolution by a simple majority of the votes cast, representing no more than one-third of the issued share capital.

Under our articles of association, directors can only be dismissed by the general meeting by a simple majority of the votes cast, provided that our board of directors proposes the dismissal. In other cases, the general meeting can only pass such a resolution by at least a two-thirds majority of the votes cast, representing more than half of the issued share capital. However, the DCGC recommends that the general meeting can pass such a resolution to dismiss a director by simple majority, representing no more than one-third of the issued share capital.

Remuneration (best practice provisions 3.1.2, 3.2.3, 3.3.2 and 3.3.3)

The DCGC recommends against providing equity awards as part of the compensation of a non-executive director. However, we deviate from this recommendation and have granted equity awards in the form of options to our non-executive directors, consistent with U.S. market practice. We believe that such remuneration structure is appropriate due to our listing on Nasdaq.

Our long-term incentive plan allows us to set the terms and conditions of awards granted thereunder. Under the Plan, we may grant (and have granted) common shares that are not subject to a lock-up period of at least five years after the date of grant, and we may grant (and have granted) options without restricting the exercisability of those options during the first three years after the date of grant. In those cases, this would cause a deviation from the DCGC.

The DCGC recommends disclosing the pay ratios within the company and any changes in these ratios compared to at least five previous financial years. The Company only compared the pay ratios to the previous two years, in which we were a public company, instead of the previous five years.

Vice-chairman (best practice provision 2.3.7)

The DCGC recommends that our board to appoint a vice chairman. We believe that our board will function properly, as it currently does, without a vice chairman and therefore do not see the need for appointing one of our non-executive directors to that position.

9.1.2 Code of business conduct and ethics and other corporate governance practices

The Company has adopted a code of business conduct and ethics which can be accessed at https://ir.lavatherapeutics.com/corporate-governance/governance-overview. The values included in our code of business conduct and ethics contribute to sustainable long-term value creation for the Company and its stakeholders. To ensure compliance with the code of business conduct and ethics, we provide annual training on our code of business conduct and ethics to our employees, directors and officers and we have not identified any compliance issues with our code of business conduct and ethics.

To ensure that the interests of our relevant stakeholders are considered, including in connection with the sustainability aspects of our strategy, the Company has adopted a stakeholder dialogue policy, which can be accessed at https://ir.lavatherapeutics.com/corporate-governance/governance-overview. The purpose of this policy is to establish a framework for conducting stakeholder dialogue that is open, transparent and inclusive.

The Company has adopted a shareholder dialogue policy which covers the manner of dialogue between us on the one hand and one or more of our shareholders on the other hand. Our shareholder dialogue policy can be accessed at https://ir.lavatherapeutics.com/corporate-governance/governance-overview.

The Company does not voluntarily apply other formal codes of conduct or corporate governance practices.

9.2 General Meeting of Shareholders

9.2.1 Functioning of our General Meeting of Shareholders

Annually, at least one general meeting of the Company must be held. This annual general meeting of shareholders must be held within six months after the end of the Company's fiscal year. A general meeting of shareholders must also be held within three months after our board of directors has decided that it is likely that the Company's equity has decreased to or below 50% of its paid up and called up share capital. In addition, without prejudice to the relevant best practice provisions of the DCGC with respect to invoking a 'response period' or the provisions under Dutch law with respect to invoking a 'cooling-off period', a general meeting of shareholders must be held when requested by one or more shareholders and/or others with meeting rights under Dutch law collectively representing at least 10% of the Company's issued share capital, provided that certain criteria are met. Any additional general meeting of shareholders shall be convened whenever our board of directors would so decide. Each general meeting of Shareholders must be held in Utrecht, Amsterdam, Arnhem, Assen, Haarlem, 's-Hertogenbosch, Groningen, Leeuwarden, Lelystad, Maastricht, Middelburg, Rotterdam, Haarlemmermeer (Schiphol), The Hague or Zwolle, the Netherlands.

For purposes of determining who have voting rights and/or meeting rights under Dutch law at a general meeting of shareholders, our board of directors may set a record date. The record date, if set, shall be the 28th day prior to that of our general meeting of shareholders. Those who have voting rights and/or meeting rights under Dutch law on the record date and are recorded as such in one or more registers designated by our board of directors shall be considered to have those rights at our general meeting of shareholders, irrespective of any changes in the composition of the shareholder base between the record date and the date of our general meeting of shareholders. The Company's articles of association require shareholders and others with meeting rights under Dutch law to notify the Company of their identity and their intention to attend our general meeting of shareholders. This notice must be received by the Company ultimately on the seventh day prior to our general meeting of shareholders, unless indicated otherwise when such meeting is convened.

9.2.2 Powers of our general meeting of shareholders

All powers that do not vest in our board of directors pursuant to applicable law, the Company's articles of association or otherwise, vest in the Company's general meeting of shareholders. The main powers of our general meeting of shareholders include, subject in each case to the applicable provisions in the Company's articles of association:

a. the appointment, suspension and dismissal of our directors;

b. the approval of certain resolutions of our board of directors concerning a material change to the identity or the character of the Company or its business;

c. the reduction of the Company's issued share capital through a decrease of the nominal value, or cancellation, of shares in its capital;

d. the adoption of the Company's statutory annual accounts;

e. the appointment of the Dutch independent auditor to examine the Company's statutory annual accounts;

f. amendments to the Company's articles of association;

g. approving a merger or demerger by the Company, without prejudice to the authority of our board of directors to resolve on certain types of mergers and demergers if certain requirements are met; and

h. the dissolution of the Company.

In addition, our general meeting of shareholders has the right, and our board of directors must provide any information reasonably requested by our general meeting of shareholders, unless this would be contrary to an overriding interest of the Company.

9.2.3 Shareholder rights

Each share in the Company's capital, irrespective of its class, carries one vote. Shareholders, irrespective of whether or not they have voting rights, have meeting rights under Dutch law (including the right to attend and address our general meeting of shareholders, subject to the concept of a record date as described in chapter 1.1.1). Furthermore, each share in the Company's capital carries an entitlement to dividends and other distributions as set forth in the Company's articles of association. Pursuant to the Company's articles of association, any such dividend or other distribution shall be payable on such date as determined by our board of directors and our board of directors may also set a record date for determining who are entitled to receive any such dividend or other distribution (irrespective of subsequent changes in the shareholder base). The record date for dividends and other distributions shall not be earlier than the date on which the dividend or other distribution is announced. In addition, shareholders have those rights awarded to them by applicable law.

9.3 Evaluation

During the fiscal year to which this report relates, our board of directors has evaluated its own functioning, the functioning of the committees of our board of directors and that of the individual directors on the basis of self-evaluation form distributed to, and completed by, the directors. As part of these evaluations, our board of directors has considered (i) substantive aspects, mutual interaction, (ii) events that occurred in practice from which lessons may be learned and (iii) the desired profile, composition, competencies and expertise of our board of directors. These evaluations are intended to facilitate an examination and discussion by our board of directors of its effectiveness and areas for improvement. The self-evaluation supported that the composition and structure of the Board and its committees are appropriate for the Company and that additional succession planning could be considered. In additional to general corporate education on Dutch law and Nasdaq, the board may also explore additional educational opportunities, such as cybersecurity. On the basis of these evaluations, our board of directors has concluded that it is functioning properly.

9.4 Diversity and inclusion

The Company has a diversity and inclusion policy with respect to the composition of our board of directors and the Company's senior management (as defined in that policy). The Company is committed to supporting, valuing and leveraging the value of diversity in the composition of the board of directors and senior management, but also believes that there is a fine line between diversity and unintentional discrimination. For that reason, the importance of diversity, in and of itself, should not set aside the overriding principle that someone should be recommended, nominated and appointed for being "the right person for the job". The Company believes that it is important for our board of directors and senior management to represent a diverse composite mix of personal backgrounds, experiences, qualifications, knowledge, abilities and viewpoints. The Company seeks to combine the skills and experience of long-standing members of our board of directors and senior management with the fresh perspectives, insights, skills and experiences of new members. To further increase the range of viewpoints, perspectives, talents and experience within our board of directors and senior management, the Company strives for a mix of ages in the composition of those

bodies, but also does not set a specific target in this respect. The Company recognises and welcomes the value of diversity and inclusion with respect to race, ethnicity, nationality, sexual orientation and other important cultural differences. The Company is committed to seeking broad diversity and inclusion in the composition of our board of directors and senior management and will consider these attributes when evaluating new candidates in the best interests of the Company and its stakeholders. In terms of experience and expertise, the Company intends for our board of directors and senior management to be composed of individuals who are knowledgeable in one or more specific areas detailed in the Company's diversity and inclusion policy.

The Company believes that the composition of our board of directors and our senior management is such, that the Company's diversity objectives, as outlined above, have been achieved, except for the Company's diversity targets in term of gender within senior management. This is primarily due to the selection of the current members of our board of directors and our senior management based on the required profile and their backgrounds, experiences, qualifications, knowledge, abilities and viewpoints without positive or negative bias on gender. In the future, this will continue to be the Company's basis for selection of new members of our board of directors and our senior management.

The table below provides certain information regarding the diversity of members of our Board as of the date of this Annual Report:

Board Diversity Matrix

Country of Principal Executive Offices	The Netherlands			
Foreign Private Issuer	Yes			
Disclosure Prohibited Under Home Country Law	No			
Total Number of Directors	8			
	Female	Male	Non-Binary	Did not disclose
Part I: Gender Identity				
Directors	3	5	—	—
Part II: Demographic Background				
Underrepresented Individual in Home Country			1	
LGBTQ+			—	
Did Not Disclose Demographic Background			—	

To the extent possible and practicable, the Company intends for the composition of our board of directors to remain as balanced as reasonably possible, provided for a minimum target of at least 70% of the directors to be male and at least 30% of them to be female.

For the purposes of evaluating diversity, the Company has defined its senior management. The Company's senior management consists of management at the vice president level and above. As of December 31, 2023, 7 out of 10 senior management members were male and 3 out of 10 senior management members were female. The Company targets a gender ratio in which at least 70% of senior management is male and at least 30% is female. The Company is continuously monitoring the gender ratio when new positions are filled or promotions are considered.

The diversity policy of the Company has been revised in September 2023 whereby the above objectives have been updated. Under the current diversity policy, the Company intends for the composition of our board of directors to remain as balanced as reasonably possible, provided for a minimum target of at least 30% of the board of directors to be female and targets a gender ratio in which at least 30% of senior management is female by the end of 2024. In our hiring process we continue to scout for diverse and inclusive candidates to ensure our current organizational spread continues to reflect a multitude of backgrounds.

The Company employs 37 persons as of December 31, 2023, of which 16 are male and 21 are female. The Company targets an overall gender ratio among its employees of 50% male employees and 50% female employees.

Given the gender ratios both in our board of directors as well as in senior management, we are overall satisfied with our efforts towards improving gender diversity and we believe that our activities in this respect work well overall.

9.5 Corporate Values and Code of Business Conduct and Ethics

The Company has adopted a Code of Business Conduct and Ethics (Code of Ethics), approved by the board of directors, which is applicable to all employees, including our principal executive officer, principal financial officer, principal accounting officer and controller.

In August 2023, our board of directors adopted an amendment to our Code of Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer and controller, which specifies that such officers are required to avoid any conflict or potential conflict between their personal interests (including those of their significant others and immediate family) and the best interests of the Company, and that officers may seek authorizations and determinations from the Audit Committee for conflict of interest matters.

A copy of this Code of Ethics is available on our Company website at https://ir.lavatherapeutics.com/corporate-governance/governance-overview.

Our corporate values are embedded in our Code of Business Conduct and Ethics.

10 PROTECTIVE MEASURES

Under Dutch law, various protective measures are possible and permissible within the boundaries set by Dutch law and Dutch case law.

In this respect, our general meeting authorized our board of directors to grant a call option during a period of five years following the closing of this offering to an independent foundation under Dutch law (if and when incorporated), or protective foundation, to acquire preferred shares pursuant to a call option agreement, or the call option agreement, that may be entered into between us and such protective foundation after the closing of this offering. This call option, if and when granted, shall be continuous in nature and can be exercised repeatedly on multiple occasions. If the protective foundation, if and when incorporated, would exercise such call option, if and when granted, a number of preferred shares up to 100% of our issued share capital held by others than the protective foundation, minus one share, will be issued to the protective foundation. These preferred shares would then be issued to the protective foundation under the obligation to pay up 25% of their nominal value. In order for the protective foundation to finance the issue price in relation to the preferred shares, the protective foundation may enter into a finance arrangement with a bank or other financial institution. As an alternative to securing this external financing, subject to applicable restrictions under Dutch law, the call option agreement, if and when entered into, may provide that the protective foundation may request us to provide, or cause our subsidiaries to provide, sufficient funding to the protective foundation to enable it to satisfy the payment obligation (or part thereof) in cash and/or to charge an amount equal to the payment obligation (or part thereof) against our profits and/or reserves in satisfaction of such payment obligation. The articles of association of the protective foundation, if and when incorporated, will provide that it will promote and protect the interests of our company, the business connected with it and our stakeholders from time to time, and repressing possible influences which could threaten the strategy, continuity, independence and/or identity of our company or the business connected with it, to such an extent that this could be considered to be damaging to the aforementioned interests. These influences may include a third party acquiring a significant percentage of our common shares, the announcement of an unsolicited public offer for our common shares, shareholder activism, other concentration of control over our common shares or any other form of undue pressure on us to alter our strategic policies. The protective foundation, if and when incorporated, shall be structured to operate independently of us. The voting rights of our shares are based on nominal value and, as we expect our common shares to trade substantially in excess of their nominal value, preferred shares issued at 25% of their nominal value can carry significant voting power for a substantially reduced price compared to the price of our common shares and thus can be used as a defensive measure. These preferred shares, if and when issued, will have both a liquidation and dividend preference over our common shares and will accrue cash dividends at a fixed rate calculated over the amount paid-up on those preferred shares pro rata tempore for the period during which they were outstanding. The protective

foundation would be expected to require us to cancel its preferred shares, if and when issued to the protective foundation, once the perceived threat to our company, its business and its stakeholders has been removed or sufficiently mitigated or neutralized. However, subject to the same limitations described above, the protective foundation would, in that case, continue to have the right to exercise the call option in the future in response to a new threat to the interests of our company, our business and our stakeholders from time to time.

Also, certain provisions of our articles of association may make it more difficult for a third party to acquire control of us or effect a change in the composition of our board of directors. These include:

- a provision that our directors are appointed on the basis of a binding nomination prepared by our board of directors which can only be overruled by a two-thirds majority of votes cast representing more than half of our issued share capital;
- a provision that our directors may only be dismissed by the general meeting by a two-thirds majority of votes cast representing more than half of our issued share capital, unless the dismissal is proposed by our board of directors in which latter case a simple majority of the votes cast would be sufficient;
- a provision allowing, among other matters, the former chairperson of our board of directors or our former Chief Executive Officer to manage our affairs if all of our directors are dismissed and to appoint others to be charged with our affairs, including the preparation of a binding nomination for directors as discussed above, until new directors are appointed by the general meeting on the basis of such binding nomination; and
- a requirement that certain matters, including an amendment of our articles of association, may only be resolved upon by our general meeting if proposed by our board of directors.

Dutch law also allows for staggered multi-year terms of our directors, as a result of which only part of our directors may be subject to appointment or re-appointment in any given year.

Furthermore, in accordance with the DCGC, shareholders who have the right to put an item on the agenda for our general meeting of shareholders or to request the convening of a general meeting of shareholders shall not exercise such rights until after they have consulted our board of directors. If exercising such rights may result in a change in our strategy (for example, through the dismissal of directors), our board of directors must be given the opportunity to invoke a reasonable period of up to 180 days to respond to the shareholders' intentions. If invoked, our board of directors must use such response period for further deliberation and constructive consultation, in any event with the shareholder(s) concerned and exploring alternatives. At the end of the response time, our board of directors shall report on this consultation and the exploration of alternatives to our general meeting of shareholders. The response period may be invoked only once for any given general meeting of shareholders and shall not apply (i) in respect of a matter for which a response period or a cooling-off period (as referred to below) has been previously invoked or (ii) if a shareholder holds at least 75% of our issued share capital as a consequence of a successful public bid.

In addition, our board of directors can invoke a cooling-off period of up to 250 days when shareholders, using their right to have items added to the agenda for a general meeting of shareholders or their right to request a general meeting, propose an agenda item for our general meeting of shareholders to dismiss, suspend or appoint one or more directors (or to amend any provision in the Company's articles of association dealing with those matters) or when a public offer for our company is made or announced without our support, provided, in each case, that our board of directors believes that such proposal or offer materially conflicts with the interests of our company and its business. During a cooling-off period, our general meeting of shareholders cannot dismiss, suspend or appoint directors (or amend the provisions in the Company's articles of association dealing with those matters) except at the proposal of our board of directors.

During a cooling-off period, our board of directors must gather all relevant information necessary for a careful decision-making process and at least consult with shareholders representing 3% or more of our issued share capital at the time the cooling-off period was invoked, as well as with our Dutch works council. Formal statements expressed by these stakeholders during such consultations must be published on our website to the extent these stakeholders have approved that publication. Ultimately one week following the last day of the cooling-off period, our board of directors must publish a report in respect of its policy and conduct of affairs

during the cooling-off period on our website. This report must remain available for inspection by shareholders and others with meeting rights under Dutch law at our office and must be tabled for discussion at the next general meeting of shareholders. Shareholders representing at least 3% of our issued share capital may request the Enterprise Chamber of the Amsterdam Court of Appeal (the "Enterprise Chamber") for early termination of the cooling-off period.

The Enterprise Chamber must rule in favor of the request if the shareholders can demonstrate that:

- our board of directors, in light of the circumstances at hand when the cooling-off period was invoked, could not reasonably have concluded that the relevant proposal or hostile offer constituted a material conflict with the interests of our company and its business;
- our board of directors cannot reasonably believe that a continuation of the cooling-off period would contribute to careful policymaking; or
- other defensive measures, having the same purpose, nature and scope as the cooling-off period, have been activated during the cooling-off period and have not since been terminated or suspended within a reasonable period at the relevant shareholders' request (i.e., no 'stacking' of defensive measures).

Signature page to the Dutch statutory board report of LAVA Therapeutics N.V. for the fiscal year ended December 31, 2023

Executive Director:

S.A. Hurly

Non-Executive Directors:

K. Dhingra

K.J. Wilson

J. Backstrom

J. Noble

P.A. Kiener

M.E. Wadlinger

C. Oliger

Utrecht, May 29, 2024

11 FINANCIAL INFORMATION

11.1 Consolidated Financial Statements

LAVA Therapeutics N.V.
Consolidated statement of loss and other comprehensive loss
(In thousands, except share and per share amounts)

	Notes	For the Year Ended December 31, 2023	2022	2021
Revenue:				
Revenue from contracts with customers	4	$ 6,769	$ 19,391	$ 5,350
Cost of sales of goods		(2,546)	—	—
Cost of providing services		(936)	—	—
Gross profit		**3,287**	**19,391**	**5,350**
Operating expenses:				
Research and development	5	(33,814)	(40,105)	(36,945)
General and administrative	6	(12,726)	(14,124)	(12,018)
Total operating expenses		**(46,540)**	**(54,229)**	**(48,963)**
Operating loss		**(43,253)**	**(34,838)**	**(43,613)**
Interest income (expense), net	7	2,970	257	(625)
Foreign currency exchange (loss) gain, net	8	(1,412)	2,923	2,040
Total non-operating income		**1,558**	**3,180**	**1,415**
Loss before income tax		**(41,695)**	**(31,658)**	**(42,198)**
Income tax expense	9	(279)	(249)	(157)
Loss for the year		**$ (41,974)**	**$ (31,907)**	**$ (42,355)**
Items that may be reclassified to profit or loss				
Foreign currency translation adjustment	2	2,073	(6,749)	(5,642)
Total comprehensive loss		**$ (39,901)**	**$ (38,656)**	**$ (47,997)**
Loss per share:				
Loss per share, basic and diluted	10	$ (1.57)	$ (1.23)	$ (2.14)
Weighted-average common shares outstanding, basic and diluted	10	26,732,556	25,924,005	19,758,169

The accompanying Notes are an integral part of these consolidated financial statements.

LAVA Therapeutics N.V.
Consolidated statement of financial position
(In thousands)

	Notes	As of December 31, 2023	2022
Assets			
Non-current assets:			
Property and equipment, net	11	$ 1,602	$ 1,432
Right-of-use assets	12	892	651
Other non-current assets and security deposits		319	809
Total non-current assets		**2,813**	**2,892**
Current assets:			
Receivables and other	4	1,459	3,254
Prepaid expenses and other current assets	4	1,627	4,411
VAT receivable		240	—
Investments	13	51,340	32,535
Cash and cash equivalents	14	44,231	100,333
Total current assets		**98,897**	**140,533**
Total assets		**$ 101,710**	**$ 143,425**
Equity and Liabilities			
Equity:			
Share capital	15	$ 3,715	$ 3,715
Equity-settled employee benefits reserve		12,005	8,942
Foreign currency translation reserve	2	(10,899)	(12,972)
Additional paid-in capital	15	194,424	194,424
Accumulated deficit		(106,093)	(76,162)
Loss for the year		(41,974)	(31,907)
Total equity		**51,178**	**86,040**
Non-current liabilities:			
Deferred revenue	4	35,000	35,000
Lease liabilities	12	591	431
Total non-current liabilities		**35,591**	**35,431**
Current liabilities:			
Trade payables and other	17	4,446	3,965
VAT payable		—	45
Borrowings	16	5,282	4,640
Lease liabilities	12	440	379
License liabilities	24	—	4,732
Accrued expenses and other current liabilities	18	4,773	8,193
Total current liabilities		**14,941**	**21,954**
Total liabilities		**50,532**	**57,385**
Total equity and liabilities		**$ 101,710**	**$ 143,425**

The accompanying Notes are an integral part of these consolidated financial statements.

LAVA Therapeutics N.V.
Consolidated statements of changes in equity
(In thousands, except for share amounts)

	Note	Preference						Number of Common shares	Common Share capital	Equity-settled employee benefits reserve	Foreign currency translation reserve	Additional paid-in capital	Accumulated deficit	Loss for the year	Total
		Number of Series A shares	Series A Share premium	Number of Series B shares	Series B Share premium	Number of Series C shares	Series C Share premium								
Balance at January 1, 2021		**1,037,595**	**$ 722**	**3,899,766**	**$ 18,340**	**4,133,805**	**$ 22,026**	**281,775**	**$ —**	**$ 922**	**$ (581)**	**$ —**	**$ (17,880)**	**$ (15,927)**	**$ 7,622**
Loss for period		—	—	—	—	—	—	—	—	—	—	—	—	(42,355)	(42,355)
Appropriation of the result of preceding year		—	—	—	—	—	—	—	—	—	—	—	(15,927)	15,927	—
Share split		—	(143)	—	(536)	—	(589)	—	1,308	—	—	(40)	—	—	—
Issuance of Series C Preferred shares ($6.22 per share), net of offering costs of $92		—	—	—	—	9,945,221	60,373	—	1,425	—	—	—	—	—	61,798
Repurchase of Series A and common shares		(718,250)	(400)	—	—	—	—	(165,750)	(122)	—	—	(4,760)	—	—	(5,282)
Conversion of preference shares		(319,345)	(179)	(3,899,766)	(17,804)	(14,079,026)	(81,810)	18,298,137	—	—	—	99,793	—	—	—
Issuance of common stock in initial public offering ($15.00 per share), net of offering costs of $11.5 million		—	—	—	—	—	—	6,700,000	947	—	—	87,779	—	—	88,726
Issuance of overallotment option		—	—	—	—	—	—	425,712	61	—	—	5,877	—	—	5,939
Issuance of Amsterdam UMC common stock		—	—	—	—	—	—	235,664	34	—	—	3,621	—	—	3,655
Share-based compensation expense	20	—	—	—	—	—	—	—	—	3,907	—	—	—	—	3,907
Foreign currency translation adjustment		—	—	—	—	—	—	—	—	—	(5,642)	—	—	—	(5,642)
Balance at December 31, 2021		**—**	**—**	**—**	**—**	**—**	**—**	**25,775,538**	**3,653**	**4,829**	**(6,223)**	**192,270**	**(33,807)**	**(42,355)**	**118,367**
Loss for period		—	—	—	—	—	—	—	—	—	—	—	—	(31,907)	(31,907)
Appropriation of the result of preceding year		—	—	—	—	—	—	—	—	—	—	—	(42,355)	42,355	—
Option exercises		—	—	—	—	—	—	22,197	3	—	—	12	—	—	15
Issuance of Amsterdam UMC common stock		—	—	—	—	—	—	491,352	59	—	—	2,142	—	—	2,201
Share-based compensation expense	20	—	—	—	—	—	—	—	—	4,113	—	—	—	—	4,113
Foreign currency translation adjustment		—	—	—	—	—	—	—	—	—	(6,749)	—	—	—	(6,749)
Balance at December 31, 2022		**—**	**—**	**—**	**—**	**—**	**—**	**26,289,087**	**3,715**	**8,942**	**(12,972)**	**194,424**	**(76,162)**	**(31,907)**	**86,040**
Loss for period		—	—	—	—	—	—	—	—	—	—	—	—	(41,974)	(41,974)
Appropriation of the result of preceding year		—	—	—	—	—	—	—	—	—	—	—	(31,907)	31,907	—
Reclassification lapsed options	20	—	—	—	—	—	—	—	—	(1,976)	—	—	1,976	—	—
Share-based compensation expense	20	—	—	—	—	—	—	—	—	5,039	—	—	—	—	5,039
Foreign currency translation adjustment		—	—	—	—	—	—	—	—	—	2,073	—	—	—	2,073
Balance at December 31, 2023		**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**26,289,087**	**$ 3,715**	**$ 12,005**	**$ (10,899)**	**$ 194,424**	**$ (106,093)**	**$ (41,974)**	**$ 51,178**

The accompanying Notes are an integral part of these consolidated financial statements.

LAVA Therapeutics N.V.
Consolidated statement of cash flows
(In thousands, except for share amounts)

	Notes	For the Year Ended December 31, 2023	2022	2021
Cash flows from operating activities:				
Loss before income tax		$ (41,695)	$ (31,658)	$ (42,198)
Adjusted for:				
Depreciation and amortization of non-current assets		616	504	331
Foreign currency exchange loss (gain), net		1,412	(2,923)	(2,040)
Depreciation of right-of-use assets		662	277	227
Share-based compensation expense	20	5,039	4,113	3,907
Income tax expense		(279)	(249)	(157)
Amortization of premium on investments		(1,900)	(134)	446
Changes in working capital:				
Receivables and other		1,870	(2,891)	777
VAT receivable		(281)	416	(35)
Prepaid expenses and other assets		3,385	(1,857)	(2,859)
Trade accounts payable and other		334	1,413	1,618
Deferred offering & financing costs		—	—	1,623
Deferred revenue	4	—	33,510	(4,649)
License liabilities		(4,797)	(2,828)	13,713
Other liabilities		(3,338)	6,350	649
Net cash (used in) provided by operating activities		**(38,972)**	**4,043**	**(28,647)**
Cash flows from investing activities:				
Purchases of property and equipment		(730)	(587)	(764)
Purchases of investments		(90,082)	(70,877)	(45,291)
Maturities of investments		73,177	80,810	2,510
Net cash (used in) provided by investing activities		**(17,635)**	**9,346**	**(43,545)**
Cash flows from financing activities:				
Proceeds from option exercises		—	15	—
Proceeds from common shares from initial public offering, net	15	—	—	94,189
Proceeds from Series C financing, net		—	—	61,798
Payment of Series A preferred and common shares repurchased		—	—	(5,167)
Proceeds from borrowings		470	611	680
Payment of principal portion of lease liabilities		(1,041)	(343)	(340)
Net cash (used in) provided by financing activities		**(571)**	**283**	**151,160**
Net (decrease) increase in cash and cash equivalents		**(57,178)**	**13,672**	**78,968**
Cash and cash equivalents at beginning of year		100,333	90,869	15,818
Effects of exchange rate changes		1,076	(4,208)	(3,917)
Cash and cash equivalents at end of year		**$ 44,231**	**$ 100,333**	**$ 90,869**
Supplemental schedule of noncash operating and financing activities:				
Issuance of 491,352 common shares to Amsterdam UMC in lieu of payment for license liabilities		$ —	$ 2,201	$ —
Issuance of 235,664 common shares to Amsterdam UMC in lieu of payment for license liabilities		$ —	$ —	$ 3,655
Supplemental schedule of interest cash flows included in cash flows from operating activities:				
Interest received		$ 3,671	$ 851	$ 37
Interest paid		$ —	$ 97	$ 224

The accompanying Notes are an integral part of these consolidated financial statements.

Notes to the consolidated financial statements

1. Corporate and Company information

1.1 Corporate Information

LAVA Therapeutics N.V., formerly LAVA Therapeutics B.V., was founded in 2016 and is incorporated and domiciled in the Netherlands. The Company's registered office is Yalelaan 62, 3584 CM in Utrecht. The Company is registered at the Chamber of Commerce under number 65335740. In connection with becoming a public company, on March 29, 2021 the Company changed its business structure from a private limited company (*besloten vennootschap)* to a limited liability public company (*naamloze vennootschap*), and consequently, its name changed from "LAVA Therapeutics B.V." to "LAVA Therapeutics N.V."

The Company and its subsidiary are a clinical-stage immuno-oncology company dedicated to rapidly developing new cancer treatments that leverage the immune system to save patients' lives. Using its Gammabody platform,the Company is developing a portfolio of novel bispecific and multispecific antibodies designed to engage and leverage the potency and precision of gamma delta ($\gamma\delta$) T cells to elicit a robust anti-tumor immune response and improve outcomes for cancer patients. The Company is advancing its Gammabody pipeline for the development of potential therapeutics in both hematologic malignancies and solid tumors.

The consolidated financial statements of LAVA Therapeutics N.V. were authorized for issue by the Company's board of directors on May 29, 2024.

1.2 Company information

The consolidated financial statements of the Company include:

Name	Legal seat	Country of incorporation	% of equity interest 2023	% of equity interest 2022
Lava Therapeutics N.V.	Utrecht	The Netherlands	100 %	100 %
Lava Therapeutics Inc.	Delaware	United States of America	100 %	100 %

The Company's 100% subsidiary, LAVA Therapeutics, Inc., which was founded in August 2019, is incorporated in the United States of America and acts as a service provider to the parent, LAVA Therapeutics N.V.

2. Summary of significant accounting policies

The principal accounting policies applied in the preparation of these consolidated financial statements are included below. These policies have been consistently applied to all of the years presented, unless otherwise stated.

(a) Basis of preparation

The consolidated financial statements of the Company have been prepared in accordance with and comply with International Financial Reporting Standards as adopted by the European Union (EU-IFRS) and with Part 9 of Book 2 of the Dutch Civil Code.

The consolidated financial statements of the Company have been prepared on a historical cost basis.

The preparation of the consolidated financial statements in conformity with EU-IFRS requires the application of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the accounting policies. The areas involving a greater degree of judgment or complexity, or areas in which assumptions and estimates are significant to the consolidated financial statements, are disclosed in Note 3.

Going concern

These consolidated financial statements have been prepared by management on the assumption that the Company will be able to continue as a going concern, which presumes that the Company will, for the foreseeable future, be able to realize its assets and discharge its liabilities in the normal course of business.

Through December 31, 2023, the Company funded its operations with proceeds from sales of equity financings, collaboration and licensing agreements, government grants and borrowings under various agreements. Since inception of the Company, it has incurred net losses. The Dutch Research and Development Act (WBSO) provides compensation for a part of research and development wages and other costs through a reduction in payroll taxes. WBSO grant amounts are offset against wages and salaries and included in research and development expenses in the consolidated statements of loss and comprehensive loss.

As of December 31, 2023, the Company had an accumulated deficit of $148.1 million. The Company expects to continue to generate operating losses in the foreseeable future. It expects that its cash, cash equivalents and investments of $95.6 million as of December 31, 2023 will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 12 months following the issuance of these financial statements. Accordingly, the consolidated financial statements have been prepared on a going concern basis.

Until the Company can generate sufficient product revenue to satisfy its cash requirements, which it may never do, it expects to finance its future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. Disruptions in the financial markets in general may make equity and debt financing more difficult to obtain and may have a material adverse effect on its ability to meet its fundraising needs. If it is unable to obtain sufficient funding in a timely manner or on commercially acceptable terms, it may have to delay, reduce the scope of, or eliminate one or more of its research programs, and consider other cost reduction initiatives, such as downsizing its operations or withholding initiation or expansion of clinical trials or research. In addition, in the event the Company is not able to generate sufficient funds, it may be unable to continue as a going concern and its business, financial condition and/or results of operations could be materially and adversely affected and could reduce the price of its common shares and it may ultimately go into insolvency. In addition, any perceived or actual inability by the Company to finance its clinical development activities and other business activities may cause the market price of its common shares to decline.

Global Conditions

There may be adverse effects on its 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 international hostilities, including the Russian invasion of Ukraine and the Hamas and Israel war.

(b) Basis of consolidation

Subsidiaries are all entities over which the Company has control. Control is achieved when the Company is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Subsidiaries are consolidated from the date on which control over the subsidiary is transferred to the Company and are deconsolidated from the date that control over the subsidiary ceases.

When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies into line with the Company's accounting policies. All intercompany assets and liabilities, equity, income, expenses, and cash flows relating to transactions between members of the Company are eliminated in full, upon consolidation. Certain prior year amounts have been reclassified to reflect current year's presentation.

Since the Company's statement of profit or loss for 2023 is recognized in the consolidated financial statements, it is sufficient in the Company financial statements to present a condensed statement of profit or loss in accordance with Art. 2:402 DCC.

c) Foreign currency

Items included in the financial statements of each of the Company's entities are measured using the currency of the primary economic environment in which the entity operates. The Company's consolidated financial statements are presented in USD. The parent company, LAVA Therapeutics N.V., has the functional currency of EUR. The subsidiary company, LAVA Therapeutics, Inc., has the functional currency of USD.

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year end exchange rates are recognized within foreign currency exchange gain (loss), net, in the consolidated statements of loss and comprehensive loss.

For presentation purposes in USD, all assets and liabilities denominated in foreign currencies are translated into USD using exchange rates in effect as of the date of the balance sheet date. Revenue and expense transactions are translated at the monthly average exchange rates, and certain specific equity transactions are translated at the exchange rate in effect at the time of the transaction. All resulting exchange differences were recognized within currency translation adjustment in the consolidated statements of loss and other comprehensive loss and as a separate component of shareholders' equity.

d) Segment information

Operating segments are identified based on whether the allocation of resources and/or the assessment of performance of a particular component of Company's activities are regularly reviewed as a separate operating segment by Company's Chief Operating Decision Maker. The Company's business activities are organized into one reportable segment, which is consistent with the basis of the internal reports that the management regularly reviews in allocating resources and assessing performance.

e) Cash flow statement

The cash flow statement has been prepared using the indirect method. For the purposes of the consolidated statements of cash flows, cash and cash equivalents consist of cash and short-term deposits, as defined below, net of outstanding bank overdrafts.

f) Research and License Revenue

The Company may enter into collaboration and licensing arrangements for research and development, manufacturing, and commercialization activities with counterparties for the development and commercialization of its product candidates. These arrangements may contain multiple components, such as (i) licenses, (ii) research and development activities, and (iii) the manufacturing of certain materials. Payments pursuant to these arrangements may include non-refundable and refundable payments, payments upon the achievement of significant regulatory, development and commercial milestones, sales of product at certain agreed-upon amounts, and royalties on product sales.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under a collaboration agreement, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are capable of being distinct; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue as the Company satisfies each performance obligation.

g) Research and development expenses

The Company expenses research and development expenses as incurred and does not capitalize them. Internal development expenditures are capitalized when the criteria for recognizing an asset are met in accordance with IAS - 38 Intangible Assets, usually when a regulatory filing has been made in a major market and approval is considered highly probable. Where regulatory and other uncertainties are such that the criteria are not met, the expenditures are recognized in the consolidated statements of loss and other comprehensive loss. The Company's research and development expenses consist primarily of costs incurred

in performing research and development activities, including personnel-related expenses such as salaries, share-based compensation and benefits, facility costs, depreciation and external costs of outside vendors engaged to conduct preclinical and clinical development activities. It accounts for a governmental research and development payroll tax subsidy from *Wet Bevordering Speur en Ontwikkelingswerk* (WBSO) as a reduction of the research and development personnel-related expenses when incurred.

h) General and administrative expenses

The Company's general and administrative expenses consist of personnel-related expenses for employees involved in general corporate functions, including accounting, finance, insurance, tax, legal and human relations, costs associated with outside professional fees such as legal counsel and auditors, costs associated with use by these functions of facilities and equipment, such as depreciation expenses, premises maintenance expenses and other general corporate expenses. General and administrative expenses are expensed as incurred.

i) Share-based awards

Share options granted to employees and consultants providing similar services are measured at the grant date fair value of the equity instruments granted. The grant date fair value is determined through the use of an option-pricing model considering the following variables:

a) the exercise price of the option;

b) the expected life of the option;

c) the current value of the underlying shares;

d) the expected volatility of the share price;

e) the dividends expected on the shares; and

f) the risk-free interest rate for the life of the option.

The Company accounts for these awards as equity-settled share-based payment awards. For its share option plans, management's judgment is that the Black-Scholes valuation formula is the most appropriate method for determining the fair value of the options considering the terms and conditions attached to the grants made and to reflect exercise behavior. Prior to its IPO, as a private company there was no published share price information available. Consequently, the Company estimated the fair value of its shares and the expected volatility of that share value for option grants prior to the IPO. These assumptions and estimates are further discussed in Note 20 to the financial statements.

The result of the share option valuations and the related compensation expense that is recognized for the respective vesting periods during which services are received is dependent on the model and input parameters used. Even though management considers the fair values reasonable and defensible based on the methodologies applied and the information available, others might derive a different fair value for the options.

j) Employee benefits

The Company provides defined contribution plans to its employees. Contributions to defined contribution plans are expensed when employees provide services. The Company has no further payment obligations once the contributions have been paid. The Company's post-employment schemes do not include any defined benefit plans. Expenses associated with the servicing of defined contribution plans were $0.6 million for each of the years ended December 31, 2023, 2022 and 2021.

k) Income taxes

Income tax expense comprises current and deferred tax. It is recognized in profit or loss except to the extent that it relates to a business combination, or items recognized directly in equity or in other comprehensive income. Current tax comprises the expected tax payable or receivable on the taxable income or loss for the year and any adjustment to tax payable or receivable in respect of previous years. It is measured using

tax rates enacted or substantively enacted at the reporting date. Current tax also includes any tax arising from dividends. Current tax assets and liabilities are offset only if certain criteria are met.

Deferred tax is recognized in respect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Deferred tax is not recognized for:

- temporary differences on the initial recognition of assets or liabilities in a transaction that is not a business combination and that affects neither accounting nor taxable profit or loss, or does not give rise to equal taxable and deductible temporary differences;
- temporary differences related to investments in subsidiaries, associates, and joint arrangements to the extent that the Company is able to control the timing of the reversal of the temporary differences and it is probable that they will not reverse in the foreseeable future; and
- taxable temporary differences arising on the initial recognition of goodwill.

Deferred tax assets are recognized for unused tax losses, unused tax credits and deductible temporary differences to the extent that it is probable that future taxable profits will be available against which they can be used. Deferred tax assets are reviewed at each reporting date and are reduced to the extent that it is no longer probable that the related tax benefit will be realized; such reductions are reversed when the probability of future taxable profits improves.

Unrecognized deferred tax assets are reassessed at each reporting date and recognized to the extent that it has become probable that future taxable profits will be available against which they can be utilized.

Deferred tax is measured at the tax rates that are expected to be applied to temporary differences when they reverse, using tax rates enacted or substantively enacted at the reporting date.

The measurement of deferred tax reflects the tax consequences that would follow from the manner in which the Company expects, at the reporting date, to recover or settle the carrying amount of its assets and liabilities.

When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized, which is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2023 and 2022, the Company does not have any material uncertain tax positions.

l) Cash and cash equivalents

Cash and cash equivalents in the consolidated statements of financial position comprise of cash at banks and on hand and short-term, highly liquid investments that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

For the purposes of the consolidated statements of cash flows, cash and cash equivalents consist of cash and short-term deposits, as defined above, net of outstanding bank overdrafts.

m) Investments

The Company’s investments in debt securities consist entirely of investments in U.S. Treasury securities, with maturities ranging from three months to one year. All of these investments are classified as current assets in its consolidated statements of financial position. It has the intent and ability to hold all investments in debt securities until maturity. Accordingly, all investments are recorded at amortized cost on its consolidated statements of financial position, with the amortization of premiums or discounts and earned interest income recorded in its consolidated statements of loss.

n) Property and equipment

Property, plant, and equipment are stated at cost less accumulated depreciation and accumulated impairment losses, if any. The cost of an item of property, plant and equipment is recognized as an asset if it is probable that future economic benefits associated with the item will flow to the entity and the cost of the item can be measured reliably.

Property, plant, and equipment include major expenditures for new assets, improvements and replacement assets that extend the useful lives of assets or increase their revenue-generating capacities. Repair and maintenance costs are expensed as incurred.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets, as follows:

	years
Building improvements	10
Laboratory equipment	5
Office equipment	5
Information and communication equipment (ICT)	5

The estimated useful life for building improvements is the shorter of the estimated useful life and the lease term. Depreciation of property, plant and equipment used for laboratory equipment and ICT equipment is included within research and development expenses in the consolidated statements of loss and other comprehensive loss. Depreciation of all other property, plant and equipment is allocated between research and development and general and administrative expenses based on headcount.

The carrying amount of an item of property, plant and equipment is derecognized on disposal, or when no future economic benefits are expected from its use or disposal. The gain or loss arising from the derecognition of an item of property, plant, and equipment (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in “Gain / (loss) on disposal of non-current assets, net” in the consolidated statements of loss and other comprehensive loss when the asset is derecognized.

Management reviews the carrying amount of property, plant, and equipment for impairment when there is an indication that the carrying amount may exceed the expected recoverable amount.

o) Impairment of long-lived assets

Assets that are subject to depreciation or amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. An impairment loss is recognized in the consolidated statements of loss and other comprehensive loss consistent with the function of the assets, for the amount by which the asset’s carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset’s fair value less costs of disposal and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are largely independent cash inflows. Prior impairments of non-financial assets (other than goodwill) are reviewed for possible reversal each reporting period.

p) Provisions

Provisions are recognized when the Company has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation, and a reliable estimate can be made of the amount of the obligation. Provisions are reviewed at the end of each reporting period and adjusted to reflect the current best estimate. If it is no longer probable that an outflow of resources embodying economic benefits will be required to settle the obligation, the provision is reversed.

q) Value added tax

Expenses and assets are recognized net of the amount of value added tax (VAT) except when the VAT incurred on a purchase of assets or services is not recoverable from the taxation authority, in which case the VAT is recognized as part of the cost of acquisition of the asset or as part of the expense item.

The net amount of the VAT recoverable from, or payable to, the taxation authority is included as part of receivables or payables in the consolidated statements of financial position.

r) Financial instruments

(i) *Financial assets*

The Company's financial assets are comprised of cash and cash equivalents, investments, trade and other receivables, security deposits, other current and non-current assets. All financial assets are recognized initially at fair value plus transaction costs that are attributable to the acquisition of the financial asset, and follow its business model of standard working capital purposes. These financial assets are subsequently measured at amortized cost, which in general, approximates to the fair value.

Purchases and sales of financial assets are recognized on the settlement date; the date that the Company receives or delivers the asset. The Company classifies its financial assets primarily as cash and cash equivalents and receivables. Receivables are non-derivative financial assets, with fixed or determinable payments that are not quoted in an active market. They are included in current assets.

Financial assets are derecognized when the rights to receive cash flows from the asset have expired, or the Company has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full.

(ii) *Financial liabilities*

The Company's financial liabilities are comprised of trade and other payables, lease liabilities, and borrowings. All financial liabilities are recognized initially at fair value, adjusted for transaction costs.

After initial recognition, borrowings are subsequently measured at amortized cost using the effective interest method, minus transaction costs that are directly attributable to the financial liability. The effective interest method amortization is included in finance costs in the consolidated statements of loss and other comprehensive loss.

Payables and borrowings are classified as current liabilities unless the Company has an unconditional right to defer settlement of the liability for at least the next 12 months after the reporting date.

Financial liabilities are derecognized when the obligation under the liability is discharged, cancelled, or expires.

(iii) *Fair value measurements*

The Company does not hold any financial assets and financial liabilities other than those measured at amortized cost, as its business model is such that the Company has the intent to hold these instruments for the sole purpose of collecting contractual cash flows, and the contractual terms give rise to cash flows that are solely for payments of principal and interest. Management assessed that the carrying values of the Company's financial assets and financial liabilities measured at amortized cost are a reasonable approximation of their fair values.

s) Leases

The Company is party to lease contracts relating to laboratory and office facilities located in the Netherlands and the United States.

(i) *Right-of-use assets*

The Company recognizes right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are initially measured at cost, which comprises the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred and an estimate of costs to restore the underlying asset, less any lease incentives received. Subsequent to initial recognition, the lease asset is measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The recognized right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term. Right-of- use assets are subject to impairment.

(ii) ***Lease liabilities***

At the commencement date of the lease, the Company recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees.

In calculating the present value of lease payments, the Company uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured at the incremental borrowing rate at the lease modification date, if there is a modification, a change in the lease term, a change in the in-substance fixed lease payments or a change in the assessment to purchase the underlying asset.

3. Material accounting judgments, estimates and assumptions

The preparation of the Company's consolidated financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets, liabilities, and equity in the consolidated financial statements and the accompanying disclosures. Estimates and judgments are based on historical experience and other factors, including expectations of future events, and are continually evaluated. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

Judgments

In the process of applying the Company's accounting policies, management has made the following judgments, which have the most significant effect on the amounts recognized in the consolidated financial statements:

Clinical trial expenses

As part of the process of preparing its financial statements, the Company is required to estimate its clinical trial expenses. The clinical trial accrual process seeks to account for expenses resulting from its obligations under contracts with vendors, consultants and CROs and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. The objective is to reflect the appropriate clinical trial expenses in its financial statements by matching the appropriate expenses with the period in which services and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by subject progression and the timing of various aspects of the trial.

The Company determines accrual estimates based on estimates of the services received and efforts expended that take into account discussions with applicable personnel and outside service providers as to the progress or state of completion of trials. During the course of a clinical trial, it adjusts its clinical expense recognition if actual results differ from its estimates. It makes estimates of its accrued expenses and prepaid assets as of each balance sheet date in its financial statements based on the facts and circumstances known to us at that time. The clinical trial accrual and prepaid assets are dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Although the Company does not expect its estimates to differ materially from amounts it actually incurs, the Company's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period.

Deferred tax assets

Deferred tax assets have not been recognized in respect of tax losses and capitalization of IP development costs for Dutch corporate income tax purposes, because the Company has no history of generating taxable profits and at the statement of financial position date, there is no convincing evidence that sufficient taxable profit will be available against which the tax losses and amortization of the capitalized IP development costs can be utilized.

In order to promote innovative technology development activities and investments in new technologies, a corporate income tax incentive has been introduced in Dutch tax law called the Innovation Box. Profits from self-developed qualifying intangible assets are effectively subject to a 9% income tax rate for 2021 and future years, instead of the general headline rate of 25.8% as of 2022. The Company believes it qualifies for the Innovation Box and is currently in the process of obtaining advance certainty from the Dutch tax authorities.

Estimates and assumptions

The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date, which have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below. The Company based its assumptions and estimates on parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond its control. Such changes are reflected in the assumptions when they occur.

Revenue from contracts with customers

The Company must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation, which determines how the transaction price is allocated among the performance obligations. The estimation of the stand-alone selling price may include such estimates as forecasted revenues and costs, development timelines, discount rates and probabilities of regulatory and commercial success. The Company also applies significant judgment when evaluating whether contractual obligations represent distinct performance obligations, allocating transaction price to performance obligations within a contract, determining when performance obligations have been met, assessing the recognition and future reversal of variable consideration and determining and applying appropriate methods of measuring progress for performance obligations satisfied over time.

New standards, interpretations and amendments adopted by the Company

New standards, interpretations, and amendments issued recently effective

In May 2021, the IASB issued amendments to IAS 12 – Income Taxes, Deferred Tax related to Assets and Liabilities arising from a Single Transaction. The amendments narrowed the scope of the recognition exemption in paragraphs 15 and 24 of IAS 12 (recognition exemption) so that it no longer applies to transactions that, on initial recognition, give rise to equal taxable and deductible temporary differences. The amendments also apply to taxable and deductible temporary differences associated with right-of-use assets and lease liabilities, and decommissioning obligations and corresponding amounts recognized as assets. The amendments apply to transactions that occur on or after the beginning of the earliest comparative period presented. The amendments are effective for annual reporting periods beginning on or after January 1, 2023. The adoption of these amendments did not materially impact its consolidated financial statements.

New standards, amendments to standards, and interpretations issued not yet effective

In January 2020, IASB issued amendments to paragraphs 69 to 76 of International Accounting Standard 1, Presentation of Financial Statements, to specify the requirements for classifying liabilities as current or non-current, effective for annual reporting periods beginning on or after January 1, 2024. The Company determined the amendment has no impact.

4. Revenue

	For the Year Ended December 31,		
(in thousands)	*2023*	*2022*	*2021*
Pfizer Inc. - Pfizer Agreement	$ 3,666	$ 17,901	$ —
Pfizer Inc. - Additional services	613	—	—
Jansen Biotech Inc. - Janssen Agreement	2,490	1,490	5,350
	$ 6,769	**$ 19,391**	**$ 5,350**

Pfizer Agreement

In September 2022, the Company entered the Pfizer Agreement to develop, manufacture and commercialize PF-8046052 (formerly 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, it received a $50.0 million nonrefundable upfront payment in October 2022 and could receive up to approximately $650.0 million in potential development, regulatory and commercial milestones, and royalties ranging from high single-digit to mid-teen percentages on future sales. The agreement also provides Pfizer with the opportunity to exclusively negotiate rights to apply LAVA's proprietary Gammabody platform on up to two additional tumor targets until mid-2024 for an additional payment to the Company.

The Company is entitled to receive tiered royalties based on commercial sales levels from high single-digit to mid-teen percentages of net sales of licensed products. Pfizer has also granted it a one-time option to obtain increased royalties if it exercises a buy-up option within a certain amount of time from certain key early clinical data becoming available for the first licensed product. The Company has a specified period of time after notice of such buy-up option to pay Pfizer a one-time fee of $35.0 million (buy-up fee). In the event the Company exercises the buy-up option and pays the buy-up fee, it is entitled to receive increased future royalty percentages to a range of low double-digit to high mid-teen percentages on future sales, and certain future milestones will be decreased by 30%. The deferred revenue balance related to the buy-up option is considered as a monetary item.

Royalties are payable on a licensed product-by-licensed product and country-by-country basis beginning with the first commercial sale of such licensed product in such country of sale and expiring ten years after such sale, subject to specified and capped reductions for the market entry of biosimilar products, loss of patent coverage of licensed products, and for payments owed to third parties for additional rights necessary to commercialize licensed products in the territory.

Under the Pfizer Agreement the Company is also entitled to receive reimbursement of up to $6.5 million for certain agreed to research, manufacturing and supply activities, as well as the transfer of all manufacturing-related know-how and materials, including all CMC documentation, data and processes, to enable the manufacture of licensed compounds and products by Pfizer. In 2023, the Company recognized $4.3 million of revenue of which $3.7 million relates to this agreement. In addition, it recognized $0.6 million of revenue for reimbursement of additional other services requested by Pfizer.

The Company determined that the Pfizer Agreement and the research, manufacturing and supply activities and materials transfer fall within the scope of IFRS 15, *Revenue from Contracts with Customers* (IFRS 15). In calculating the transaction price, it determined the following four performance obligations under the agreement: (i) provide exclusive license; (ii) provide manufacturing technology transfer activities; (iii) provide initial drug supply; and (iv) research activities, including data and support for regulatory submission.

The Company allocated the transaction price to the performance obligations as of December 31, 2023 and 2022 as follows:

(in thousands)	Transaction Price	Revenue Recognized for the twelve months ended December 31, 2023	Cumulative Revenue Recognized as of December 31, 2023	Other assets as of December 31, 2023
License	$ 50,000	$ —	$ 15,165	$ —
Manufacturing technology transfer activities	2,167	199	2,272	—
Initial supply	3,583	3,443	3,443	—
Research activities	750	24	687	—
Buy-up fee (*)	(35,000)	—	—	—
	$ 21,500	**$ 3,666**	**$ 21,567**	**$ —**

(*) Buy-up fee remains deferred until option expires or is exercised

(in thousands)	Transaction Price	Revenue Recognized for the twelve months ended December 31, 2022	Cumulative Revenue Recognized as of December 31, 2022	Other assets as of December 31, 2022
License	$ 50,000	$ 15,165	$ 15,165	$ —
Manufacturing technology transfer activities	2,167	2,073	2,073	—
Initial supply	3,583	—	—	3,309
Research activities	750	663	663	—
Buy-up fee (*)	(35,000)	—	—	—
	$ 21,500	**$ 17,901**	**$ 17,901**	**$ 3,309**

(*) Buy-up fee remains deferred until option expires or is exercised

For each of the performance obligations described above, the Company has determined the following methods of revenue recognition:

- **License:** The Company recognizes revenue from the license at a point in time. Upon signing the Pfizer Agreement, ownership of the license was immediately transferred to Pfizer. The Company no longer has any rights to the license other than to fulfill its obligations under the Pfizer Agreement, and the Company does not have the obligation to improve, modify or update the license transferred. As such there is no significant continued involvement in the license provided. Pfizer can begin to use and benefit from the license after effective date of the Agreement as they are now the sole 'owner' of the underlying patents and know-how. In connection with the license performance obligation, the Company recognized revenue of $15.2 million for the year ended December 31, 2022. See below for further discussion on the considerations of the buy-up fee.
- **Manufacturing technology transfer activities:** The Company recognizes manufacturing technology transfer activities over time. These activities under the Pfizer Agreement are performed by the Company at the direction of Pfizer. As such, the Company record revenue related to these activities over time as they occur, measured based on a cost-to-cost method. Based on the manufacturing technology transfer activities performed during the year ended December 31, 2023, it recognized revenue of $0.2 million. Based on the manufacturing technology transfer activities performed during the year ended December 31, 2022, it recognized revenue and recorded a receivable of $2.1 million.
- **Initial supply:** During the year ended December 31, 2023, the Company recognized $3.4 million revenue from the initial supply of drug product at a point in time. At December 31, 2022 the Company recorded $3.3 million in prepaid expenses and other current assets, representing the value of the initial supply of drug product the Company has developed. In doing so, it also reduced research and development expenses related to this drug supply previously recorded in 2022. It is obligated to transfer this initial supply to Pfizer after entering into a separate supply and materials transfer agreement with Pfizer. This supply and materials transfer agreement was executed in January 2023. During 2023, the Company transferred the initial supply of drug product to Pfizer, triggering the recognition of revenue at the point in time. After this transfer to Pfizer, it has no further rights or ownership to the drug product. It did not recognize any revenue related to the initial supply of drug product for the year ended December 31, 2022.
- **Research activities:** The Company recognizes research activities over time. These activities under the Pfizer Agreement are performed by the Company at the direction of Pfizer. As such, it records revenue related to these activities over time as they occur, measured based on a cost-to-cost method. Based on the manufacturing and supply activities performed during the year ended December 31, 2023, it recognized revenue of less than $0.1 million. Based on the manufacturing and supply activities performed during the year ended December 31, 2022, it recognized revenue and recorded a receivable of $0.7 million.

- **Buy-up fee:** The Company recognizes revenue from the buy-up fee at a point in time. It determined that the one-time buy-up fee of $35.0 represents variable consideration, for which it has deferred revenue recognition until such time the option is exercised or expires. Accordingly, it received the non-refundable upfront payment of $50.0 million in October 2022, and recorded a deferred revenue liability of $35.0 million on its consolidated statement of financial position as of December 31, 2022 and 2023. If it does not exercise this buy-up option, the revenue related to this performance obligation will be recognized. If it does exercise this buy-up option, this amount will be accounted for as a refund of the transaction price to the customer. The Company expects to make a decision on whether or not to exercise the buy-up option in 2026.

Janssen Agreement

In May 2020, the Company entered into a research collaboration and license agreement (Janssen Agreement) with Janssen Biotech, Inc. (Janssen). As part of the Janssen Agreement, the Company received a non-refundable upfront payment of $8.0 million, which was recognized on a straight-line basis over the two-year term of the research activities under the agreement. The straight-line method of recognition materially approximates the cost-to-cost method of revenue recognition. As of December 31, 2023, the Company had no remaining unearned income related to this payment.

The Company is entitled to receive tiered royalties based on commercial sales levels from low to mid-single digit percentages of net sales of licensed products. Royalties are payable on a licensed product-by-licensed product and country-by-country basis beginning with the first commercial sale of such licensed product in such country of sale and expiring ten years after such sale, subject to specified and capped reductions for the market entry of biosimilar products, loss of patent coverage of licensed products, and for payments owed to third parties for additional rights necessary to commercialize licensed products in the territory and expires 10 years after such sale. The Company is eligible to receive a research milestone and further payments upon the achievement of certain development and commercial milestones.

Development milestones

In December 2020, the Company achieved the first Research Milestone, as defined in the Janssen Agreement, triggering a milestone payment of $1.0 million. In September 2021, the Company achieved the second Research Milestone, triggering a milestone payment of $1.0 million. Revenue for these development milestones was recognized at the point in time the milestone was achieved.

In May 2023, a milestone payment of $2.5 million from Janssen was triggered under the terms of the Janssen Agreement following selection of a lead bispecific antibody utilizing the Gammabody platform for an undisclosed tumor associated antigen for the treatment of cancer. Efforts are underway to advance the candidate towards the clinic. This milestone payment was recognized as revenue and the payment of the $2.5 million milestone was received in July 2023. No milestone revenue was recognized in the year ended December 31, 2022.

Deferred Revenue

The Company's deferred revenue balance relates to amounts received, but not yet earned under both the Janssen Agreement and Pfizer Agreement as described above. As of December 31, 2021, the deferred revenue balance related only to the Janssen Agreement, which was fully recognized in 2022. As of December 31, 2022, the Company established a deferred revenue balance related to the Pfizer Agreement buy-up option as described above. The buy-up option to pay a one-time fee of $35.0 million to Pfizer is considered as a monetary item. The following table presents changes in the deferred revenue balance:

(in thousands)	
Balance at January 1, 2022	**$ (1,527)**
Deferral of revenue	(35,000)
Recognized during the period	1,490
Foreign currency translation difference	37
Balance at December 31, 2022	**(35,000)**
Deferral of revenue	**—**
Recognized during the period	—
Foreign currency translation difference	—
Balance at December 31, 2023	**$ (35,000)**

Revenue segmentation

All revenue is provided in one geographical area, the United States of America.

5. Research and development expenses

Research and development expenses include the following categories:

	For the Year Ended December 31,		
(in thousands)	**2023**	**2022**	**2021**
Pre-clinical and clinical trial expenses	$ 20,421	$ 28,178	$ 14,188
Personnel-related expenses	6,629	6,150	4,955
Research and development activities expenses	2,680	2,241	1,843
Facilities and other research and development expenses	2,356	1,546	814
Share-based compensation expense	1,728	1,975	788
Amsterdam UMC and other license expenses	-	15	14,357
	$ 33,814	**$ 40,105**	**$ 36,945**

Refer to Note 24 for additional information about Amsterdam UMC license expenses. Government grants, which are a reduction of payroll taxes in the Netherlands, amounted to $2.0 million in 2023, $1.6 million in 2022 and $1.7 million in 2021. These amounts are an offset to wages and salaries that are part of its research and development expenses in the income statement. Depreciation expenses of our property and equipment included in the research and development expenses amounted to $599 thousand in 2023, $490 thousand in 2022 and $324 thousand in 2021.

6. General and administrative expenses

General and administrative expenses include the following categories:

	For the Year Ended December 31,		
(in thousands)	**2023**	**2022**	**2021**
Personnel-related expenses	$ 3,812	$ 5,010	$ 3,800
Share-based compensation expense	3,311	2,138	3,119
Professional and consultant fees	2,869	3,954	2,593
Insurance, facilities, fees and other related costs	2,734	3,022	2,506
	$ 12,726	**$ 14,124**	**$ 12,018**

Depreciation expenses of our property and equipment included in the general and administrative expenses amounted to $17 thousand in 2023, $14 thousand in 2022 and $7 thousand in 2021.

7. Interest income (expense), net

(in thousands)	For the Year Ended December 31, 2023	2022	2021
Interest (income) expense on borrowings and deposits, net	$ (3,202)	$ (339)	$ 564
Interest expense related to leases	232	82	61
	$ (2,970)	**$ (257)**	**$ 625**

8. Foreign currency exchange gain (loss), net

Changes in foreign currency exchange gain (loss), net were primarily due to the impact of the fluctuation of the USD currency rate compared to the Euro on transaction gains and losses on cash and investments and other transactions denominated in USD held and occurring in a Euro functional currency entity. Foreign currency exchange loss for the year ended December 31, 2023 was $1.4 million and foreign currency exchange gain for the years ended December 31, 2022 and 2021 were $2.9 million and $2.0 million, respectively.

9. Income tax expense

The Company is subject to income taxes in the Netherlands and the United States.

Netherlands

No tax charge or income was recognized during the reporting periods since the Company is in a loss-making position and has a history of losses. As of December 31, 2023 the Company has Dutch tax loss carryforwards of $70.3 million. The 2023 taxable amount is not final as the 2023 Dutch corporate income tax return is still in draft. The 2021 and 2022 Dutch corporate income tax returns are final and have been filed in time.

As a result of the Dutch corporate income tax law, tax loss carryforwards are not subject to a time limitation and remain available for offset indefinitely. Actual utilization of these losses with taxable income in the future is however limited to 50% of the taxable amount that exceeds EUR 1 million.

The following table provides an overview of its unrecognized tax loss carryforwards by year:

(in thousands)	Loss per year
2017	$ 860
2018	2,749
2019	1,081
2020	—
2021	12,230
2022	269
2023	53,133
	$ 70,322

In order to promote innovative technology development activities and investments in new technologies, a corporate income tax incentive has been introduced in Dutch tax law called the “Innovation Box.” The effective rate for Innovation Box profits is 9%. The Company applied for the Innovation Box and its request is currently under final review with the Dutch Tax Authorities. For tax purposes, the Company expensed capitalized IP development costs of $14.8 million in the year ended December 31, 2023 and the Company capitalized IP development costs of $27.8 million and $33.9 million in its draft tax return for the year ended 2022 and final tax return for the year ended 2021, respectively. In total, $72.1 million of IP development costs was capitalized. This amount will reduce future taxable income due to future tax amortization of capitalized IP development costs. The deferred tax asset in this regard has not been recognized.

Deferred income tax assets can only be recognized for tax losses and capitalization of IP development costs for Dutch corporate tax purposes to the extent that the realization of the related tax benefit through future taxable profits is probable. The Company recognizes deferred tax assets arising from unused tax losses or tax credits only to the extent there is convincing other evidence that sufficient taxable profit will be available against which the unused tax losses or unused tax credits can be utilized by us. Management concluded that there is not sufficient probability as per IAS 12, *Income Taxes,* that there will be future taxable profits available in the foreseeable future against which the unused tax losses and deduction of capitalized IP development costs can be used; therefore, a deferred tax asset has not been recognized.

The statute of limitation in the Netherlands is five years, starting from the day after the end of the tax year and prolonged with any extensions granted for filing the corporate income tax returns. The tax authorities are allowed to audit years for which a final assessment has already been imposed. Since the Company's inception was in 2016, all tax years are currently open for an audit by the Dutch tax authorities.

United States

A tax charge was recognized during the reporting periods due to the U.S. profitable position. The activities of LAVA Therapeutics, Inc. are limited and regard only to the CEO, CFO and CMO for LAVA Therapeutics N.V. and related staff who are domiciled in the U.S. The remuneration of LAVA Therapeutics, Inc. is based on the costs incurred for the services rendered including a profit mark-up.

Reconciliation of income tax expense at statutory tax rate and the income expenses as reported in the consolidated statement of loss and other comprehensive income is as follows:

	For the Year Ended December 31,		
(in thousands)	**2023**	**2022**	**2021**
Loss before income tax	$ (41,695)	$ (31,658)	$ (42,198)
Computed 25.8% tax on Loss (2022: 25.8% 2021: 25%)	(10,757)	(8,168)	(10,549)
Tax effect of:			
Non-deductible costs	1,268	1,080	982
Difference in overseas tax rates	75	72	46
Change in unrecognized deferred tax asset	9,693	7,265	9,678
Total corporate tax	**$ 279**	**$ 249**	**$ 157**
Effective tax rate	0.7%	0.8%	0.4%

	For the Year Ended December 31,		
(in thousands)	**2023**	**2022**	**2021**
Current tax on result	$ 279	$ 249	$ 139
Deferred tax prior years	—	—	18
Total corporate tax expense	**$ 279**	**$ 249**	**$ 157**

On the basis of the 2023 annual accounts, there are accounting-to-tax differences of $9.7 million. These differences primarily relate to the amortization of IP development costs capitalized for Dutch corporate income tax purposes in preceding years, the capitalization of IP development costs incurred in 2023 for Dutch corporate income tax purposes and IFRS 16 lease amounts. Other differences relate to non-deductible share-based payment expenses, expenses which were treated as non-deductible for Dutch corporate income tax purposes and other non-deductible mixed expenses.

Recognized deferred tax assets and liabilities

Deferred tax assets and liabilities have been recognized in respect of the following items related to the temporary differences of the IFRS 16 Leases.

	For the Year Ended December 31,		
(in thousands)	2023	2022	2021
Deferred Tax Asset - Lease Liability	$ 230	$ 168	$ 125
Deferred Tax Liability - Lease Right-of-use assets	(230)	(168)	(125)
Total net deferred tax asset	**$ —**	**$ —**	**$ —**

The valuation of the deferred tax asset on the lease liability was maximized to the value of the corresponding deferred tax liability on the lease right of use assets. The unrecognized part of the deferred tax asset on the lease liability is included in the item deductible temporary differences of the unrecognized deferred tax assets as presented below, because it is not probable that future taxable profit will be available against which the Company can use the benefit therefrom.

Unrecognized deferred tax assets

Deferred tax assets have not been recognized in respect of the following items, because it is not probable that future taxable profit will be available against which the Company can use the benefit therefrom.

	For the Year Ended December 31,		
(in thousands)	2023	2022	2021
Deductible temporary differences	$ 86,887	$ 83,933	$ 59,683
Tax losses	70,322	5,900	5,746
Total unrecognized deferred tax assets	**$ 157,209**	**$ 89,833**	**$ 65,429**
Total tax effect 25.8% (2022: 25.8% 2021: 25%)	**$ 40,560**	**$ 23,177**	**$ 16,357**

10. Earnings per share (EPS)

Basic EPS is calculated by dividing the profit/(loss) for the period attributable to common equity holders of the parent by the weighted average number of common shares outstanding during the period. Vested share-based awards for little to no consideration are considered as issuable common shares, and therefore included in the common shares outstanding.

Diluted EPS is calculated by dividing the profit/(loss) attributable to common equity holders of the parent (after adjusting for the effect of dilution) by the weighted average number of common shares outstanding, adjusted for the effects of potentially dilutive share-based awards.

As of December 31, 2023, 2022 and 2021, potentially dilutive share-based awards for a total number of zero, 593,555 and 250,149, respectively, were excluded from the calculation of the diluted weighted average number of common shares outstanding, because their effect on the loss per share would have been anti-dilutive.

The following table reflects the loss and share data used in the basic and diluted EPS calculations:

	For the Year Ended December 31,		
(in thousands, except for share and per share amounts)	2023	2022	2021
Loss for the year	$ (41,974)	$ (31,907)	$ (42,355)
Weighted average number of common shares	26,732,556	25,924,005	19,758,169
Basic and diluted loss per share	$ (1.57)	$ (1.23)	$ (2.14)

11. Property and equipment, net

Movements in property and equipment were as follows:

(in thousands)	Building improvements	Laboratory equipment	Office equipment	ICT equipment	Total
Cost					
Balance at January 1, 2022	**$ 123**	**$ 1,724**	**$ 36**	**$ 192**	**$ 2,075**
Additions	—	525	6	56	587
Foreign currency translation adjustment	(6)	(108)	(2)	(10)	(126)
Balance at December 31, 2022	**117**	**2,141**	**40**	**238**	**2,536**
Additions	275	388	25	42	730
Disposals	(23)	(12)	—	—	(35)
Foreign currency translation adjustment	9	81	2	14	106
Balance at December 31, 2023	**$ 378**	**$ 2,598**	**$ 67**	**$ 294**	**$ 3,337**
Accumulated depreciation					
Balance at January 1, 2022	**$ 19**	**$ 538**	**$ 16**	**$ 57**	**$ 630**
Charge for the year	87	366	8	43	504
Foreign currency translation adjustment	(1)	(26)	—	(3)	(30)
Balance at December 31, 2022	**105**	**878**	**24**	**97**	**1,104**
Charge for the year	44	505	12	55	616
Disposals	(23)	(12)	—	—	(35)
Foreign currency translation adjustment	4	40	1	5	50
Balance at December 31, 2023	**$ 130**	**$ 1,411**	**$ 37**	**$ 157**	**$ 1,735**
Carrying amounts					
Property and equipment, net at December 31, 2022	**$ 12**	**$ 1,263**	**$ 16**	**$ 141**	**$ 1,432**
Property and equipment, net at December 31, 2023	**$ 248**	**$ 1,187**	**$ 30**	**$ 137**	**$ 1,602**

12. Leases

The following table provides information about the Company's right-of-use assets:

(in thousands)	
Balance at January 1, 2022	**$ 501**
Additions	400
Depreciation charges	(277)
Foreign currency exchange difference	27
Balance at December 31, 2022	**651**
Additions	825
Depreciation charges	(662)
Foreign currency exchange difference	78
Balance at December 31, 2023	**$ 892**

The additions during the year ended December 31, 2023 primarily relate to the new 3-year lease of laboratory and office space at Yalelaan 62 in Utrecht, the Netherlands in the first quarter of 2023. In August 2023, we notified the landlord that we would terminate a portion of this lease in the first quarter of 2024, resulting in a corresponding depreciation charge of the Company's right-of-use assets in the year ended December 31, 2023.

The following table provides information about the maturities of the Company's lease liabilities at December 31, 2023:

(in thousands)	
2024	$ 550
2025	442
2026	201
2027	—
Total lease commitments	**1,193**
Less: imputed lease interest	(162)
Total lease liabilities	**$ 1,031**
Current portion	**$ 440**
Non-current portion	**$ 591**

The average incremental borrowing rate applied to the lease liabilities was 15.60% and 15.69% during the years ended December 31, 2023 and 2022, respectively.

Cash outflows related to leases during the years ended December 31, 2023, 2022 and 2021 were $1.0 million, $0.3 million and $0.3 million, respectively.

The Company leases consist of leases for office and laboratory space in the Netherlands and the United States, expiring in 2025 and 2026 respectively. Both leases contain renewal options which the Company concluded are not reasonably certain to be exercised, and therefore did not include the effects of the extension options in the measurement of the lease liabilities and right-of-use assets. During the years ended December 31, 2023, 2022, and 2021 the variable lease payments not included in the measurement of the lease liabilities were immaterial and related to utility, common area maintenance and real estate tax charges. All leasehold improvements were paid for in full by the Company.

13. Investments

The Company's investments in debt securities consist of investments in U.S. Treasury securities, with maturities ranging from three months to one year. All of these investments are classified as held to maturity and recorded in current assets on the Company's consolidated statements of financial position at amortized cost. As of December 31, 2023, the carrying value of the Company's investments was $51.3 million, which approximates fair value. Given the high quality ratings of these investments in debt securities, the Company has not recorded an allowance for credit losses as of December 31, 2023.

14. Cash and cash equivalents

	As of December 31,	
(in thousands)	2023	2022
Short-term deposits	$ 10,326	$ 9,965
Current bank accounts	33,905	90,368
	$ 44,231	**$ 100,333**

Short-term deposits are made for varying periods of between one day and three months, depending on its immediate cash requirements, and earn interest at the respective short-term deposit rates. Information about the credit risk over cash and cash equivalents is presented in Note 22.

Cash and cash equivalents are not subject to any restrictions.

15. Share capital, share premium and other capital reserves

The following table provides information about the Company's share capital as of December 31, 2023, 2022 and 2021:

(in thousands, except for share and per share amounts)	Authorized December 31,			Issued and fully paid December 31,			Additional paid-in capital December 31,		
	2023	2022	2021	2023	2022	2021	2023	2022	2021
Preference shares of $0.14 each	45,000,000	45,000,000	45,000,000	—	—	—	$ —	$ —	$ —
Common shares of $0.14 each	45,000,000	45,000,000	45,000,000	26,289,087	26,289,087	25,775,538	194,424	194,424	192,270
	90,000,000	**90,000,000**	**90,000,000**	**26,289,087**	**26,289,087**	**25,775,538**	**$ 194,424**	**$ 194,424**	**$ 192,270**

The corresponding value of the issued and fully paid share capital amounts to $3.7 million for each of December 31, 2023 and 2022 and zero for December 31, 2021.

Preferred Series Shares

In 2017, the Company issued and sold 1,755,845 Series A Preferred at a price of $0.68 per share for gross proceeds of $1.2 million. It incurred minimal issuance costs.

In 2018, the Company issued and sold 3,899,766 Series B Preferred at a price of $4.61 per share for gross proceeds of $17.9 million. It incurred minimal issuance costs.

In 2020, the Company closed an oversubscribed financing of Series C Preferred that resulted in tranche-based commitments of $84.4 million gross and $73.2 million net. In connection with the Series C Preferred financing, it agreed to sell the Series C Preferred in three tranches. In connection with the funding of the tranches it was obligated to repurchase 1,436,500 shares of Series A preferred of approximately $10.3 million and 331,500 common shares.

In 2020, the first tranche of gross proceeds of $22.7 million, with $0.6 million of issuance costs and 4,133,805 shares of Series C Preferred, was funded, and 718,250 shares amounting to $4.9 million of Series A Preferred were repurchased, resulting in net proceeds of $17.2 million.

In 2021, the Company effected a 221:1 share split of its issued and outstanding common shares and a proportional adjustment to the existing conversion ratios for convertible preferred shares. The par value per share and authorized common and convertible preferred shares were adjusted as a result of the share split. All common shares and common share per share amounts within the financial statements and notes thereto have been adjusted for all periods presented to give effect to this share split, including reclassifying an amount equal to the change in par value of common shares to additional paid-in capital.

In 2021, the remaining milestones required to fund the remaining two tranches of the Series C Preferred financing were waived, and the funding of both tranches prior to the completion of the IPO was authorized. The two remaining tranches funded additional net proceeds of $56.6 million in the aggregate, after repurchasing the 718,250 shares of Series A Preferred and 165,750 common shares from one investor.

Automatic Conversion of Preferred Shares to common shares in connection with the IPO – In 2021, the Company effected an amendment to its Articles of Association, as amended. This amendment eliminated the minimum price per common share for an underwritten public offering that would result in the automatic conversion of all outstanding Series A, Series B, and Series C preferred shares to common shares of the Company.

Common shares

In 2021, the Company completed an IPO of common shares pursuant to its registration statement on Form F-1, as amended (file 333-253795) under the symbol "LVTX" in the United States on Nasdaq. Pursuant to the registration statement, it issued and sold 6,700,000 shares of $0.14 par value common share at a price of

$15.00 per share. Net proceeds from the IPO were approximately $89.0 million after deducting underwriting discounts and commissions of $7.0 million and offering costs of $4.5 million.

In 2021, underwriters of its IPO consummated the exercise of their option to purchase 425,712 common shares from the Company at the price of $15.00 per share resulting in additional IPO proceeds of $5.9 million after deducting underwriting discounts and commissions of $0.4 million.

In 2021, the Company issued 235,664 common shares to Amsterdam UMC representing the $3.7 million payable in accordance with the Amsterdam UMC agreement.

In 2022, the Company issued 491,352 common shares to Amsterdam UMC representing 50% of the payable in accordance with the Amsterdam UMC agreement.

In 2022, the Company issued 22,197 common shares to former employees upon exercise of outstanding stock options.

In 2023, no common shares were issued.

The following table provides information about the Company's major shareholders on a non-diluted basis:

	As of December 31,	
	2023	2022
Gilde Healthcare	20.6 %	20.6 %
Versant Venture Capital VI, L.P.	17.5	17.5
Redmile Biopharma Investments	7.9	10.6
Sanofi Foreign Participations B.V.	7.3	7.3
Novo Holdings A/S	7.1	12.7
Other shareholders	39.6	31.3
	100.0 %	**100.0 %**

Appropriation of result

In 2023, the loss for the year ended December 31, 2022, of $31.9 million was charged to the accumulated deficit.

Pursuant to article 31 of the Company's articles of association, it is proposed by our board of directors that the loss for the year ended December 31, 2023, of $42.0 million is charged to the accumulated deficit.

16. Borrowings

			As of December 31,	
			2023	2022
(in thousands)	Stated interest rate	Maturity	Amount, incl. accrued interest	Amount, incl. accrued interest
Innovation Credit	10.0 %	9/30/2025	$ 5,282	$ 4,640
Current			**$ 5,282**	**$ 4,640**
Non-current			**$ —**	**$ —**

In 2019, the Company applied for and received a $5.5 million Innovation Credit (the "Credit") from Rijksdienst voor Ondernemend Nederland (RVO). The Credit contributed to the development of LAVA-051, and certain assets of that project are pledged as a guarantee.

Borrowings under the Credit bear interest at 10.0% and were received in quarterly installments, based on the level of the underlying cost base of the project in each period. The initial repayment of principal and accrued interest is due on September 30, 2025.

The Credit contains customary limitations on the Company and its shareholders, including its shareholders not being permitted to subtract assets (including cash) by means of dividend, interest, or repayment of loans

as long as the Credit has not been repaid in full. The Company filed a progress report after each of the first four reporting periods: March 2020, December 2020, December 2021, October 2022. In April 2023, the reporting dates for the last 3 reporting periods were extended by 18 months.

In June 2023, the Company announced the discontinuance of the LAVA-051 program. This discontinuance ended the receipt of future installments. The Company is currently preparing the required Project Settlement Report because of the discontinuance of the LAVA-051 program and expect RVO to make their decision on repayment of the Innovation Credit in the second half of 2024. As a result, the Company has classified the Innovation Credit as a current liability.

As of December 31, 2023 and 2022, the Company had $5.3 million and $4.6 million, respectively in borrowings under the Credit, all of which was classified as short-term, and includes accrued interest.

As of December 31, 2023, the Company was in compliance with all of the terms of the Credit.

Interest expense incurred from the Credit during the years ended December 31, 2023, 2022 and 2021 was $0.5 million, $0.4 million and $0.3 million, respectively.

17. Trade payables and other

The Company had accounts payable balances of $4.4 million and $4.0 million as of December 31, 2023 and 2022, respectively. The average credit period on domestic purchases of certain goods was 7 to 30 days. No interest was charged on the trade payables from the invoices received. The maturity of all balances is within one year. Information about the Company's exposure to currency and liquidity risk in relation to its trade and other payables is included in Note 22.

18. Working capital

Prepaid expenses and other current assets

	As of December 31,	
(in thousands)	2023	2022
Deferred contract costs	$ —	$ 3,309
Prepaid project expenses	969	382
Prepaid other expenses	658	720
	$ 1,627	**$ 4,411**

The Company had deferred contract costs of $3.3 million as of December 31, 2022 related to the initial supply of drug product to be delivered to Pfizer. During 2023, the Company transferred the initial supply of drug product to Pfizer. As of December 31, 2023, the Company had no deferred contract costs.

Accrued expenses and other current liabilities

	As of December 31,	
(in thousands)	2023	2022
Research and development external project costs	$ 2,293	$ 5,399
Personnel-related expenses	1,475	1,903
Professional fees	523	486
Other	482	405
	$ 4,773	**$ 8,193**

19. Restructuring

In June 2023, the Company announced that the clinical trial of LAVA-051 targeting the CD1d-expressing hematological tumors, multiple myeloma (MM), chronic lymphocytic leukemia (CLL), and acute myeloid leukemia, was no longer recruiting and would be discontinued after no patients remain on treatment. LAVA-051 was being evaluated in an open-label, multi-center Phase 1/2a clinical trial in patients with relapsed or refractory CLL and MM to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity, and preliminary anti-tumor activity of LAVA-051. The decision to discontinue the LAVA-051 clinical trial followed a review of the competitive landscape that has continued to evolve. The decision was not

due to safety concerns. As a result of the discontinuation, the Company expensed $1.4 million in June 2023 for costs associated with contract manufacturing and bioanalytical activities for LAVA-051. Of this amount, invoices have been received for an amount of $1.0 million in 2023 and the remaining $0.4 million was recorded in accrued expenses and other current liabilities on its consolidated statements of financial position as of December 31, 2023. The Company reviewed the relevant items of its consolidated statements of financial position and did not identify any asset that would be subject to impairment as a result of the discontinuation of the clinical trial of LAVA-051.

In August 2023, the Company finalized a reduction in workforce of approximately 36% in the United States and the Netherlands to better align the Company's resources with the Company's focus on LAVA-1207 and other research and development activities. In connection with the reduction in force, the Company expensed $0.5 million, during the year ended December 31, 2023. The implementation of headcount reductions, including cash payments, was completed by the end of 2023.

20. Employee benefits

20.1 Share-based compensation

Description of equity incentive plans

In 2018, the Company established the 2018 Stock Option Plan that entitles employees, directors, and consultants providing services to purchase depository receipts for its common shares. Under this plan, holders of vested options are entitled to purchase common shares at the exercise price determined at the date of the grant.

In 2020, the Company established the 2020 U.S. Stock Option Plan that entitles employees, directors and consultants providing services to give the right to acquire a number of common shares. Under this plan, holders of vested options are entitled to purchase common stock at the exercise price determined at the date of the grant.

In March 2021, the Company established the 2021 Long-term Incentive Option Plan, as an incentive for all our employees, members of its board of directors and select external consultants. As of March 25, 2021, the 2018 Stock Option Plan and the 2020 U.S. Stock Option Plan ceased to have any future shares available.

Under the option plans, the options granted generally have a maximum term of 10 years and can generally have the following vesting schemes:

- 25% of the options vest on the first anniversary of the vesting commencement date, and the remaining 75% of the options vest in 36 monthly installments for each full month of continuous service provided by the option holder thereafter, such that 100% of the options shall become vested on the fourth anniversary of the vesting commencement date.
- the options vest in 48 monthly installments for each full month of continuous service provided by the option holder thereafter, such that 100% of the options shall become vested on the fourth anniversary of the vesting commencement date.
- the options vest in 12 monthly installments for each full month of continuous service provided by the option holder thereafter, such that 100% of the options shall become vested on the first anniversary of the vesting commencement date.
- the options vest 100% on the first anniversary of the vesting commencement date.

Share-based options

During 2023 and 2022, the board of directors granted 879,771 and 2,358,458 options respectively, to employees and non-employees.

The following table provides information about share-based awards as of December 31, 2023 and 2022:

	2018 Stock Option Plan			2020 U.S. Stock Option Plan			2021 Long-term Incentive Option Plan		
	Number of options	Weighted average exercise price $	Weighted average remaining contractual term (yrs)	Number of options	Weighted average exercise price $	Weighted average remaining contractual term (yrs)	Number of options	Weighted average exercise price $	Weighted average remaining contractual term (yrs)
Outstanding at January 1, 2022	**620,347**	**0.01**	**(*)**	**1,563,136**	**5.90**	**8.90**	**1,307,150**	**6.03**	**9.90**
Granted to employees	—	—		—	—		1,478,458	6.51	
Granted to statutory directors	—	—		—	—		800,000	3.64	
Granted to board of directors (non-executive)	—	—		—	—		80,000	3.64	
Exercised	(16,073)	0.01		(6,124)	2.76		—	—	
Lapsed	(778)	0.01		(72,773)	15.00		(20,419)	5.16	
Forfeited	(3,039)	0.01		(212,160)	12.96		(237,595)	5.80	
Outstanding at December 31, 2022	**600,457**	**0.01**	**(*)**	**1,272,079**	**4.22**	**7.83**	**3,407,594**	**4.66**	**9.54**
Granted to employees	—	—		—	—		779,771	3.23	
Granted to board of directors (non-executive)	—	—		—	—		100,000	2.70	
Lapsed	—	—		(153,389)	3.75		(204,639)	5.69	
Forfeited	—	—		(118,935)	2.76		(422,420)	4.50	
Outstanding at December 31, 2023	**600,457**	**0.01**	**(*)**	**999,755**	**4.46**	**7.04**	**3,660,306**	**4.27**	**8.73**
Exercisable at December 31, 2023	488,972			792,401			1,158,244		

(*) contract term does not have fixed end date

As of December 31, 2023, outstanding options had exercise prices ranging from $0.01 to $15.00.

The weighted-average share price at the date of exercise was $2.94 in the year ended December 31, 2022. There were no options exercised in 2023.

The number of common shares authorized for issuance for future grants under the 2021 Long-term Incentive Option Plan as of January 1, 2024 totaled 2,009,068.

Total share-based compensation expenses for the years ended December 31, 2023, 2022 and 2021 were $5.0 million, $4.1 million and $3.9 million, respectively, as referenced in Notes 5 and 6. In the year ended December 31, 2023 the Company transferred $2.0 million from the equity settled employee benefits reserve to accumulated deficit as a result of lapsed vested options. For these lapsed vested options there is no longer a requirement for a reserve as there are no limitations for distribution within equity.

Measurement of fair values

The fair value of the equity-settled employee share options has been measured using the Black-Scholes formula, for all stock option grants issued after the Company's IPO in March 2021. The service conditions attached to the transactions were not taken into account in measuring fair value.

The assumptions used in the measurement of the fair values and the weighted average fair value of the share options granted during the years ended on December 31, 2023, 2022 and 2021:

	December 31, 2023	December 31, 2022	December 31, 2021	
	NL & US	NL & US	NL	US
Expected annual average volatility	88.4%	83.9%	80.1%	80.1%
Expected life, years	6.08	6.08	6.08	6.08
Fair value of the share options	$ 1.06 - 2.92	$ 1.71 - 3.91	$ 3.42 - 5.23	$ 3.12 - 8.71
Exercise price	$ 1.40 - 3.86	$ 2.34 - 5.50	$ 5.10 - 7.77	$ 5.10 - 15.00
Dividend yield	—	—	—	—
Risk-free interest rate	3.46% - 4.98%	1.65% - 3.78%	(0.30%) - (0.53%)	0.94% - 1.34%
Weighted average grant date fair value	$ 2.39	$ 4.01	$ 3.61	$ 5.95

In 2023 and 2022, all options were granted in USD. In 2021, options were granted with a contractual exercise price in both EUR and USD. Since the Company was a private company until March 2021, limited company-specific historical and implied volatility information is available. Expected volatility is therefore estimated based on the observed daily share price returns of publicly traded peer companies over a historic period equal to the period for which expected volatility is estimated, as well as its own limited historical stock performance and its own stock-price volatility. The group of comparable listed companies are publicly traded entities active in the business of developing antibody-based therapeutics, treatments and drugs and are selected taking into consideration the availability of meaningful trading data history and market capitalization. The Company will continue to use this method for calculation of expected volatility data until sufficient historical market data is available for estimating the volatility of its common shares.

Valuation of common shares

As of our IPO in March 2021, the fair value of the common shares is determined by the market value of our shares on the Nasdaq Global Select Market under the symbol “LVTX.”

Prior to our IPO, the fair value of the common shares was determined by the Company’s management board and supervisory board and took into account the most recently available valuation of common shares performed by an independent valuation firm and the assessment of additional objective and subjective factors the Company believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant.

The Company’s management board and supervisory board considered numerous objective and subjective factors to determine their best estimate of the fair value of our common shares as of each grant date, including:

- the progress of its research and development programs;
- achievement of enterprise milestones, including entering into collaboration and licensing agreements, as well as funding milestones;
- contemporaneous third-party valuations of the Company’s common shares for its most recent share issuances;
- its need for future financing to fund operations;
- the rights and preferences of its preference shares and its preference shares relative to the Company’s common shares;
- the likelihood of achieving a discrete liquidity event, such as a sale of the Company or an initial public offering given prevailing market conditions; and
- external market and economic conditions impacting its industry sector.

In determining the fair values of the common shares as of each grant date, three generally accepted approaches were considered: income approach, market approach and cost approach. In addition, the guidance prescribed by the American Institute of Certified Public Accounts *Audit and Accounting Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation* had been considered. The "prior sale of company stock" method, a form of the market approach, had been applied to estimate the total enterprise value. The prior sale of company stock method considers any prior arm's length sales of the Company's equity securities. Considerations factored into the analysis included: the type and amount of equity sold, the estimated volatility, the estimated time to liquidity, the risk-free rate, the timing compared to the common shares valuation date and the financial condition and structure of the Company at the time of the sale. As such, the value per share had been benchmarked to the external transactions of Company stock and external financing rounds. For determining the value of the Company's shares, the prior sale of company stock method had been relied on to estimate the total value of its equity. Throughout this period, financing rounds were held, which resulted in the issuance of preferred shares. The preferred shares were transacted with numerous existing and new investors, and therefore the pricing in these financing rounds was considered a strong indication of fair value.

Given that there were multiple classes of equity, the Option Pricing Method (OPM) had been applied in order to allocate equity to the various equity classes. The OPM treats securities as call options on the enterprise's equity value, with exercise prices based on the liquidation preference and conversion features of preferred stock and strike prices of options. An incremental discount for lack of marketability (DLOM) was applied with a range from 10% to 25%, corresponding to the time to exit to reflect the increased risk arising from the inability to readily sell the shares. Under this method, the cost of the put option, which can hedge the price change before the privately held shares can be sold, was considered as the basis to determine the DLOM.

20.2 Post-employee Benefit Plan

The Company has established a post-employment benefit plan for employees of the Netherlands that entitles executive officers and other staff members to retire at the age of 67 and receive annual payments based upon the average salary earned during the service period. The Company provides a defined contribution plans to its employees of the Netherlands. Contributions to defined contribution plans are expensed when employees provide services. The Group has no further payment obligations once the contributions have been paid. Company contributions to the post-employment benefit plan totaled $0.5 million, $0.6 million and $0.5 million in the years ended December 31, 2023, 2022 and 2021, respectively.

20.3 401(k) Savings Plan

The Company has a defined contribution 401(k) savings plan (the "401(k) Plan"). The 401(k) Plan covers all U.S. employees, and allows participants to defer a portion of their annual compensation on a pretax basis. The Company matches contributions to the 401(k) Plan, matching 100% of an employee's contribution up to a maximum of 4% of the participant's compensation. Company contributions to the 401(k) Plan totaled $0.1 million in each of the years ended December 31, 2023, 2022 and 2021.

21. Related parties

Key management compensation

Key management includes members of the Company's executive committee and the board of directors. The compensation paid or payable to key management for the Board and employee services includes their participation in share-based compensation arrangements. The compensation paid to these individuals are presented below for the years ended December 31, 2023, 2022 and 2021. The disclosure amounts are based on the expense recognized in the consolidated statements of loss and other comprehensive loss.

	For the Year Ended December 31,		
(in thousands)	2023	2022	2021
Key management compensation			
Short term employee benefits	$ 3,586	$ 2,673	$ 3,099
Share-based payments	3,503	1,994	2,702
Post-employment benefits	104	108	92
	$ 7,193	**$ 4,775**	**$ 5,893**

Dutch disclosure regulations require the disclosure of compensation of each individual statutory director. The Company's Chief Executive officer, Stephen Hurly who is a member of key management, is also a statutory director since November 2019. The Company's EVP and Head of Research and Development, Paul Parren served as a statutory director from June 2019 until March 2021.

The following are details of their compensation as statutory director which are also included in the above disclosure for key management personnel:

	For the Year Ended December 31,		
(in thousands)	2023	2022	2021
Stephen A. Hurly			
Salary	$ 576	$ 549	$ 501
Bonus	247	—	234
Share-based payments	1,598	901	531
Post-employment benefits	13	12	12
	$ 2,434	**$ 1,462**	**$ 1,278**
Paul Parren			
Salary	$ —	$ —	$ 358
Bonus	—	—	105
Share-based payments	—	—	266
Post-employment benefits	—	—	29
	$ —	**$ —**	**$ 758**

The compensation of Stephen A. Hurly was paid through Lava Therapeutics Inc. and the compensation of Paul Parren was paid through Lava Therapeutics N.V. Both directors were full-time employees.

Following the annual fixed pay review, the Board approved the Compensation Committee's recommendation of a fixed pay increase for the CEO, Stephen A. Hurly, of 4.5% to $602 thousand, effective from January 1, 2024. This is in line with the average increase awarded to the wider LAVA workforce, effective from January 1, 2024.

As of December 31, 2023, the following outstanding stock options were held by the individual statutory directors. Further details on the number of stock options held by these individual statutory directors are disclosed in section 5. Directors, Senior Management and Employees.

	As of December 31,					
	2023		2022		2021	
	Number of Options	Weighted average Exercise Price	Number of Options	Weighted average Exercise Price	Number of Options	Weighted average Exercise Price
Stephen A. Hurly	1,837,753	$ 3.54	1,837,753	$ 3.54	1,037,753	$ 3.46
Paul Parren	n.a.	$ n.a.	n.a.	$ n.a.	411,831	$ 1.24

Stephen A. Hurly is statutory director as well as a member of the board of directors. His compensation is disclosed in the abovementioned tables and not included in the compensation of the board of directors in the following paragraph.

Director and shareholder compensation

The Company paid board fees to the non-executive members of the board of directors since the Company became publicly listed in March 2021. The board fees do not contain profit-sharing or bonus payments.

One member of the Company's board of directors and existing shareholder, Erik J. van den Berg, received consultancy fees until March 2021. The compensation paid to this individual is presented below for the years ended December 31, 2023, 2022 and 2021. At December 31, 2023, 2022 and 2021, related party expenses of less than $0.1 million, respectively, were reported in the Company's trade payables and other balances. The disclosure amounts are based on the expense recognized in the consolidated statements of loss and other comprehensive loss.

	For the Year Ended December 31,		
(in thousands)	2023	2022	2021
Board fees			
Kapil Dhingra	$ 83	$ 75	$ 55
Karen J. Wilson	55	55	41
Jay Backstrom	47	24	—
James Noble	52	24	—
Peter Kiener	39	—	—
Mary Wadlinger	40	—	—
Christy Oliger	38	—	—
Stefan Luzi (1)	6	47	35
Erik J. van den Berg	—	24	36
Joël J.P. Jean-Mairet (2)	—	—	—
Nanna Lüneborg	—	23	23
Guido Magni	—	49	37
	$ 360	**$ 320**	**$ 227**
Consultancy fees			
Erik J. van den Berg	$ —	$ —	$ 20
	$ —	**$ —**	**$ 20**

(1) Compensation for Dr. Luzi is paid to Gilde Healthcare.
(2) Dr. Jean-Mairet waived any director fees he was entitled to for his service on our Board during the years ended December 31, 2022 and 2021.

As of December 31, 2023, the following outstanding stock options were held by the individual members of our board of directors. Further details on the number of stock options held by these individual directors are disclosed in section 5. Directors, Senior Management and Employees.

	As of December 31,					
	2023		2022		2021	
	Number of Options	Weighted average Exercise Price	Number of Options	Weighted average Exercise Price	Number of Options	Weighted average Exercise Price
Kapil Dhingra	247,740	$ 8.67	247,740	$ 8.67	227,740	$ 8.37
Jay Backstrom	40,000	$ 3.62	20,000	$ 3.64	—	$ —
James Noble	40,000	$ 3.62	20,000	$ 3.64	—	$ —
Peter A. Kiener (1)	20,000	$ 2.10	—	$ —	—	$ —
Christy Oliger (2)	20,000	$ 2.10	—	$ —	—	$ —
Mary E. Wadlinger (1)	20,000	$ 2.10	—	$ —	—	$ —
Karen J. Wilson	64,261	$ 8.38	64,261	$ 8.38	44,261	$ 10.53

(1) Dr. Kiener and Ms. Wadlinger were appointed to the Board effective January 1, 2023.
(2) Ms. Oliger was appointed to the Board effective March 9, 2023.

22. Financial instruments, risk management and capital management

22.1 Financial assets and financial liabilities

The following table shows the carrying amounts of financial assets and financial liabilities. The Company does not hold any financial assets and financial liabilities other than those measured at amortized cost. Management assessed that the carrying values of the Company's financial assets and financial liabilities measured at amortized cost are a reasonable approximation of their fair values.

22.2 Financial risk management

	As of December 31,	
(in thousands)	2023	2022
Financial assets measured at amortized cost		
Cash and cash equivalents (Note 14)	$ 44,231	$ 100,333
Investments (Note 13)	51,340	32,535
Other non-current assets and security deposits	319	809
Receivables and other	1,459	3,254
Total financial assets	**$ 97,349**	**$ 136,931**
Financial liabilities measured at amortized cost		
Borrowings (Note 16)	$ 5,282	$ 4,640
Trade payables and other (Note 17)	4,446	3,965
Accrued expenses and other current liabilities (Note 18)	4,773	8,193
Lease liabilities (Note 12)	1,031	810
Total financial liabilities	**$ 15,532**	**$ 17,608**

The Company is exposed to a variety of financial risks: market risk and credit risk. Its overall risk management program seeks to minimize potential adverse effects of these financial risk factors on our financial performance.

22.2.1 Market risk

Market risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate because of changes in market prices. Market risk, which mostly impacts the Company, comprises two types of risk:

interest rate risk and currency risk. Financial instruments affected by market risk include cash, cash equivalents, investments, accounts receivable and trade and other payables. All of these financial instruments generally are short-term in nature, with maturities and settlement dates between one and 12 months.

The Company does not enter into any derivative financial instruments to manage its exposure to foreign currency risk and interest rate risk. During 2023, the foreign currency exchange rate between USD and EUR fluctuated throughout the year, with a 7.4% difference between the high and low rates, which had an impact on the results of our operations presented in USD, including foreign currency exchange losses of $1.4 million for the year ended December 31, 2023. Continued variations in exchange rates similar to this could have impacted its loss for the year by approximately $5.9 million as additional gain or loss. Due to the nature of its investment portfolio and other financial instruments, the Company does not believe an immediate 1.0% increase in interest rates would have a material effect on the fair market value of our portfolio, and accordingly the Company does not expect a sudden change in market interest rates to affect materially our operating results or cash flows.

22.2.2 Credit risk

Cash and cash equivalents

The Company held cash and cash equivalents as of December 31, 2023 and 2022 of $44.2 million and $100.3 million, respectively.

Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument or customer contract, leading to a financial loss. The Company is exposed to credit risk from its operating activities (primarily accounts receivable) and from its cash and cash equivalents held with three banks. Cash and cash equivalents, and short-term marketable securities are financial instruments that potentially subject the Company to concentrations of credit risk. As of December 31, 2023 and 2022, its cash consists of cash deposited with three financial institutions and account balances may exceed insured limits.

On March 10, 2023, Silicon Valley Bank, Santa Clara, California, or SVB, was closed by the California Department of Financial Protection and Innovation and the Federal Deposit Insurance Corporation, or FDIC, was appointed receiver. On March 26, 2023, First–Citizens Bank & Trust Company, Raleigh, North Carolina, or First Citizens, purchased all deposits and loans of SVB, and the former SVB reopened as First-Citizens Bank & Trust Company on Monday, March 27, 2023. The Company had a banking relationship with SVB, including $32.0 million as of December 31, 2022 held in Euros. Although most SVB depositors received full access to their funds on March 13, 2023, the Company had disrupted and delayed access to funds held in multi-currency accounts while the systems' conversions were being completed to allow full–service banking, which has been resolved. As of December 31, 2023 the Company had no cash held at SVB as First-Citizens Bank & Trust Company. The majority of its cash is held at other financial institutions that can be used to fund operations. Management believes that the Company is not currently exposed to significant credit risk due to the financial strength of these institutions.

Investments

The Company invests its cash in accordance with a policy objective that seeks to ensure both liquidity and safety of principal. The policy limits investments to instruments issued by the U.S. government, certain SEC-registered money market funds that invest only in U.S. government obligations and various other low-risk liquid investment options, and places restrictions on portfolio maturity terms. The Company does not believe its current investments give rise to a material credit risk.

22.3 Capital management

The Company manages its capital to ensure that it will be able to continue as a going concern while maximizing return to shareholders through the optimization of the debt and equity balance.

The Company's capital structure consists of net debt (leases as detailed in Note 12 and borrowings as detailed in Note 16 offset by cash and cash equivalents) and equity (as detailed in the consolidated statements of financial position).

In order to achieve this overall objective, its capital management, among other things, aims to ensure that it meets financial covenants attached to the borrowings that define capital structure requirements.

No changes were made in the objectives, policies, or processes for managing capital during the year ended December 31, 2023.

22.4 Liquidity Risk

As of December 31, 2023, the Company held cash, cash equivalents, and investments of $95.6 million, which it believes is sufficient to service its current liabilities of $14.9 million, as well as fund its operations for at least the next 12 months. Refer to Note 2, “Going Concern” for additional information. The Company does not believe it is exposed to material liquidity risk as of December 31, 2023.

23. Average number of employees

The average number of employees can be specified as follows:

	For the Year Ended December 31,	
	2023	2022
Average number of employees		
R&D	45.2	46.7
G&A	10.0	10.8
	55.2	**57.5**

As of December 31, 2023, the Company had 35.3 full-time employees (December 31, 2022: 63.3)

As of December 31, 2023, a total of 11 employees were active outside the Netherlands (12 in 2022).

24. Commitments and Contingencies

Legal proceedings

From time to time, the Company is involved in legal proceedings and adjudications generally incidental to its normal business activities, none of which has had, individually or in the aggregate, a material adverse impact on the Company. The Company accrues for loss contingencies when a present obligation (legal or constructive) has arisen as a result of a past event, payment is probable, and the amount can be estimated reliably. These estimates are based on an analysis made by internal and external legal counsel considering information known at the time. Legal costs in connection with loss contingencies are expensed as incurred. The Company believes that the resolution of any current legal matters will not have a material adverse impact on its financial position or results of operations.

Contingent liabilities and commitments

In January 2017, the Company entered into an agreement with the Amsterdam UMC (formerly VUmc prior to its merger with UMC effective January 2024 (the Amsterdam UMC Agreement)) under which the Amsterdam UMC granted the Company an exclusive, although non-exclusive with respect to certain intangible know-how, worldwide, sublicensable license for certain patent rights and know-how owned by Amsterdam UMC, effectively including research and other services provided in collaboration by Amsterdam UMC to develop, make, and sell licensed products related to such patent rights and know-how. Amsterdam UMC retains the right to use the patent rights and know-how for solely non-commercial research and educational purposes, but it may not conduct such work with respect to any product that is directed to a specified target for a specified time period.

The Company is obligated to pay Amsterdam UMC sub to low single-digit tiered royalties on net sales of products covered by claims included in the assigned patent rights. Royalties are payable on a country-by-country basis for a royalty term that expires upon the expiration of the last valid claim in the assigned patent rights in such country that would be infringed by the use, manufacture, or sale of a product in such country in the absence of us having rights to such patent right.

25. Subsequent events

In January 2024, the Company announced it had entered into a clinical trial collaboration and supply agreement with Merck & Co., Inc. to evaluate its anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in combination with LAVA-1207. Under the terms of this agreement, we will be provided with pembrolizumab for the dose escalation and expansion phases of our ongoing Phase 1/2a study of LAVA-1207 (NCT05369000) (KEYNOTE-F73), with the combination arm expected to be initiated in the first half of 2024. Other than providing pembrolizumab to the Company for the Company's ongoing LAVA 1207 1/2a study, the collaboration with Merck & Co., Inc does not have any financial impact on the Company.

In March 2024, the Company announced that Pfizer had achieved a clinical development milestone for PF-08046052, resulting in the first milestone payment of $7 million to the Company under the Pfizer Agreement.

11.2 Company Financial Statements

LAVA Therapeutics N.V.
Company only statement of loss
(In thousands, except share and per share amounts)

	Notes	For the Year ended December 31, 2023	2022
Result participations after taxes	27	$ 508	$ 436
Company result after taxes		(42,482)	(32,344)
Loss for the year (after taxes)		**$ (41,974)**	**$ (31,907)**

The results for the year are fully attributable to the owners of LAVA Therapeutics N.V.

The accompanying Notes are an integral part of these financial statements.

LAVA Therapeutics N.V.
Company only statement of financial position
(In thousands)

	Notes	As of December 31, 2023	2022
Assets			
Non-current assets:			
Property and equipment, net	26	$ 1,560	$ 1,383
Right-of-use assets	12	892	651
Financial fixed assets	27	1,309	801
Other non-current assets and security deposits	28	310	800
Total non-current assets		**4,071**	**3,635**
Current assets:			
Receivables and other	29	1,455	3,254
VAT receivable		240	—
Prepaid expenses and other current assets	30	1,563	4,364
Investments	13	51,340	32,535
Cash and cash equivalents	31	43,289	100,027
Total current assets		**97,887**	**140,180**
Total assets		**$ 101,958**	**$ 143,815**
Equity and Liabilities			
Equity:			
Share capital	15	$ 3,715	$ 3,715
Share premium	15	194,424	194,424
Legal reserves	33	(10,899)	(12,972)
Other reserves	33	12,005	8,942
Accumulated deficit		(106,093)	(76,162)
Loss for the year		(41,974)	(31,907)
Total equity		**51,178**	**86,040**
Non-current liabilities:			
Lease liabilities	12	591	431
Deferred revenue	4	35,000	35,000
Total non-current liabilities		**35,591**	**35,431**
Current liabilities:			
Borrowings	16	5,282	4,640
Lease liabilities	12	440	379
Trade payables and other	32	4,226	3,794
Intercompany payable	27	1,410	1,807
VAT payable		—	45
License liabilities	24	—	4,732
Accrued expenses and other current liabilities	34	3,831	6,948
Total current liabilities		**15,189**	**22,345**
Total liabilities		**50,780**	**57,775**
Total equity and liabilities		**$ 101,958**	**$ 143,815**

The accompanying Notes are an integral part of these financial statements.

Notes to the company financial statements

As the financial data of the Company are included in the Consolidated financial statements, the statements of profit and loss in the Company financial statements is presented in its condensed form. In case no other policies are mentioned, refer to the accounting policies as described in the accounting policies in the Consolidated financial statements. For an appropriate interpretation, the Company financial statements should be read together with the Consolidated financial statements. Reference made to Notes 1 to 25 can be found in the Notes to the Consolidated financial statements.

Significant Accounting Policies

Basis of Preparation

Lava Therapeutics N.V.'s Company financial statements have been prepared in accordance with Part 9, Book 2 of the Dutch Civil Code on an unconsolidated basis of the entity as a standalone entity. In accordance with Art. 2:362 sub 8 DCC, the determination of profit and the recognition and measurement principles applied in these separate financial statements are the same as those applied in the consolidated financial statements (see Note 2 to the consolidated financial statements). These principles also include the classification and presentation of financial instruments, being equity instruments or financial liabilities.

For a description of the impact of the adoption of new accounting standards on the separate financial statements, see Note 3 to the consolidated financial statements.

Since the Company's statement of profit or loss for 2023 is recognized in the consolidated financial statements, it is sufficient in the company financial statements to present a condensed statement of profit or loss in accordance with Art. 2:402 DCC.

Financial fixed assets

Investments in consolidated subsidiaries

Consolidated subsidiaries are all entities (including intermediate subsidiaries) over which the company has control. The company controls an entity when it is exposed, or has rights, to variable returns from its involvement with the subsidiary and has the ability to affect those returns through its power over the subsidiary. Subsidiaries are recognized from the date on which control is transferred to the company or its intermediate holding entities. They are derecognized from the date that control ceases.

Subsidiaries, over which significant influence can be exercised, are valued according to the net asset value method. In the event that 20% or more of the voting rights can be exercised, it may be assumed that there is significant influence.

The net asset value is calculated in accordance with the accounting principles that apply for these financial statements; with regard to subsidiaries in which insufficient data is available for adopting these principles, the valuation principles of the respective subsidiary are applied.

If the valuation of a subsidiary based on the net asset value is negative, it will be stated at nil. If and insofar as Lava Therapeutics N.V. can be held fully or partially liable for the debts of the subsidiary or has the firm intention of enabling the subsidiary to settle its debts, a provision is recognised for this. Newly acquired subsidiaries are initially recognized on the basis of the fair value of their identifiable assets and liabilities at the acquisition date. For subsequent valuations, the principles that apply for these financial statements are used, with the values upon their initial recognition as the basis.

The amount by which the carrying amount of the subsidiary has changed since the previous special purpose financial statements as a result of the net result achieved by the subsidiary is recognised in the profit and loss account.

Subsidiaries over which no significant influence can be exercised are valued at historical cost. The result represents the dividend declared in the reporting year, whereby dividend not distributed in cash is valued at fair value.

In the event of an impairment loss, valuation takes place at the recoverable amount; an impairment is recognised and charged to the profit and loss account. See also Note 2, Impairment of long-lived assets.

Result from subsidiaries (valued at net asset value):

The result is the amount by which the carrying amount of the subsidiary has changed since the previous financial statements as a result of the earnings achieved by the subsidiary to the extent that this can be attributed to Lava Therapeutics N.V.

Additional Information

For 'Additional information' within the meaning of Art. 2:392 DCC, refer to Section 12 entitled "Other Information", of this report.

26. Property and equipment, net

Movements in property and equipment were as follows:

(in thousands)	Building improvements	Laboratory equipment	Office equipment	ICT equipment	Total
Cost					
Balance at January 1, 2022	**$ 109**	**$ 1,724**	**$ 36**	**$ 165**	**$ 2,034**
Additions	—	525	2	40	567
Foreign currency translation adjustment	(6)	(109)	(2)	(9)	(126)
Balance at December 31, 2022	**103**	**2,140**	**36**	**196**	**2,475**
Additions	275	388	25	38	726
Disposals	(23)	(12)	—	—	(35)
Foreign currency translation adjustment	9	82	2	13	106
Balance at December 31, 2023	**$ 364**	**$ 2,598**	**$ 63**	**$ 247**	**$ 3,272**
Accumulated depreciation					
Balance at January 1, 2022	**$ 18**	**$ 538**	**$ 17**	**$ 55**	**$ 628**
Charge for the year	85	366	7	36	494
Foreign currency translation adjustment	—	(26)	(1)	(3)	(30)
Balance at December 31, 2022	**103**	**878**	**23**	**88**	**1,092**
Charge for the year	43	505	11	46	605
Disposals	(23)	(12)	—	—	(35)
Foreign currency translation adjustment	4	40	1	5	50
Balance at December 31, 2023	**$ 127**	**$ 1,411**	**$ 35**	**$ 138**	**$ 1,712**
Carrying amounts					
Property and equipment, net at December 31, 2022	**$ —**	**$ 1,262**	**$ 13**	**$ 108**	**$ 1,383**
Property and equipment, net at December 31, 2023	**$ 237**	**$ 1,187**	**$ 28**	**$ 109**	**$ 1,560**

Depreciation expenses of our property and equipment included in the research and development expenses amounted to $594 thousand in 2023 and $489 thousand in 2022. Depreciation expenses of our property and equipment included in the general and administrative expenses amounted to $11 thousand in 2023 and $5 thousand in 2022.

27. Financial fixed assets

List of group companies

Lava Therapeutics N.V. has direct interests in the subsidiary listed in Note 2 (in the Notes to the consolidated financial statements).

The composition of the financial assets is as follows:

(in thousands)	share in capital	As of December 31, 2023	2022
Subsidiary Lava Therapeutics Inc., Philadelphia, USA	100%	**$ 1,309**	**$ 801**

The movement in the investment in the subsidiary Lava Therapeutics Inc. is as follows:

(in thousands)	Investments in consolidated subsidiaries
Balance at January 1, 2022	**$ 365**
Investments	—
Share of result of subsidiary	436
Balance at December 31, 2022	**801**
Investments	—
Share of result of subsidiary	508
Balance at December 31, 2023	**$ 1,309**

Lava Therapeutics Inc. was founded in August 2019 as a 100% subsidiary of Lava Therapeutics N.V. and started its activities in January 2020.

Intercompany payables

(in thousands)	As of December 31, 2023	2022
Intercompany account Lava Therapeutics Inc., USA	**$ (1,410)**	**$ (1,807)**

All receivables/payables from group companies fall due within one year. The fair value of the intercompany receivables/payables approximates the book value, due to their short-term character.

Result of subsidiaries

(in thousands)	For the Year Ended December 31, 2023	2022
Result from Lava Therapeutics Inc., USA	**$ 508**	**$ 436**

28. Other non-current assets and security deposits

(in thousands)	As of December 31, 2023	2022
Security deposit leased facilities	$ 171	$ 21
Prepaid project expenses	139	779
	$ 310	**$ 800**

Security deposits leased facilities as of December 31, 2023 increased compared to December 31, 2022 due to the lease of new facilities in The Netherlands in the first quarter of 2023. Prepaid non-current project expenses as of December 31, 2023 decreased compared to December 31, 2022 due to maturity within one year.

29. Receivables and other

Receivables and other primarily consist of trade receivables and WBSO subsidy receivables. All positions will be settled within one year.

30. Prepaid expenses and other current assets

	As of December 31,	
(in thousands)	2023	2022
Deferred contract costs	$ —	$ 3,309
Prepaid project expenses	969	382
Prepaid other expenses	594	673
	$ 1,563	**$ 4,364**

The Company had deferred contract costs of $3.3 million as of December 31, 2022 related to the initial supply of drug product to be delivered to Pfizer. During 2023, the Company transferred all the initial supply of drug product to Pfizer. As a result, the Company had no deferred contract costs as of December 31, 2023.

31. Cash and cash equivalents

	As of December 31,	
(in thousands)	2023	2022
Short-term deposits	$ 10,326	$ 44,740
Current bank accounts	32,963	55,287
	$ 43,289	**$ 100,027**

Short-term deposits are made for varying periods of between one day and three months, depending on the immediate cash requirements of the Company, and earn interest at the respective short-term deposit rates. Information about the credit risk over cash and cash equivalents is presented in Note 21 of the consolidated financial statements.

Cash and cash equivalents are not subject to any restrictions.

32. Trade payables and other

The Company had accounts payable balances of $4.2 million and $3.8 million as of December 31, 2023 and 2022, respectively. The average credit period on domestic purchases of certain goods was 7 to 30 days. No interest was charged on the trade payables from the invoices received. The maturity of all balances is within one year. Information about the Company's exposure to currency and liquidity risk in relation to its trade and other payables is included in Note 22 of the consolidated financial statements.

33. Equity

The legal reserve relates to accumulated foreign currency differences from the translation of the financial statements into our USD reporting currency.

	Note	Preference						Number of Common shares	Common Share capital	Share Premium	Legal reserve	Other reserves	Accumulated deficit	Loss for the year	Total
		Number of Series A shares	Series A Share premium	Number of Series B shares	Series B Share premium	Number of Series C shares	Series C Share premium								
Balance at January 1, 2021		**1,037,595**	**$ 722**	**3,899,766**	**$ 18,340**	**4,133,805**	**$ 22,026**	**281,775**	**$ —**	**$ —**	**$ (581)**	**$ 922**	**$ (17,880)**	**$ (15,927)**	**$ 7,622**
Loss for period		—	—	—	—	—	—	—	—	—	—	—	—	(42,355)	(42,355)
Appropriation of the result of preceding year		—	—	—	—	—	—	—	—	—	—	—	(15,927)	15,927	—
Share split		—	(143)	—	(536)	—	(589)	—	1,308	(40)	—	—	—	—	—
Issuance of Series C Preferred shares ($6.22 per share), net of offering costs of $92		—	—	—	—	9,945,221	60,373	—	1,425	—	—	—	—	—	61,798
Repurchase of Series A and common shares		(718,250)	(400)	—	—	—	—	(165,750)	(122)	(4,760)	—	—	—	—	(5,282)
Conversion of preference shares		(319,345)	(179)	(3,899,766)	(17,804)	(14,079,026)	(81,810)	18,298,137	—	99,793	—	—	—	—	—
Issuance of common stock in initial public offering ($15.00 per share), net of offering costs of $11.5 million		—	—	—	—	—	—	6,700,000	947	87,779	—	—	—	—	88,726
Issuance of overallotment option		—	—	—	—	—	—	425,712	61	5,877	—	—	—	—	5,939
Issuance of Amsterdam UMC common stock		—	—	—	—	—	—	235,664	34	3,621	—	—	—	—	3,655
Share-based compensation expense	20	—	—	—	—	—	—	—	—	—	—	3,907	—	—	3,907
Foreign currency translation adjustment		—	—	—	—	—	—	—	—	—	(5,642)	—	—	—	(5,642)
Balance at December 31, 2021		**—**	**—**	**—**	**—**	**—**	**—**	**25,775,538**	**3,653**	**192,270**	**(6,223)**	**4,829**	**(33,807)**	**(42,355)**	**118,367**
Loss for period		—	—	—	—	—	—	—	—	—	—	—	—	(31,907)	(31,907)
Appropriation of the result of preceding year		—	—	—	—	—	—	—	—	—	—	—	(42,355)	42,355	—
Option exercises		—	—	—	—	—	—	22,197	3	12	—	—	—	—	15
Issuance of Amsterdam UMC common stock		—	—	—	—	—	—	491,352	59	2,142	—	—	—	—	2,201
Share-based compensation expense	20	—	—	—	—	—	—	—	—	—	—	4,113	—	—	4,113
Foreign currency translation adjustment		—	—	—	—	—	—	—	—	—	(6,749)	—	—	—	(6,749)
Balance at December 31, 2022		**—**	**—**	**—**	**—**	**—**	**—**	**26,289,087**	**3,715**	**194,424**	**(12,972)**	**8,942**	**(76,162)**	**(31,907)**	**86,040**
Loss for period		—	—	—	—	—	—	—	—	—	—	—	—	(41,974)	(41,974)
Appropriation of the result of preceding year		—	—	—	—	—	—	—	—	—	—	—	(31,907)	31,907	—
Reclassification lapsed options	20	—	—	—	—	—	—	—	—	—	—	(1,976)	1,976	—	—
Share-based compensation expense	20	—	—	—	—	—	—	—	—	—	—	5,039	—	—	5,039
Foreign currency translation adjustment		—	—	—	—	—	—	—	—	—	2,073	—	—	—	2,073
Balance at December 31, 2023		—	**$ —**	—	**$ —**	—	**$ —**	**26,289,087**	**$ 3,715**	**$ 194,424**	**$ (10,899)**	**$ 12,005**	**$ (106,093)**	**$ (41,974)**	**$ 51,178**

The other reserves relate to the share-based payments reserve.

Reference is made to Note 15 in the consolidated financial statements for further information on equity.

34. Accrued expenses and other current liabilities

(in thousands)	As of December 31, 2023	2022
Research and development external project costs	$ 2,290	$ 5,399
Personnel-related expenses	588	804
Professional fees	523	486
Other	430	259
	$ 3,831	**$ 6,948**

35. Average number of employees

The average number of employees can be specified as follows:

	For the Year Ended December 31, 2023	2022
Average number of employees		
R&D	40.2	41.8
G&A	4.4	5.2
	44.6	**47.0**

As of December 31, 2023, the Company had 25.3 full-time employees (December 31, 2022: 52.3)

One employee was active outside the Netherlands (one in 2022).

36. Directors' remuneration

Reference is made to Note 20 in the consolidated financial statements for the directors' remuneration disclosure as referred to in Art. 2:383 DCC.

37. Independent Auditor's fee

The following fees were charged by PricewaterhouseCoopers Accountants N.V. to the Company and its subsidiary, as referred to in Art. 2:382a sub 1 and 2 DCC. The costs are allocated to the year which the services are related to.

A. Audit Fees

Audit fees in 2023 and 2022 were $0.5 million and $0.5 million, respectively, and relate to audit services provided by our principal accountants, PricewaterhouseCoopers Accountants N.V., in connection with our annual audits, quarterly reviews, and review of registration statements.

B. Audit-Related Fees

None.

C. Tax Fees

None.

D. All Other Fees

None.

38. Disclosure of government subsidies

Government subsidies:

The company accounted for the following government subsidies in 2023:

Subsidy for research and development (WBSO) amounting to $2.0 million (2022: $1.6 million). The subsidy is deducted from the Research & Development personnel related cost.

39. Related party transactions

Reference is made to Note 20 of the consolidated financial statements.

40. Subsequent events

Reference is made to Note 25 of the consolidated financial statements.

Signature page to the LAVA Therapeutics N.V. 2023 financial statements

Executive Director:

S.A. Hurly

Non-Executive Directors:

K. Dhingra

K.J. Wilson

J. Backstrom

J. Noble

P.A. Kiener

M.E. Wadlinger

C. Oliger

Utrecht, May 29, 2024

12 OTHER INFORMATION

12.1 Independent auditor's report

The independent auditor's report is included in the next page.

12.2 Profit appropriation provisions

Pursuant to article 31 of the Company's articles of association, any profits shown in the adopted statutory annual accounts of the Company shall be appropriated as follows, and in the following order of priority:

a. to the extent that any preferred shares have been cancelled without full repayment as described in the articles of association and without such deficit subsequently having been paid in full, an amount equal to any such (remaining) deficit shall first be distributed to those who held those preferred shares at the moment of such cancellation becoming effective;

b. if preferred shares are issued and outstanding and to the extent that the mandatory annual distribution on the preferred shares (i.e., an amount equal to the applicable interest rate calculated over the aggregate amount paid up on those preferred shares, calculated in accordance with the relevant provisions of the articles of association), or part thereof, in relation to previous financial years has not yet been paid in full, an amount equal to any such (remaining) deficit shall be distributed on the preferred shares;

c. if preferred shares are issued and outstanding, the mandatory annual distribution (as described above under b.) payable on preferred shares shall then be distributed on the preferred shares;

d. following those distributions, our board of directors shall determine which part of the remaining profits shall be added to the Company's reserves; and

e. subject to a proposal by our board of directors to that effect, the remaining profits shall be at the disposal of our general meeting of shareholders for distribution on the common shares.

12.3 Shares carrying limited economic entitlement

The preferred shares in the Company's capital carry a limited entitlement to the Company's profit and reserves. As of December 31, 2023, no preferred shares in the Company's capital were issued.

12.4 Branches

The Company has one branch office located at 520 Walnut Street, Suite 1150, Philadelphia Pennsylvania, 19106, United States of America.

Independent auditor's report

To: the general meeting of LAVA Therapeutics N.V.

Report on the audit of the financial statements 2023

Our opinion

In our opinion:

- the consolidated financial statements of LAVA Therapeutics N.V. together with its subsidiary ('the Group') give a true and fair view of the financial position of the Group as at 31 December 2023 and of its result and cash flows for the year then ended in accordance with International Financial Reporting Standards as adopted in the European Union ('EU-IFRS') and with Part 9 of Book 2 of the Dutch Civil Code;
- the company financial statements of LAVA Therapeutics N.V. ('the Company') give a true and fair view of the financial position of the Company as at 31 December 2023 and of its result for the year then ended in accordance with Part 9 of Book 2 of the Dutch Civil Code.

What we have audited

We have audited the accompanying financial statements 2023 of LAVA Therapeutics N.V., Utrecht. The financial statements comprise the consolidated financial statements of the Group and the company financial statements.

The consolidated financial statements comprise:

- the consolidated statement of financial position as at 31 December 2023;
- the following statements for 2023: the consolidated statements of loss and other comprehensive loss, the consolidated statements of changes in equity and the consolidated statement of cash flows; and
- the notes to the financial statements, including material accounting policy information and other explanatory information.

The company financial statements comprise:

- the company only statement of financial position as at 31 December 2023;
- the company only statement of loss for the year then ended; and
- the notes, comprising a summary of the accounting policies applied and other explanatory information.

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The financial reporting framework applied in the preparation of the financial statements is EU-IFRS and the relevant provisions of Part 9 of Book 2 of the Dutch Civil Code for the consolidated financial statements and Part 9 of Book 2 of the Dutch Civil Code for the company financial statements.

The basis for our opinion

We conducted our audit in accordance with Dutch law, including the Dutch Standards on Auditing. We have further described our responsibilities under those standards in the section 'Our responsibilities for the audit of the financial statements' of our report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Independence

We are independent of LAVA Therapeutics N.V. in accordance with the 'Wet toezicht accountantsorganisaties' (Wta, Audit firms supervision act), the 'Verordening inzake de onafhankelijkheid van accountants bij assuranceopdrachten' (ViO, Code of Ethics for Professional Accountants, a regulation with respect to independence) and other relevant independence regulations in the Netherlands. Furthermore, we have complied with the 'Verordening gedrags- en beroepsregels accountants' (VGBA, Dutch Code of Ethics).

Our audit approach

We designed our audit procedures with respect to the key audit matters, fraud and going concern, and the matters resulting from that, in the context of our audit of the financial statements as a whole and in forming our opinion thereon. The information in support of our opinion, such as our findings and observations related to individual key audit matters, the audit approach fraud risk and the audit approach going concern was addressed in this context, and we do not provide separate opinions or conclusions on these matters.

Overview and context

LAVA Therapeutics N.V. is a clinical-stage biopharmaceutical company focused on new cancer treatments that leverage the immune system. The Group is comprised of one component and a branch in the US. We therefore considered our group audit scope and approach as set out in the section 'The scope of our group audit'. We paid specific attention to the areas of focus driven by the operations of the Group, as set out below.

As part of designing our audit, we determined materiality and assessed the risks of material misstatement in the financial statements. In particular, we considered where the board of directors made important judgements, for example, in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. In these considerations, we paid attention to, amongst others, the assumptions underlying the physical and transition risk related to climate change. In paragraph 3 of the consolidated financial statements, the Company describes the areas of judgement in applying accounting policies and the key sources of estimation uncertainty regarding revenue recognition. Given the significant estimation uncertainty and the related higher inherent risks of material misstatement in revenue recognition for research and license revenue, we considered this matter as key audit matter as set out in the section 'Key audit matters' of this report.

Another area of focus, that was not considered as key audit matter, was the correct recognition and estimation of accruals, specifically those relating to clinical-trial expenses.

We ensured that the audit team (performing the audit at group and component level) included the appropriate skills and competences which are needed for the audit of a clinical-stage biopharmaceutical company. We therefore included experts and specialists in the areas of among others revenue recognition and share-based compensation expenses in our team.

The outline of our audit approach was as follows:

Materiality

- Overall materiality: $2,084,000

Audit scope

- We conducted audit work in the Netherlands.
- Our scope included the wholly owned subsidiary of the group (LAVA Therapeutics Inc.) as the financial reporting and accounting function for the Group is operated and managed centrally.
- Audit coverage: 100% of consolidated revenue, 100% of material items of the consolidated total assets and 100% of material items of the consolidated loss before tax.

Key audit matters

- Revenue recognition for research and license revenue.

Materiality

The scope of our audit was influenced by the application of materiality, which is further explained in the section 'Our responsibilities for the audit of the financial statements'.

Based on our professional judgement we determined certain quantitative thresholds for materiality, including the overall materiality for the financial statements as a whole as set out in the table below. These, together with qualitative considerations, helped us to determine the nature, timing and extent of our audit procedures on the individual financial statement line items and disclosures and to evaluate the effect of identified misstatements, both individually and in aggregate, on the financial statements as a whole and on our opinion.

Overall group materiality	$2,084,000 (2022: $540,000).
Basis for determining materiality	We used our professional judgement to determine overall materiality. As a basis for our judgement, we used 5% of loss before tax.
Rationale for benchmark applied	We used loss before tax as the primary benchmark, a generally accepted auditing practice, based on our analysis of the common information needs of the users of the financial statements. On this basis, we believe that loss before tax is the most relevant metric for the financial performance of the Company. In previous year we used 1% of the total operating expenses as basis for determining materiality, for 2023 we changed our basis for determining materiality to 5% of loss before tax.

We also take misstatements and/or possible misstatements into account that, in our judgement, are material for qualitative reasons.

We agreed with the board of directors that we would report to them any misstatement identified during our audit above $104,200 (2022: $27,000) as well as misstatements below that amount that, in our view, warranted reporting for qualitative reasons.

The scope of our group audit

LAVA Therapeutics N.V. is the parent company of a group of entities. The financial information of this group is included in the consolidated financial statements of LAVA Therapeutics N.V.

We tailored the scope of our audit to ensure that we, in aggregate, performed sufficient work on the financial statements to enable us to provide an opinion on the financial statements as a whole, taking into account the management structure of the Group, the nature of operations of its components, the accounting processes and controls, and the markets in which the components of the Group operate. All audit procedures for the audit of the consolidated and company financial statements are performed in the Netherlands as the financial reporting and accounting for both entities in the Group are kept centrally in Utrecht (the Netherlands). As LAVA Therapeutics Inc. is limited in size and the accounting of both the parent entity and the subsidiary are performed centrally within the same control environment, we adopted an audit approach based on a consolidated perspective with the consolidated financial information as subject matter that also provided sufficient and appropriate audit evidence for our opinion on the company financial information.

By performing the procedures outlined above at the components, combined with additional procedures exercised at group level, we have been able to obtain sufficient and appropriate audit evidence on the Group's financial information, to provide a basis for our opinion on the financial statements.

Audit approach fraud risks

We identified and assessed the risks of material misstatements of the financial statements due to fraud. During our audit we obtained an understanding of LAVA Therapeutics N.V. and its environment and the components of the internal control system. This included the board of directors' risk assessment process, the board of directors' process for responding to the risks of fraud and monitoring the internal control system and how the board of directors exercised oversight, as well as the outcomes. We note that the board of directors has not formalised its fraud risk assessment.

We evaluated the design and relevant aspects of the internal control system with respect to the risks of material misstatements due to fraud and in particular the fraud risk assessment, as well as the code of conduct, whistle-blower procedures, incident registration among other things. We evaluated the design and the implementation and, where considered appropriate, tested the operating effectiveness of internal controls designed to mitigate fraud risks.

We asked the board of directors and members of the senior management team whether they are aware of any actual or suspected fraud. This did not result in signals of actual or suspected fraud that may lead to a material misstatement.

As part of our process of identifying fraud risks, we evaluated fraud risk factors with respect to financial reporting fraud, misappropriation of assets and bribery and corruption. We evaluated whether these factors indicate that a risk of material misstatement due to fraud is present.

We identified the following fraud risks and performed the following specific procedures:

Identified fraud risks	*Our audit work and observations*
The risk of management override of controls Management is in a unique position to perpetrate fraud because of management's ability to manipulate accounting records and prepare fraudulent financial statements by overriding controls that otherwise appear to be operating effectively. That is why, in all our audits, we pay attention to the risk of management override of controls in: • the appropriateness of journal entries and other adjustments made in the preparation of the financial statements; • estimates; • significant transactions, if any, outside the normal course of business for the entity.	We evaluated the design and implementation of the internal control system in the processes of generating and processing journal entries, making estimates, and monitoring projects. We also paid specific attention to the access safeguards in the IT system and the possibility that these lead to violations of the segregation of duties. We have identified deficiencies in the internal control system with respect to internal control over financial reporting. We have reported our findings in writing to management. Please refer to note 8 'Controls and procedures' in the consolidated financial statements for disclosure by management. We performed primarily substantive-based audit procedures. We selected journal entries based on risk criteria and conducted specific audit procedures for these entries. These procedures include, among others, inspection of the entries to source documentation to assess the validity of the business rationale and substantiation of corroborating evidence. In this context, we also tested consolidation and elimination entries. We performed substantive audit procedures on significant transactions outside the normal course of business. We also performed specific audit procedures related to important estimates of management, including revenue recognition. We refer to the key audit matters. We specifically paid attention to the inherent risk of bias of management in estimates. Our audit procedures did not lead to specific indications of fraud or suspicions of fraud with respect to management override of controls.

Identified fraud risks	*Our audit work and observations*
The risk of fraud in revenue recognition As part of our risk assessment and based on a presumption that there are risks of fraud in revenue recognition, we evaluated the revenue recognition of both the Janssen and the Pfizer (Seagen) agreements.	We evaluated the design and implementation of the internal control system in the processes related to revenue reporting. We have identified deficiencies in the internal control system with respect to internal control over financial reporting. We have reported our findings in writing to management. Please refer to note 8 'Controls and procedures' in the consolidated financial statements for disclosure by management. We performed primarily substantive-based audit procedures. We refer to the paragraph 'Key audit matters' in this auditor's report for the procedures performed on revenue recognition. Our audit procedures did not lead to specific indications of fraud or suspicions of fraud with respect to the existence, occurrence, and cut off of the revenue reporting.
Fraud risk in outgoing payments exist due to a lack of segregation of duties As disclosed in note 8 'Controls and procedures' in the consolidated financial statements, due to the existence of the material weaknesses identified related to the design and maintenance of appropriate segregation of duties, we identified the risk of unauthorised/fraudulent payments as a fraud risk.	We evaluated the design and implementation of the internal control system and assessed the effectiveness of relevant controls in the payment process. We performed our audit procedures fully substantively. We tested, on a sample basis, whether payments were made to the correct bank account for services rendered and/or goods delivered based on the supporting invoices. Our audit procedures did not lead to specific indications of fraud or suspicions of fraud with respect to outgoing payments.

We incorporated an element of unpredictability in our audit. We reviewed any relevant correspondence with regulators. During the audit, we remained alert to indications of fraud. Furthermore, we considered the outcome of our other audit procedures and evaluated whether any findings were indicative of fraud or non-compliance with laws and regulations.

Audit approach going concern

As disclosed in section *'Going concern'* as part of note 2. summary of significant accounting policies of the financial statements the board of directors performed their assessment of the entity's ability to continue as a going concern for at least twelve months from the date of preparation of the financial statements and has not identified events or conditions that may cast significant doubt on the entity's ability to continue as a going concern (hereafter: going-concern risks). Our procedures to evaluate the board of directors' going-concern assessment included, amongst others:

- considering whether the board of directors' going-concern assessment included all relevant information of which we were aware as a result of our audit and inquiring with the board of directors regarding the board of directors' most important assumptions underlying its going-concern assessment. Amongst others, the board of directors took into consideration the fact that the Company has incurred recurring net losses since inception; and

- evaluating the board of directors' current budget including cash flows for at least twelve months from the date of preparation of the financial statements taken into account current developments in the industry and all relevant information of which we were aware as a result of our audit; and
- analysing whether the current and the required financing has been secured to enable the continuation of the entirety of the entity's operations; and
- performing inquiries of the board of directors as to its knowledge of going-concern risks beyond the period of the board of directors' assessment.

Our procedures did not result in outcomes contrary to the board of directors' assumptions and judgements used in the application of the going-concern assumption.

Key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in the audit of the financial statements. We have communicated the key audit matters to the board of directors. The key audit matters are not a comprehensive reflection of all matters identified by our audit and that we discussed. In this section, we described the key audit matters and included a summary of the audit procedures we performed on those matters.

Key audit matter	***Our audit work and observations***
Revenue recognition for research and license revenue *Refer to note 4 in the consolidated financial statements* A total of $6.8 million in research and license revenue was recognised in 2023. This amount includes revenue related to agreements with multiple performance obligations. *Pfizer Agreement:* The exclusive license agreement with Pfizer dated September 2022 includes each of the following performance obligations: license, manufacturing and technology transfer activities, initial supply, and research activities. For 2023 an amount of $3.6 million was recognised which mainly relates to the delivery of initial supplies. During 2022 an upfront payment was received, of which a buy-up option to pay Pfizer a one-time fee of $35.0 million is accounted for as deferred revenue as of 31 December 2022. At 31 December 2023 the option is not exercised and still accounted for as deferred revenue. *Janssen Agreement* In May 2020, the Company entered into a research collaboration and license agreement (Janssen Agreement) with Janssen Biotech, Inc. (Janssen).	As part of our audit, we evaluated, among other things, management's process for estimating the allocation period relating to the upfront payment under the Pfizer Agreement. Additionally, we have read and obtained an understanding of the underlying collaboration agreement. We verified the performance obligations in the collaboration agreements by reviewing the contracts and LAVA's accounting position papers (prepared in previous years with updates in the current year). For the revenue related to the initial supply we performed the following procedures: • Identification of the initial supply as a separate performance obligation based on the agreement. • Validated that the initial supply was delivered to Pfizer in 2023. • Validated that initial supply was invoiced in line with the pricing agreements. • Validated that the related invoices have been paid in 2023. The buy-up option is not exercised and is appropriately presented as deferred revenue.

Key audit matter	*Our audit work and observations*
In May 2023, a milestone payment of $2.5 million from Janssen was triggered under the terms of the Janssen Agreement. Against this background, research and license revenue was relatively complex and required judgments primarily in identifying performance obligations, determining the measurement and allocation of the arrangement consideration. The proper application of the accounting standards for revenue recognition is considered to be complex and to a certain extent based on estimates and assumptions made by the board of directors, this matter was therefore of particular significance for our audit. Therefore, we considered this as a key audit matter in our audit.	For the milestone payment of Janssen we performed the following audit procedures: • Identification of the milestone payment as a separate performance obligation based on the agreement. • Validated that Janssen confirmed the trigger for the milestone payment. • Validated that Janssen paid the milestone in 2023. We were able to satisfy ourselves that the estimates and assumptions made by the board of directors are supportable by appropriate documentation for recognition of research and license revenue from the collaboration agreement in accordance with EU-IFRS. Finally, we evaluated the related disclosures and considered these to be appropriate.

Report on the other information included in the financial information

The financial information contains other information. This includes all information in the financial information in addition to the financial statements and our auditor's report thereon.

Based on the procedures performed as set out below, we conclude that the other information:
- is consistent with the financial statements and does not contain material misstatements; and
- contains all the information regarding the directors' report and the other information that is required by Part 9 of Book 2 of the Dutch Civil Code.

We have read the other information. Based on our knowledge and the understanding obtained in our audit of the financial statements or otherwise, we have considered whether the other information contains material misstatements.

By performing our procedures, we comply with the requirements of Part 9 of Book 2 of the Dutch Civil Code and the Dutch Standard 720. The scope of such procedures was substantially less than the scope of those procedures performed in our audit of the financial statements.

The board of directors is responsible for the preparation of the other information, including the directors' report and the other information in accordance with Part 9 of Book 2 of the Dutch Civil Code.

Report on other legal and regulatory requirements

Our appointment

We were appointed as auditors of LAVA Therapeutics N.V. on 28 August 2018 by the board of directors. This followed the passing of a resolution by the shareholders at the annual general meeting held on 4 October 2018. Our appointment has been renewed annually by shareholders and now represents a total period of uninterrupted engagement of six years.

Responsibilities for the financial statements and the audit

Responsibilities of the board of directors

The board of directors is responsible for:

- the preparation and fair presentation of the financial statements in accordance with EU-IFRS and Part 9 of Book 2 of the Dutch Civil Code; and for
- such internal control as the board of directors determines is necessary to enable the preparation of the financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the board of directors is responsible for assessing the Company's ability to continue as a going concern. Based on the financial reporting frameworks mentioned, the board of directors should prepare the financial statements using the going-concern basis of accounting unless the board of directors either intends to liquidate the Company or to cease operations or has no realistic alternative but to do so. The board of directors should disclose in the financial statements any event and circumstances that may cast significant doubt on the Company's ability to continue as a going concern.

Our responsibilities for the audit of the financial statements

Our responsibility is to plan and perform an audit engagement in a manner that allows us to obtain sufficient and appropriate audit evidence to provide a basis for our opinion. Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error and to issue an auditor's report that includes our opinion. Reasonable assurance is a high but not absolute level of assurance, and is not a guarantee that an audit conducted in accordance with the Dutch Standards on Auditing will always detect a material misstatement when it exists. Misstatements may arise due to fraud or error. They are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial statements.

Materiality affects the nature, timing and extent of our audit procedures and the evaluation of the effect of identified misstatements on our opinion.

A more detailed description of our responsibilities is set out in the appendix to our report.

Eindhoven, 29 May 2024
PricewaterhouseCoopers Accountants N.V.

Original has been signed by: M.M.P.W. Hormann-Buiting RA

Appendix to our auditor's report on the financial statements 2023 of LAVA Therapeutics N.V.

In addition to what is included in our auditor's report, we have further set out in this appendix our responsibilities for the audit of the financial statements and explained what an audit involves.

The auditor's responsibilities for the audit of the financial statements

We have exercised professional judgement and have maintained professional scepticism throughout the audit in accordance with Dutch Standards on Auditing, ethical requirements and independence requirements. Our audit consisted, among other things of the following:

- Identifying and assessing the risks of material misstatement of the financial statements, whether due to fraud or error, designing and performing audit procedures responsive to those risks, and obtaining audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the intentional override of internal control.
- Obtaining an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control.
- Evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the board of directors.
- Concluding on the appropriateness of the board of directors' use of the going-concern basis of accounting, and based on the audit evidence obtained, concluding whether a material uncertainty exists related to events and/or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion.
  Our conclusions are based on the audit evidence obtained up to the date of our auditor's report and are made in the context of our opinion on the financial statements as a whole. However, future events or conditions may cause the Company to cease to continue as a going concern.
- Evaluating the overall presentation, structure and content of the financial statements, including the disclosures, and evaluating whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

Considering our ultimate responsibility for the opinion on the consolidated financial statements, we are responsible for the direction, supervision and performance of the group audit. In this context, we have determined the nature and extent of the audit procedures for components of the Group to ensure that we performed enough work to be able to give an opinion on the financial statements as a whole. Determining factors are the geographic structure of the Group, the significance and/or risk profile of group entities or activities, the accounting processes and controls, and the industry in which the Group operates. On this basis, we selected group entities for which an audit or review of financial information or specific balances was considered necessary.

We communicate with the board of directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

From the matters communicated with the board of directors, we determine those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.