UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Transition period from to

Commission file number: **001 -40241**

LAVA Therapeutics N.V.

(Exact Name of Registrant as Specified in Its Charter)

The Netherlands (State or Other Jurisdiction of Incorporation or Organization)	84-2745484 (I.R.S. Employer Identification No.)
Yalelaan 62 Utrecht, The Netherlands (Address of Principal Executive Offices)	3584 CM (Zip Code)

+31 85 016 3100
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common shares, nominal value €0.12 per share	LVTX	The Nasdaq Stock Market LLC (NASDAQ Global Select Market)

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b 2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant’s executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the common shares held by non-affiliates of the registrant based on the closing price of the registrant’s common shares as reported on The Nasdaq Stock Market LLC on June 28, 2024, was approximately $29.0 million. For purposes of this disclosure, common shares held by each executive officer, director and shareholder known by the registrant to be affiliated with such individuals based on public filings and other information known to the registrant have been excluded since such persons may be deemed affiliates. This determination of executive officer or affiliate status is not necessarily a conclusive determination for other purposes.

The number of the registrant’s Common Shares outstanding as of March 21, 2025 was 26,305,295.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s definitive proxy statement to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934, for its 2025 Annual General Meeting of Shareholders are incorporated by reference in Part III of this Annual Report on Form 10-K.

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Special Note 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,” “potential,” “may,” “will,” “would” 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 Item 1A of this annual report. Forward-looking statements include, but are not limited to, statements about:

- 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 evaluation of strategic alternatives and ability to extend our capital resources, the scope and timing of the restructuring and the expected costs related to the restructuring, including the estimated timing and magnitude of the workforce reduction;
- 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;
- our plans to identify potential synergistic in-licensing opportunities, strategic alliances and sales transactions;
- 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 intend to serve;

- developments relating to our competitors and our industry; and
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012.

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, and international hostilities including the Russian invasion of Ukraine and the conflict in the Middle East.

PART I

Item 1: Business

Overview

We are a clinical stage immuno-oncology company focused on developing our proprietary Gammabody® platform of bispecific gamma delta ($\gamma\delta$) 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 $\gamma\delta$ T cells to orchestrate a robust, natural 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 $\gamma\delta$ T cells with the validated benefits of antibody-based treatments.

In February 2025, we adopted a restructuring plan to extend our capital resources in connection with initiating a process to evaluate strategic alternatives. As part of the restructuring plan, we approved a reduction of approximately 30% of our global workforce to better align our resources with our focus on LAVA-1266. We expect approximately $1.0 million of expenses related to the restructuring to be incurred during the six months ended June 30, 2025, of which approximately $0.3 million of cash payments are expected to be made during 2025.

Gamma Delta T Cells

Gamma delta 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 $\gamma\delta$ 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, $\gamma\delta$ 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 therapeutic efficacy. The therapeutic dose and the non-tolerated 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 chimeric antigen receptor T-cell therapy (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 associated antigen 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 avoiding activation of Tregs and broad systemic activation that may result in severe CRS.

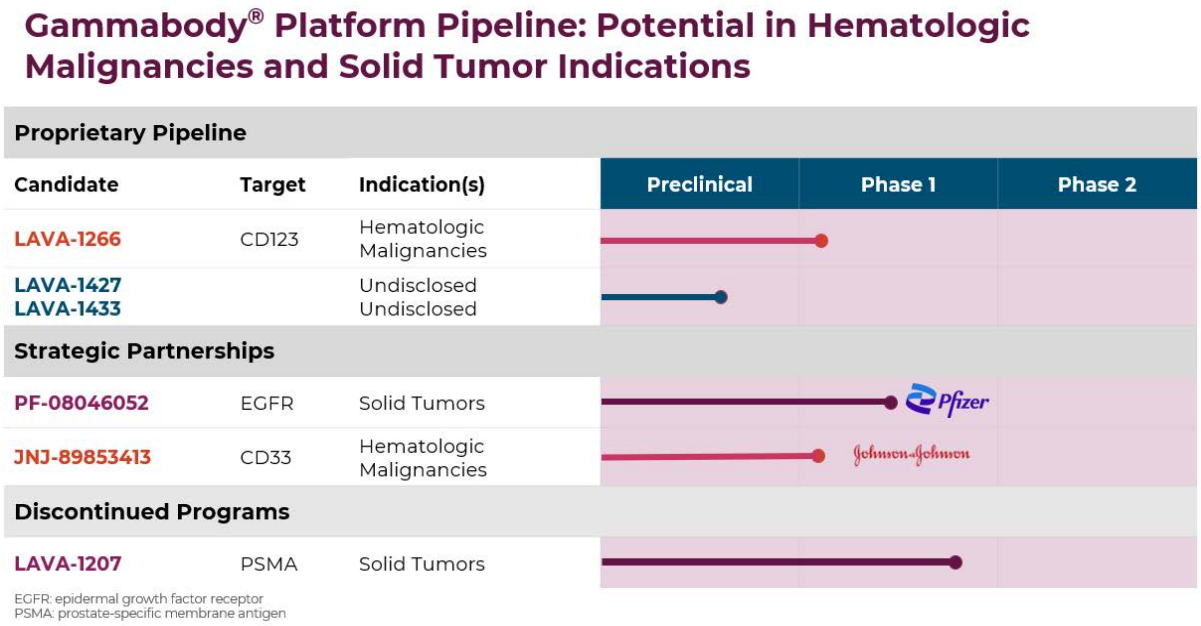
We have generated compelling preclinical data using patient tumor tissues that demonstrate the ability of our Gammabody platform to exert preferential activity against tumor cells expressing the target with relative sparing of healthy cells. Using surrogate Gammabody molecules, studies in non-human primates 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 and our partners are currently advancing our Gammabody pipeline for the development of potential therapeutics in both hematologic malignancies and solid tumors. We are developing our lead Gammabody drug candidate, LAVA-1266, which targets CD123 and has potential for the treatment of a range of hematological malignancies, and are currently investigating acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). We initiated a Phase 1, first-in-human study in the fourth quarter of 2024 and dosed our first patient in December 2024. We are also supporting the development of two other Gammabody drug candidates through our partnerships with Johnson & Johnson for JNJ-89853413 and Pfizer for PF08046052.

In December 2024, we announced that we would discontinue a first-in-human Phase 1 clinical trial for LAVA-1207, an investigational candidate that was designed to target prostate-specific membrane antigen (PSMA) -expressing cancers for patients with metastatic castration resistant prostate cancer (mCRPC).

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



LAVA-1266

LAVA-1266 is designed using our Gammabody platform to conditionally activate Vγ9Vδ2 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 is expressed in a range of hematological malignancies, including AML, MDS, acute lymphocytic leukemia (ALL) and Hodgkin Lymphoma.

We are currently conducting an open-label, multi-center Phase 1, first-in-human study of LAVA-1266 with the study currently open to recruitment in Australia at four sites. The study includes a dose escalation segment to evaluate LAVA-1266 in up to 50 adults with CD123+ relapsed/refractory (R/R) AML and intermediate, high or extremely high risk MDS. Patients will be dosed every two weeks (Q2W) at the target dose, with an initial target dose of 100 µg for the first cohort. We dosed the first patient in this trial in December 2024. We are enrolling in the second dose level at 300 µg and we expect an initial data readout by year-end 2025.

There is a clear unmet need for patients with R/R AML and intermediate, high or extremely high risk MDS. In 2024, the National Cancer Institute estimated that there were approximately 20,800 new diagnoses of AML and 11,220 estimated deaths in the United States. Ex vivo studies using AML patient samples confirmed CD123+ expression on AML cells and the presence of Vγ9Vδ2-T cells in such samples. In preclinical studies, we observed that LAVA-1266 preferentially targeted and killed CD123+ tumor cells and induced Vγ9Vδ2-T cell activation. Furthermore, in preclinical studies, we observed that treatment with LAVA-1266 produced high levels of specific tumor cell lysis, with substantially less cytokine release compared to a CD123-CD3 T cell engager, and increased survival in an AML xenograft model.

Preclinical Programs

Our internal pipeline consists of several 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 through GMP cell-line development. We generated high yield cell lines producing high quality bispecific γδ TCEs for GMP

manufacturing and further preclinical activities for potential future IND/CTA filings or potential business development opportunities.

Partnered Programs

Pfizer Partnered Program (PF-8046052/formerly LAVA-1223)

In 2022, we entered into an exclusive license agreement with Pfizer (formerly Seagen Inc.) to develop, manufacture and commercialize EGFRd2 (PF-8046052), an asset that utilizes our proprietary Gammabody technology to target EGFR-expressing solid tumors (the "Pfizer Agreement"). 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. In addition, the Pfizer Agreement contains a one-time option to pay Pfizer $35 million in exchange for an increase in the tiered percentages of royalty payments we are eligible to receive. The Pfizer Agreement also provided Pfizer with the opportunity to exclusively negotiate rights to apply our proprietary Gammabody platform on up to two additional tumor targets, which Pfizer did not exercise and have expired.

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 SGN-EGFRd2 (PF-8046052) in advanced solid tumors from the 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 EGFR expressing solid tumors.

In March 2024, Pfizer paid us $7 million for achieving a clinical milestone and highlighted this program at its R&D day in February 2024.

Johnson & Johnson Partnered Program (JNJ-89853413)

In 2020, we entered into a research collaboration and license agreement with Johnson & Johnson (formerly Janssen) ("J&J") for the discovery and development of novel bispecific antibody-based $\gamma\delta$ T cell engagers for the treatment of cancer (the "J&J Agreement"). Under the J&J Agreement, we granted J&J 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 J&J Agreement and for all purposes not granted to J&J.

In May 2023, within the framework of the J&J Agreement, J&J selected a lead bispecific antibody utilizing the Gammabody platform for an undisclosed tumor associated antigen for development and we received a $2.5 million milestone payment. Pursuant to the J&J Agreement, upon this selection, J&J initiated its efforts to develop, manufacture, and commercialize a licensed product at J&J's sole cost and expense.

In October 2024, we received a development milestone of $5 million related to the Investigational New Drug (IND) filing for JNJ-89853413, an investigational asset developed from our Gammabody platform that is designed to target CD33 and $\gamma\delta$ T cells with a Gammabody engager. In December 2024, J&J presented preclinical data for JNJ-89853413 at the Annual Meeting of the American Society of Hematology.

As of December 31, 2024, we have received $17.5 million in upfront, research and clinical milestone payments under the J&J Agreement. We are entitled to additional milestone payments from J&J if the

lead candidate progresses through certain clinical and regulatory milestones, and J&J is required to use commercially reasonable efforts to exploit one licensed product.

We are also eligible to receive up to an aggregate of approximately $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.

Discontinued programs - LAVA-1207 and LAVA-051

LAVA-1207

In December 2024, we announced that after no patients remained on treatment, we would discontinue the first-in-human Phase 1 clinical trial for LAVA-1207, an investigational candidate that was designed to target PSMA-expressing cancers for patients with mCRPC.

From 2022 through December 2024, we enrolled patients in a first-in-human clinical trial evaluating LAVA-1207 in patients with mCRPC in the United States and Europe. The open-label, multi-center, Phase 1 clinical trial was designed to evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity and preliminary anti-tumor activity of LAVA-1207 and to determine recommended Phase 2a dose(s) for optimization in Phase 2a.

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.

In June 2023, we 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 $V\gamma V\delta 2$ T cells available for engagement by LAVA-1207. Three dose limiting toxicities (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 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. 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

In January 2024, we announced we had entered into a clinical trial collaboration and supply agreement with Merck & Co., Inc. (“Merck”) to evaluate its anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in combination with LAVA-1207. Under the terms of this agreement, Merck provided us with pembrolizumab for the dose escalation and expansion phases of LAVA’s Phase 1/2a study of LAVA-1207 (NCT05369000) (KEYNOTE-F73). Upon discontinuing the LAVA-1207 study, we terminated this agreement and will wind-down the protocol in collaboration with Merck.

The Phase 1 study of LAVA-1207 did not reach our internal benchmarks and the decision was made to discontinue the development program. The drug will be made available for patients currently receiving LAVA-1207 for as long as considered necessary by their treating physician. The decision to discontinue LAVA-1207 development was not made due to safety concerns. We observed clinical signals in several patients, including PSA reductions and extended time on study for patients with higher baseline circulating Vγ9Vδ2 T cells, as well as safety and tolerability data consistent with the intended mechanism of action.

In this trial, we observed pharmacodynamic changes consistent with LAVA-1207's mechanism of action including increased Vγ9Vδ2 Tcell receptor occupancy with increasing dose. The longer time to progression observed in patients with higher numbers of circulating Vγ9Vδ2 cells at baseline, with several patients on trial beyond six months, supports continued clinical investigation of the platform.

As a result of the planned discontinuation of the LAVA-1207 clinical trial, we expensed $3.9 million of clinical trial, contract manufacturing, and bioanalytical costs during December 2024.

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 has 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. The Phase 1 dose-escalation study was discontinued because of the evolving competitive landscape before an optimal Phase 2 dose could be reached.

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 (RO) 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 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.

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 may dampen the antitumor efficacy of cytotoxic T cells through activation of immune-suppressive Tregs which has resulted in variability of clinical efficacy.

Our Strategy

Key components of our strategy include:

- Identify potential synergistic in-licensing opportunities, strategic alliances and sales transactions.
- Establish ourselves as the leader in developing bispecific $\gamma\delta$ T cell engagers (TCEs) utilizing the Gammabody platform for the treatment of cancer.

- Drive the clinical development of our lead candidate, LAVA-1266, 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 consideration of strategic partnerships and collaboration opportunities beyond the Gammabody platform.
- Leverage and continue to build our intellectual property portfolio to protect our Gammabody platform and our leadership position in bispecific γδ TCEs.

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 and our partners are studying the engagement of gamma delta T cells in early clinical trials as a potential next-generation application of TCEs and we believe our Gammabody platform may address some of 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 γδT 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 2,4,5,8,9, 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, 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

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. If we are able to identify patients and tumor types where the ratio of effector Vγ9Vδ2 T cells to target tumor cells (the E:T ratio) is adequate, or 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.

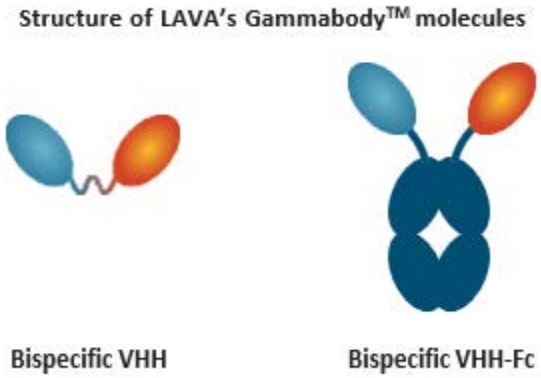
- Conditional activation with high precision. Our Gammabody molecules only trigger activation of Vγ9Vδ2 T cells upon simultaneous binding of the γδ T cell receptor and the antigen on tumor cells. This conditional activation provides a tumor-targeting mechanism and avoids a broad systemic, or non-tumor 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 had no >grade 2 CRS observed in our Phase 1 clinical trial. 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 γδ T cell-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. In the Phase 1 clinical trial, LAVA-1207 was dosed to several patients in combination with pembrolizumab.

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.



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

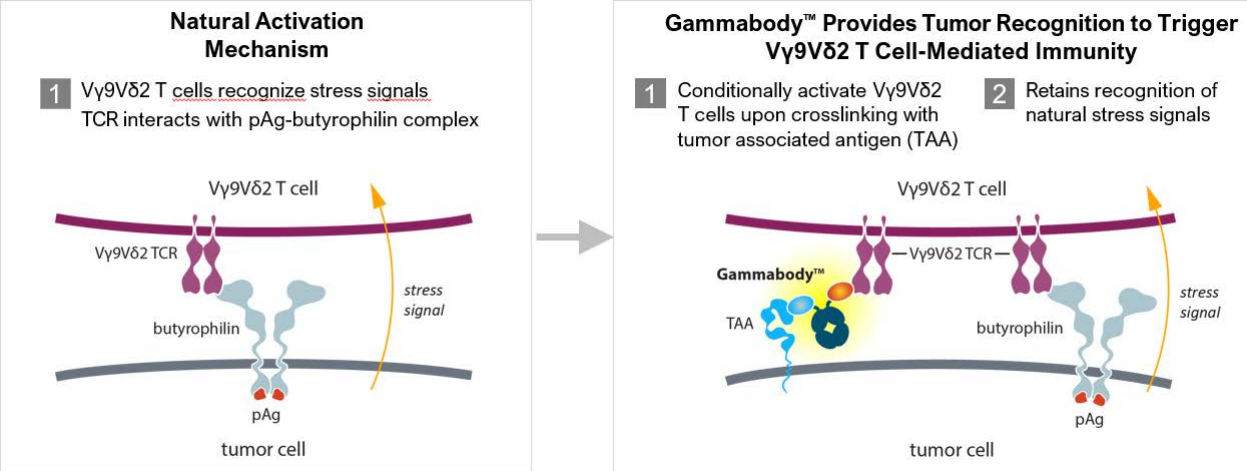
product to product. These results show a high manufacturability of our lead products, largely de-risked for future commercial manufacturing if approved.

Our Gammabody platform

We have developed a proprietary Gammabody platform that optimizes tumor-targeted activation of Vγ9Vδ2 T 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.

Our 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.

Compared to Gammabodies, bispecific pan-T cell engagers will typically activate a far larger cell population. It is possible that maximal benefit of our Gammabodies may be dependent on the size of the available effector Vγ9Vδ2 T cell population and that patients may need to be selected on the basis of their circulating effector Vγ9Vδ2 T cell counts.

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 T cell 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. Several NHP studies were performed in cynomolgus monkeys with fully cross-reactive surrogate Gammabody molecules. The bispecific γδ TCEs used were designed to trigger human and monkey γδ 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.

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 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 with percentages 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 (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 a range of low teens to high mid-teen percentages on future sales. The Pfizer Agreement also provided Pfizer with the opportunity to exclusively negotiate rights to apply our proprietary Gammabody platform on up to two additional tumor targets, which rights have expired.

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 2023, we entered into a Clinical Supply Agreement with Pfizer (the "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 also delivered to Pfizer any remaining GMP substance containing the EGFRd2 (PF-8046052) compound. Under the Pfizer Agreement and the Pfizer Clinical Supply Agreement, we were 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. As of September 30, 2023, all drug 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 initiated a Phase 1 clinical 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 milestone.

J&J Agreement

In 2020, we entered into the J&J 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 million and achieved research milestones necessary to receive $2 million, $1 million of which was received in October 2021, and $1 million of which was received in December 2020. Under the J&J Agreement, we granted J&J 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 J&J Agreement and for all purposes not granted to J&J.

Together with J&J, 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 J&J Agreement, J&J 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 J&J Agreement, J&J is responsible for the development, manufacture, and commercialization of the licensed product at J&J's sole cost and expense. J&J is required to use commercially reasonable efforts to exploit one licensed product. Efforts are underway by J&J to advance the candidate towards the clinic. The payment of the $2.5 million milestone was received in July 2023. In November 2024, we received payment for achievement of a development milestone of $5 million related to the IND filing for JNJ-89853413, an

investigational asset developed from our Gammabody platform under the J&J Agreement that is designed to target CD33 and Vδ2 T cells with a Gammabody engager. In December 2024, J&J presented preclinical data for JNJ-89853413 at the Annual Meeting of the American Society of Hematology.

We are entitled to additional milestone payments from J&J if the lead candidate progresses through certain clinical and regulatory milestone. We are also eligible to receive up to an aggregate of approximately $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 J&J 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 J&J Agreement will follow inventorship of such inventions, with certain defined exclusions. First, J&J will own any invention made by either party in the course of performing their respective activities pursuant to the J&J Agreement that is an improvement to J&J'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 J&J 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 J&J a non-exclusive, worldwide, non-royalty bearing, sublicensable license under certain know-how developed by J&J under the J&J Agreement, and patents claiming such know-how, for certain uses necessary to exploit the specific antibodies.

The J&J Agreement expires on a licensed product-by-licensed product basis upon the expiration of J&J's payment obligations. J&J may terminate the J&J 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 J&J 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 J&J 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 J&J 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 J&J under the J&J Agreement for purposes of continued development and commercialization of research results and/or product candidates developed under the J&J Agreement.

Amsterdam UMC agreements

In 2017, we entered into the Amsterdam UMC Agreement. Under the Amsterdam UMC Agreement, Amsterdam UMC 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 relevant to our collaborations with J&J and Pfizer, effectively including research and other services provided in collaboration by Amsterdam UMC since 2017 to develop, make, and sell certain 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 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 initial public offering ("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, expire 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 Head of Innovation. 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 Agreement

In January 2024, we announced we had entered into a clinical trial collaboration and supply agreement with Merck to evaluate its anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in combination with LAVA-1207. Under the terms of this agreement, Merck agreed to provide us with pembrolizumab for the dose escalation and expansion phases of our Phase 1 study of LAVA-1207 (NCT05369000) (KEYNOTE-F73). In connection with the discontinuation of the LAVA-1207 clinical trial, we terminated this agreement in December 2024 and will continue to fulfill all of the obligations related to the patients treated in that trial in collaboration with Merck.

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 including purification resins and filters, manufacturing equipment, 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.

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 targeting-therapy include Acepodia Inc., Adicet Bio, Inc., Biosion USA Inc., Cytomed Therapeutics, Ltd., Editas Medicine, Inc., Eureka Therapeutics, Inc., 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: two (2) issued U.S. patents, twenty one (21) pending U.S. patent applications, ten (10) pending European regional-phase patent applications, seven (7) pending PCT patent application, twenty one (21) issued patents in other territories and ninety

four (94) 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 γδ T cell products. We are a party to license and assignment agreements that grant us exclusive rights to use specific technologies in our γδT 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, 2024, 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 J&J an exclusive worldwide license for the development and commercialization of an investigational candidate targeting CD33 and γδ T cells with a bispecific gamma delta T cell engager (JNJ-89853413, which is advancing to Phase 1 (NCT06618001).

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

LAVA-1266

For LAVA-1266, LAVA's patent portfolio includes two (2) pending U.S. patent applications, one (1) pending European patent applications, fifteen (15) 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-1266 and partnered programs.

Platform Technology

Our patent portfolio also includes patent families relating to our Gammabody platform, including six (6) patent families that are generally related to the antibodies that activate γδ 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, four (4) pending U.S. applications, four (4) pending European applications, twenty (20) granted foreign patents, twenty-two (22) pending foreign applications, and two (2) 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 IND or a CTA 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. It also includes the general investigational plan and the protocol(s) for clinical studies. 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 GCP, which includes 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 or independent ethics committee 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 recommendations for whether or not a study should 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 a separate 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 impacted 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.

Regulation of Medicinal Products in Australia

The Therapeutic Goods Administration ("TGA") and the National Health and Medical Research Council ("NHMRC") set the GCP requirements for clinical research in Australia. Compliance with the regulations, standards and codes set by the Therapeutics TGA and NHMRC is mandatory. Under the *Therapeutic Goods Act 1989* (Cth) and the *Therapeutic Goods Regulations 1990* (Cth), it is a condition (amongst other conditions) of all clinical trials involving investigational medicinal products to comply with the National Statement on Ethical Conduct in Research Involving Humans, published by the NHMRC (the "National Statement"), and the Guideline for Good Clinical Practice published by the International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH Guidelines"). The ICH Guidelines as adopted in Australia must be complied with across all fields of clinical research involving therapeutic goods, including those related to pharmaceutical quality, nonclinical and clinical data requirements and trial designs. The basic requirements for preclinical data to support a first-in-human trial under ICH Guidelines are applicable in Australia. Requirements related to adverse event reporting in Australia are generally similar to those required in other major jurisdictions, although reporting timeframes may differ to other jurisdictions.

Clinical trials conducted using "unapproved therapeutic goods" in Australia, being those which have not yet been evaluated by the TGA for quality, safety and efficacy (and including unapproved indications of therapeutic goods which have otherwise been approved for use in Australia) must occur pursuant to either the Clinical Trial Notification Scheme ("CTN Scheme") or the Clinical Trial Approval Scheme ("CTA Scheme"). In each case, the trial is supervised by a Human Research Ethics Committee ("HREC"), an independent review committee constituted in accordance with the National Statement that aims to protect the rights, safety and well-being of human subjects involved in a clinical trial. An HREC reviews, approves and provides continuing oversight of trial protocols (including any amendments), methods and materials intended to be used in obtaining and documenting informed consent of the clinical trial subjects.

The CTN Scheme broadly involves:

- submission to an HREC, of all material relating to the proposed clinical trial, including the trial protocol;
- the HREC reviews the scientific validity of the trial design, the balance of risk versus harm of the therapeutic good, the ethical acceptability of the trial process, and approves the trial protocol. The HREC is also responsible for monitoring the conduct of the trial;
- the institution or organization at which the trial will be conducted, referred to as the "Approving Authority", giving final approval for the conduct of the trial at the site, in terms no less restrictive to those advised by the HREC; and
- the investigator submitting a 'Notification of Intent to Conduct a Clinical Trial' form ("CTN Form") to the TGA. The CTN form must be signed by the sponsor, the principal investigator, the chairman of the HREC and a person responsible from the Approving Authority. The TGA does not review any data relating to the clinical trial however CTN trials cannot commence until the trial

has been notified to the TGA. It is the responsibility of the sponsor to ensure that all relevant approvals are in place before supplying the “unapproved” therapeutic goods in clinical trials in Australia.

Under the CTA Scheme:

- a sponsor submits an application to conduct a clinical trial to the TGA for evaluation and comment, which includes payment of relevant fees;
- the TGA will undertake a preliminary assessment to ensure that there is sufficient data to begin evaluation. If critical data is missing, the TGA may request further information;
- a sponsor must forward any comments made by the TGA Delegate to the HREC(s) at the sites where the trial will be conducted;
- the HREC is responsible for considering the scientific and ethical issues of the proposed trial protocol.

A sponsor cannot commence a trial under the CTA Scheme until written advice has been received from the TGA regarding the application and approval for the conduct of the trial has been obtained from an ethics committee and the institution at which the trial will be conducted.

Approval for inclusion in the Australian Register of Therapeutic Goods (“ARTG”) is required before a therapeutic good (including pharmaceutical product) may be marketed (or supplied, imported, exported or manufactured) in Australia. Exceptions apply to therapeutic goods/pharmaceutical products that are supplied, imported, and exported to and from Australia for the purposes of a clinical trial, on the basis that certain conditions are met (e.g., the trial is conducted in accordance with the CTN or CTA scheme).

Once a sponsor decides to register a pharmaceutical product in Australia, in order to obtain registration of the product on the ARTG, it is required that (amongst others):

- the sponsor submits appropriate documentation, including the outcomes of clinical trials and studies, to allow the TGA to assess the quality, safety and efficacy of the therapeutic product/pharmaceutical product; and
- the sponsor submits evidence which demonstrates that the manufacture of the therapeutic product/pharmaceutical product complies with the applicable GMP requirements.

The TGA has the ultimate discretion to decide whether to include the therapeutic product/pharmaceutical product in the ARTG.

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.

Human capital

As of December 31, 2024, we had 34 full-time employees. In Europe, 14 of our employees work in research and development and 4 work in general and administrative areas. In the United States, 9 of our employees work in research and development and 7 work in general and administrative areas. In February 2025, we initiated a reduction in force, reducing the full-time employees in Europe to 6, effective April 30, 2025. None of our employees are subject to a collective bargaining agreement or represented by a trade or labor union, and we consider our employee relations to be good.

Our human capital objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of share-based compensation awards. All of our employees are eligible for participation in our 2021 Long-term Incentive Plan and are granted equity awards as deemed appropriate by our Board of Directors or Senior Management, typically in the form of stock options.

Corporate information

LAVA Therapeutics N.V. is a limited liability public company (naamloze vennootschap) under Dutch law, having its corporate seat in Utrecht, with address Yalelaan 62, 3584 CM Utrecht, the Netherlands and trade register number: 65335740. LAVA Therapeutics B.V. was incorporated in the Netherlands on February 15, 2016. In 2019, we established our a wholly-owned U.S. subsidiary, LAVA Therapeutics, Inc., which began business in January 2020. In connection with becoming a public company, on March 29, 2021, we changed our business structure from a private limited company (besloten vennootschap) to a public limited liability company and consequently our named changed from “LAVA Therapeutics, B.V.” to “LAVA Therapeutics N.V.” In 2024, we established a wholly-owned Australian subsidiary, LAVA Therapeutics (Australia) Pty Ltd. Our common shares are listed for trading on the Nasdaq Global Select Market under the symbol “LVTX.”

Available information

We file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is www.sec.gov. Our Company Internet address is www.lavatherapeutics.com. The information contained on our website is not a part of this annual report.

Item 1A: 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 7: Management’s Discussion and Analysis of Financial Condition and Results of Operations.” 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

- 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.
- Our limited operating history may make it difficult to evaluate the success of our business to date and 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.
- Our product candidates, development candidates and related technologies, including LAVA-1266, 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 are dependent on the successful clinical development and regulatory approval of our product candidates. We cannot give any assurance that LAVA-1266 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 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 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.
- We are conducting our Phase 1 clinical trial of LAVA-1266 outside of the United States, and we may in the future continue to use sites outside of the United States for clinical trials. The FDA may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

- 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.
- We rely on a single-source supplier for bulk drug substance and drug manufacturing for our product candidate and development programs. The loss of this supplier or its failure to supply us with bulk drug substance 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.
- 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.
- Patent terms may be inadequate to protect our competitive position on our current and future product candidates for an adequate amount of time.
- 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 with such third parties, our business, financial condition, commercialization prospects and results of operations may be adversely affected.
- 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.
- Our strategic review and workforce reduction may not achieve our intended outcomes.
- The regulatory approval process of FDA, EMA and other comparable foreign regulatory authorities 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 necessary for commercial success.
- 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. Such volatility could subject us to securities litigation.
- Shareholders may not be able to exercise pre-emption rights and, as a result, may experience substantial dilution upon future issuances of common shares.
- If we fail to satisfy all applicable requirements of Nasdaq and it determines to delist our common shares, the delisting could adversely affect the market liquidity of our common shares and the market price of our common shares could decrease.
- 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.

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 $25.1 million and $41.9 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $175.0 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-1266 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-1266 and any of our other development candidates that successfully complete clinical trials;
- discover and develop additional bispecific gamma delta ($\gamma\delta$) T cell 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., Europe and Australia;
- 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 the transition from foreign private issuer to U.S. domestic filer status;

- 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, the Russian invasion of Ukraine, the conflict in the Middle East 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 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-1266 and other product candidates, business planning and providing general and administrative support to these operations. The Phase 1 clinical trial for our product candidate, LAVA-051 in chronic lymphocytic leukemia (CLL), multiple myeloma (MM) was discontinued in June 2023 and the Phase 1 clinical trial for our product candidate LAVA-1207 in metastatic castration-resistant prostate cancer (mCRPC) was discontinued in December 2024. We are currently conducting a Phase 1 trial of LAVA-1266 in Australia. 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 clinical trial for LAVA-1266, 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 and reporting as a U.S. domestic filer. 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.

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. 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. Adequate additional financing may not be available to us on acceptable terms, or at all.

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.

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.

We expect to receive Australian government research and development income tax incentive refunds. If our research and development expenditures are not deemed to be eligible for the refund, proposed modifications to the tax incentive program are enacted, or the tax incentive program is discontinued by the Australian government, it could have a negative effect on our future cash flows and the funding of future research and development projects.

Our wholly-owned subsidiary, LAVA Therapeutics (Australia) Pty Ltd., is incorporated in Australia where we are currently conducting a Phase 1 trial of LAVA-1266. Our subsidiary is likely eligible to participate in the Australian Federal Government’s Research and Development Tax Incentive program, under which the government provides a refund for a portion of eligible research and development expenditures

(currently 43.5% to 48.5% depending on the entity's corporate tax rate) by Australian entities with less than $20 million (Australian) in revenue.

The Research and Development Tax Incentive refund is offered by the Australian federal government for eligible research and development purposes based on the filing of an annual application. As part of this program, our subsidiary intends to apply for refunds from the Australian Taxation Office, or the ATO, for a percentage of the research and development costs expended by our subsidiary in Australia.

If our research and development expenditures are not deemed to be eligible for the Research and Development Tax Incentive refund, modifications to the tax incentive program are enacted, or the tax incentive program is discontinued by the Australian government, it could have a negative effect on our future cash flows and the funding of future research and development projects.

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.

Risks related to the development and commercialization of our product candidates

Our product candidates, development candidates and related technologies, including LAVA-1266, which are based on bispecific γδ 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 γδ 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 γδ T cell engager product candidates and related technology.

To date, γδ T cells and products that induce γδ 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 γδ T cell efficacy, and other clinical trials have produced encouraging results regarding bispecifics, Phase 1 clinical trial for LAVA-1266, our discontinued Phase 1/2a clinical trials for LAVA-051 and LAVA-1207, and our collaborations with Pfizer for EGFRd2 (PF-08046052/formerly LAVA-1223) and with J&J for JNJ-89853413 are the only clinical trials conducted that utilize our Gammabody technology. We are continuing to study the relationship between antitumor activity in clinical trial patients and Vγ9Vδ2 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 clinical trial for LAVA-1266, 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-1266 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-1266 product candidate

are in early stages of development and may never be commercialized. 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 also decide to discontinue development of product candidates from our Gammabody platform for other reasons, including as a result of the developing competitive landscape, as was the case for LAVA-051, due to a failure to reach internal benchmarks, as was the case for LAVA-1207, or for other reasons. 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.

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. In our discontinued Phase 1 clinical trial of LAVA-051 we did not observe CRS greater than grade 2. In our discontinued Phase 1 clinical trial of LAVA-1207, we have observed low grade CRS (≤ grade 2) which affected the clinical protocol design of our global clinical trial and may affect potential future clinical trials of our Gammabody candidates 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 gamma delta 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 $\gamma\delta$ 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 candidates. We cannot give any assurance that LAVA-1266 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-1266 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. LAVA-1266, 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 clinical trial for LAVA-1266 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-1266 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.

We are conducting our Phase 1 clinical trial of LAVA-1266 outside of the United States, and we may in the future continue to use sites outside of the United States for clinical trials. The FDA may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We are currently conducting our Phase 1 clinical trial of LAVA-1266 in Australia. It is possible that the FDA will not authorize us to proceed with clinical studies in connection with any future IND submissions that are based solely on foreign clinical trials and we may be required to conduct additional Phase 1 clinical studies, which would be costly and time consuming, and delay aspects of our development plan, which could harm our business.

Although the FDA may accept data from clinical studies conducted entirely outside the United States and not under an IND, acceptance of such clinical study data is generally subject to certain conditions. For example, the FDA requires the clinical study to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical studies through an onsite inspection if it deems such inspection necessary. In addition, when clinical studies are conducted only at sites outside of the United States, the FDA generally does not provide advance comment on the clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non-U.S. clinical study was inadequate, which would likely require us to conduct additional clinical studies. Conducting clinical studies outside the United States also exposes us to additional risks, including risks associated with foreign regulatory requirements, foreign exchange fluctuations and compliance with foreign manufacturing, customs, shipment and storage requirements.

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-1266 is still in the early stages of development in a Phase 1 clinical trial and may fail to show the desired safety and efficacy in clinical development despite demonstrating potential in preclinical studies.

Furthermore, we do not yet have safety and clinical efficacy data for the use of LAVA-1266 in humans, as we have only recently begun enrolling patients in the Phase 1 clinical trial. 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, as we have done for LAVA-051 and LAVA-1207. 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 $\gamma\delta$ 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-1266 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, layoffs, shifting priorities under the new administration, 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, layoffs, 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. Over the last several years, the U.S. government has shut down multiple times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. If funding for the FDA or other regulatory authorities is reduced, priorities change, a prolonged government shutdown occurs, 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. In addition, the Trump Administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs, 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 may develop LAVA-1266 or 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-1266 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-1266. 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-1266 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 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 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 through the discontinued LAVA-1207 and LAVA-051 trials, 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 were observed in the LAVA-1207 trial to date. 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. 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. From the time that we initiated step dosing and amended the DLT criteria for the duration of transaminase increases through the discontinuation of the trial, no further DLTs were reported in the LDIL-2 arms of the trial. We have only recently begun enrollment in the Phase 1 clinical trial of LAVA-1266 and have not yet reported safety or efficacy data. 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-1266 and our collaborators continue their Phase 1 trials utilizing the Gammabody platform, unacceptable toxicities, SAEs, undesirable or potentially fatal side effects, high-grade CRS, viral infections, relapse of disease or unexpected characteristics may emerge. This may cause 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 or our collaborators 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 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, tariffs or public health crises, such as pandemics.

Our business could be adversely affected by general conditions in the global economy and in the global financial markets, including as a result of heightened inflation and interest rates. A severe or prolonged economic downturn, or additional global financial crises, including related to potential future pandemics or geopolitical conflicts, could result in a variety of risks to our business, including weakened demand for our product candidates, if approved, or our ability to raise additional capital when needed on acceptable

terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. We could also be affected by new and increased tariffs between the United States and other countries, and any retaliatory tariffs by those other countries. If our or the third party's activities fall within the scope of any of these or other tariffs, our costs may increase significantly.

Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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-1266 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 γδ T cell targeting-therapy include Acepodia Inc., Adicet Bio, Inc., Biosion USA Inc., Cytomed Therapeutics, Ltd., Editas Medicine, Inc., Eureka Therapeutics, Inc., 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.

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.

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.

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-1266 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-1266 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 for our product candidate and development programs. 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-1266. In the event we lose our single-source supplier, our ability to develop LAVA-1266 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-1266.

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.

We rely on third party Contract Development Manufacturing Organizations (CDMOs) to manufacture our product candidate and development candidates. If our CDMOs cannot manufacture our product candidate reliably or in sufficient amounts, 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.

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 current or future product candidates. 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 1: Business."* 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 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. 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, 2024, we own or co-own two (2) issued U.S. patents, twenty one (21) pending U.S. patent applications, ten (10) pending European regional-phase patent applications, seven (7) pending Patent Cooperation Treaty (PCT) patent applications, nineteen (19) issued patents in other territories and more than ninety (90) 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 1: Business."* 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, third party service providers, or our licensing partners and other professionals to help us comply with these requirements and pay these fees when due. 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 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 are 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.

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 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 may experience difficulties in right-sizing our organization for our stage of development, which could disrupt our operations.

As of December 31, 2024, we had 34 full-time employees. In February 2025, we initiated a reduction in force, reducing the full-time employees in Europe to 6, effective April 30, 2025. As we continue to progress LAVA-1266 while also undertaking a strategic review of our business, we may experience rapidly changing needs in the number of our employees and the scope of our operations. In order to progress our clinical development programs and any programs that we may in-license or acquire, we will need to continue to attract, retain and motivate highly qualified management, clinical and scientific personnel. At the same time, we may need to conserve cash and reduce resources in some areas. To manage our changing needs, we must continue to evaluate, implement and improve our managerial, operational and financial systems, and, where appropriate, continue to recruit and train additional qualified personnel, and we may need to either expand or reduce our facilities. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our strategic review and workforce reduction may not achieve our intended outcomes.

In February 2025, we announced a strategic review of our business and began exploring and evaluating a variety of strategic options to maximize shareholder value, including in-licensing of assets, a sale, licensing agreement, merger, acquisition, or other strategic transactions. We expect to devote substantial time and resources to exploring strategic alternatives we believe may drive shareholder value. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our Board of Directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased shareholder value.

In connection with the strategic review, we also implemented certain actions to reduce operational and workforce expenses that are no longer deemed core to our ongoing operations in order to extend our capital resources. We may experience unforeseen delays or other challenges in implementing these changes, which could adversely impact our timelines and operations and, ultimately, our ability to develop product candidates for potential commercialization. The reduction in force may result in unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended number of employees, decreased morale among our remaining employees, and the risk that we may not achieve the anticipated benefits of the reduction in force. Furthermore, we may undertake further similar cost-saving initiatives in the future, which may include additional restructuring or workforce reductions. These types of cost-reduction activities can be complex and result in unintended consequences and costs, which could adversely impact our business.

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 with 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-1266. 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-1266 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 and our financial performance.

We are currently party to multiple collaboration agreements, including with Pfizer to develop EGFRd2 (PF-08046052), an investigational clinical asset targeting EGFR-expressing solid tumors, and with J&J for the discovery and development of novel bispecific antibody-based $\gamma\delta$ T cell engagers for the treatment of cancer, including their development of JNJ-89853413 in a Phase 1 clinical trial. 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. In March 2024, we announced that Pfizer achieved a clinical milestone for PF-08046052, prompting the first milestone payment of $7.0 million to us. Pfizer is conducting a monotherapy Phase 1 dose escalation study to evaluate safety and tolerability of PF-08046052 in patients with advanced EGFR-expressing solid tumors. However it is difficult to predict how Pfizer's business strategy will change over time and could effectively end our contract and future milestones.

In addition, under the J&J Agreement, we granted J&J 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. As part of the J&J Agreement, we received a non-refundable upfront payment of $8.0 million, and we are entitled to additional milestone payments from J&J if the lead candidate progresses 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. In May 2023, within the framework of the J&J Agreement, J&J selected a lead bispecific antibody utilizing the Gammabody platform, JNJ-89853413, and we received a financial milestone payment of $5.0 million. J&J has filed with health authorities to start a Phase 1 study of JNJ-89853413. We received another development milestone of $5.0 million from J&J in October 2024 related to the IND filing for JNJ-89853413. Following each research stage, the J&J 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 J&J decides not to bring a candidate forward into further development.

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, 2024. 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.

Risks related to regulatory compliance

The regulatory approval process of FDA, EMA and other comparable foreign regulatory authorities is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our 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-1266 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-1266 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-1266 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-1266 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-1266 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, the U.S. Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, HIPAA) 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 "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 and amendments to the ACA. On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed 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, the Department of Health and Human Services (HHS) is required to (1) negotiate prices with pharmaceutical companies for certain high-cost, single source biologics covered under Part B and Part D (prescription drugs like our potential product candidates) that have been on the market for at least 11 years and (2) impose rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively starting in fiscal year 2023, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On August 15, 2024, HHS announced the agreed-upon price of the first ten drugs that were subject to price negotiations. HHS will select up to fifteen additional products covered under Part D for negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. 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 adopted in the future, particularly in light of the recent U.S. Presidential and Congressional elections, 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 of third parties with whom we work 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 with whom we work, 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 data about clinical trial participants and other health-related data), intellectual property, and trade secrets (collectively, sensitive information). Our internal computer systems, cloud-based computing

services and those of third parties with whom we work, 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 with whom we work 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 (including as a result of advanced persistent threat intrusions), credential stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, attacks by 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. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations (including our clinical trial operations), ability to provide our products or services, loss of sensitive data (such as data about clinical trial participants), reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

We have conducted information security audits or evaluations on our internal computer systems, but we cannot guarantee that our security measures or those of the third parties with whom we work 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 poses 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 third parties with whom we work will be effective in protecting against unauthorized access to our platform or such data, particularly given that our ability to monitor these third parties' data security practices is limited. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). 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.

In addition, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

The techniques used to sabotage or to obtain unauthorized access to our or the third parties with whom we work platforms, 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 the third parties with whom we work 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, and third parties may also exploit vulnerabilities in, or obtain unauthorized access to, platforms, systems, networks and/or physical facilities utilized by the third parties with whom we work.

If a cyberattack or other security incident were to occur to us or to a third party with whom we work 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 could adversely and materially 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 with whom we work. Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify individuals, regulatory authorities, investors, and other relevant stakeholders of security breaches involving certain types of data, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences. 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 the third parties with whom we work, our 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 experienced by a third party processing sensitive information on our behalf could also subject us to fines and requires us to comply with the notification obligations or to take other actions set out above.

Unauthorized access to our platform, systems, networks, or physical facilities, or to those of the third parties with whom we work, could result in litigation with or liabilities to our contractual counterparties or other relevant stakeholders, which may materially and 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 will be sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. While we maintain cybersecurity insurance, we cannot be sure that our coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. Additionally, 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 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 and shifting consumer sentiments, 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. While to the best of our knowledge our employees and personnel do not currently 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 third parties with whom we work 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 the ability of the third parties with whom we work to maintain an adequate level of service and experience. If we or the third parties with whom we work 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.

We, and the third parties with whom we work, are subject to stringent and changing U.S. and foreign laws, regulations and standards, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; 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 and the third parties with whom we work 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 data privacy issues (and consumers' data privacy expectations) is rapidly evolving, becoming increasingly stringent, 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 potentially 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). Numerous U.S. states 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, including, as applicable, the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 (CCPA) applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. While the CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, these developments may increase compliance costs and potential liability for us and the third parties with whom we work. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

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 try to comply with these and new data protection rules. If we or the third parties with whom we work fail or are perceived to have failed to comply with any such applicable 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, the European Union's General Data Protection Regulation (EU GDPR), the United Kingdom's GDPR (UK GDPR) (collectively, GDPR) and Australia's Privacy Act impose significant privacy and security compliance obligations, and the GDPR imposes additional restrictions on the transfer of personal information from Europe and other jurisdictions to the United States and most other non-European Economic Area (EEA) countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. 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. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

As a result of our clinical development, we, and the third parties with whom we work 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, and certain U.S. state comprehensive 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 data privacy and security laws and regulations may cause us to incur substantial operational costs or require us to change our business practices. Despite our efforts to try to bring our practices into compliance with such applicable 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. If we or the third parties with whom we work fail, or are perceived to have failed, to adequately address privacy concerns, even if unfounded, or to comply with applicable privacy or data protection laws, regulations and policies, we could experience additional costs and liabilities, damage to our reputation, inhibited sales, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar), litigation (including class-action claims) and mass arbitration demands, additional reporting requirements and/or oversight, bans or restrictions on processing personal data, orders to destroy or not use personal data, imprisonment of company officials, and other consequences that could 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 EU GDPR, 17.5 million pounds sterling under the UK GDPR, or in each case 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.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups, and we are, or may become subject to such obligations in the future. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies and other statements concerning data privacy and security. Regulators in the United States and other jurisdictions are increasingly scrutinizing these statements, and if these policies or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation or enforcement actions by regulators or experience other adverse consequences such as private litigation.

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.

Risks related to ownership of our common shares

If we fail to satisfy all applicable requirements of Nasdaq and it determines to delist our common shares, the delisting could adversely affect the market liquidity of our common shares and the market price of our common shares could decrease.

To maintain the listing of our common shares on Nasdaq, we are required to meet certain listing requirements, including a minimum closing bid price of $1.00 per share. On February 27, 2025, we received notice from Nasdaq that we were not in compliance with Nasdaq's Listing Rule 5450(a)(1) because the closing bid price of our common shares had fallen below $1.00 per share for 30 consecutive business days. While we received notice from Nasdaq on March 11, 2025 that we have regained compliance with this listing rule, there can be no assurance that we will maintain compliance with this listing rule or the other requirements for listing our common shares on Nasdaq. If we are unable to satisfy the Nasdaq criteria for continued listing, our common shares would be subject to delisting. A delisting of our common shares could negatively impact us by, among other things, (i) reducing the liquidity and market price of our common shares; (ii) reducing the number of investors willing to hold or acquire our common shares, which could negatively impact our ability to raise equity financing; (iii) decreasing the amount of news and analyst coverage of us; (iv) limiting our ability to issue additional securities or obtain additional financing in the future; (v) limiting our ability to use a registration statement to offer and sell freely tradable securities, thereby preventing us from accessing the public capital markets; and (vi) impairing our ability to provide equity incentives to our employees. In addition, delisting from Nasdaq may negatively impact our reputation and, consequently, our business.

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. Such volatility could subject us to securities litigation.

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-1266 and the commencement, enrollment results or termination of the development of our other or future product candidates, or those of our collaboration partners or 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;
- the progress and results of our strategic review;
- 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/or 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. Finally, there may be specific other instances, including pursuant to anti-boycott rules and regulations, where Dutch law prohibits the recognition and enforcement of a United States judgment. 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, 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.

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, 2025, in the aggregate, beneficially own shares representing approximately 73.8% 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.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our common shares, the price of our common shares could decline.

The trading market for our common shares will be influenced by the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our shares, the price of our shares could decline. If one or more of these analysts cease to cover our shares, we could lose visibility in the market for our shares, which in turn could cause our share price to decline.

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.

We are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common shares less attractive to investors.

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; not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation, including golden parachute compensation and being permitted to provide only two years of audited financial statements. As a result, the information we provide shareholders will be different than the information that is available with respect to other public companies.. 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.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have availed ourselves of this extended transition period and we cannot predict whether investors will find our common shares less attractive due to this election.

We are also a "smaller reporting company" and we may continue to be a smaller reporting company if either (i) the market value of our common shares held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our common shares held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth

companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

We will continue to 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 and corporate governance practices.

As a public company, and particularly after we are no longer an EGC, 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.

We may become subject to the Dutch large company regime which would affect our governance structure, including how members of our board are appointed and dismissed.

We may become subject to the large company regime (*structuurregime*) under Dutch law if we have filed a statement with the trade register of the Dutch Chamber of Commerce, for a consecutive period of three years, stating that: (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 a statutory requirement 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. If we become subject to a large

company regime, this would 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 under this regime for at least the next three years.

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 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 our ability to design and maintain appropriate segregation of duties.

We took measures to remediate these material weaknesses and to further enhance our internal control over financial reporting. As of December 31, 2024, these material weaknesses were fully remediated.

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 taken measures to design and implement an effective control environment, we cannot assure you that the measures we have taken or that we take in the future will be sufficient to prevent future material weaknesses.

Any future material weaknesses could result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected.

Our management team has broad discretion in the use of our cash reserves and may not use them effectively.

Our management has broad discretion to use our cash reserves and could use our cash reserves in ways that do not improve our results of operations or enhance the value of our common shares. The failure by our management to apply these funds effectively could harm our business, financial condition, results of operations and prospects. Pending their use, we may invest our cash reserves in a manner that does not produce income or that loses value.

Item 1B: Unresolved Staff Comments

None.

Item 1C: Cybersecurity

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third-party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, employee personal information, and clinical trial data (Information Systems and Data).

We leverage third-party service providers to help management identify, assess, and manage our cybersecurity threats and risks. With the assistance of our third-party service providers, we identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment and our risk profile using various methods including, for example multiple layers of automated tools to assess and mitigate real-time threats, continual and periodic scans of the threat environment, and conducting internal/external audits, and third-party threat assessments.

Depending on the environment and system, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: an incident response policy, tools designed to assist with incident detection and response, data encryption for certain data, network security controls, data segregation for certain data, access controls, penetration testing, and employee training. We also maintain an information security policy and cybersecurity insurance.

We use third-party service providers to assist management in identifying, assessing, and managing material risks from cybersecurity threats, including, for example, outside legal counsel, threat intelligence service providers, cybersecurity consultants, cybersecurity software providers, and managed cybersecurity service providers. Additionally, our third-party service providers perform a variety of functions throughout our business, such as application providers, hosting companies, contract research organizations, contract manufacturing organizations, distributors, and supply chain resources. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our review of that third party’s security program, due diligence may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this annual report on Form 10-K, including risks related to regulatory compliance and general risk factors.

Governance

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The audit committee of the board is responsible for overseeing our cybersecurity risk management processes, including overseeing mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain senior management, including the Chief Financial Officer (CFO), leveraging the expertise of our third-party service providers, including our part-time IT and security consultant, who has over 23 years of experience in IT and 16 years of IT security experience.

The CFO has 22 years of experience managing IT departments in life science companies and has devoted significant attention to evaluation of risks posed by cybersecurity threats and means to mitigate those risks, while evaluating strategies to gain a high level of cyber security.

The CFO is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, communicating key priorities to relevant personnel, approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response policy is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including to the General Counsel. Members of management, including the General Counsel and CFO, will work with our incident response team to help us mitigate and remediate cybersecurity incidents of which they are notified. In addition, our incident response policy includes reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee receives quarterly reports from management concerning our information security policy and incident response policy and the processes we have implemented to address them. The audit committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties

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 December 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.

Item 3. Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently subject to any material legal proceedings.

Item 4: Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrants Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information for Common Shares

Our common shares began trading on the Nasdaq Global Select Market on March 26, 2021, under the symbol “LVTX.” Prior to that time, there was no public market for our common shares.

Shareholders

As of March 21, 2025, there were 2,313 holders of record of our common shares. This number was derived from our shareholder records and does not include beneficial owners of our common shares whose shares are held in “street” name with various dealers, clearing agencies, banks, brokers and other fiduciaries.

Dividend Policy

We have never paid or declared any cash dividends in the past on our common shares, and we do not anticipate paying any cash dividends on our common shares in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Under Dutch law, a Dutch public company with limited liability (*naamloze vennootschap)* may only pay dividends and other distributions from our reserves to the extent our shareholders’ equity (*eigen vermogen)* exceeds the sum of the paid-up and called-up share capital plus the reserves required to be maintained by Dutch law or our articles of association and (if it concerns a distribution of profits) after adoption of its statutory annual accounts by its general meeting from which it appears that such dividend distribution is allowed. Subject to such restrictions, any future determination to pay dividends or other distributions from our reserves will be at the discretion of our general meeting upon the proposal of our board of directors. Any future approval will depend upon the board’s review of several factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board deems relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds from our Public Offering of Common Stock

The offer and sale of shares in our IPO was registered under the Securities Act pursuant to a Registration Statement on Form F-1 (File No. 333-253795), which was declared effective by the SEC on March 24, 2021. As a result of the IPO, we received net proceeds of approximately $94.2 million, after deducting underwriting discounts, commissions and estimated offering expenses borne by us. We have invested the net proceeds from the offering in money market funds, short-term investments, and long-term investments. There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on March 26, 2021.

Item 6. Reserved

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following management's discussion and analysis of financial condition and results of operations describes the principal factors affecting our results of operations, liquidity, capital resources and contractual cash obligations. This discussion should be read in conjunction with "Item 1A. Risk Factors", the accompanying audited consolidated financial statements and related notes thereto, as well as other cautionary statements and risks described elsewhere in this Annual Report on Form 10-K.

Overview

We are a clinical-stage immuno-oncology company focused on developing our proprietary Gammabody® platform of bispecific gamma delta ($\gamma\delta$) 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 $\gamma\delta$ T cells to orchestrate a robust, natural anti-tumor immune response and improve outcomes for cancer patients. We are advancing our Gammabody pipeline for the development of potential therapeutics in both hematologic malignancies and solid tumors.

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 $\gamma\delta$ 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 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 $\gamma\delta$ T cell engagers were well tolerated and did not induce high-grade CRS.

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 investigating the Gammabody drug candidate, LAVA-1266. LAVA-1266 is designed using our Gammabody platform to conditionally activate Vγ9Vδ2 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 is expressed in a range of hematological malignancies, including AML, MDS, acute lymphocytic leukemia (ALL) and Hodgkin Lymphoma.

We are conducting an open-label, multi-center Phase 1, first-in-human study of LAVA-1266 with the study open to recruitment in Australia at four sites. The study includes a dose escalation segment to evaluate LAVA-1266 in up to 50 adults with CD123+ relapsed/refractory (R/R) AML and intermediate, high or extremely high risk MDS. Patients will be dosed every two weeks (Q2W) at the target dose, with an initial

target dose of 100 µg for the first cohort. We dosed the first patient in this trial in December 2024, and we expect an initial data readout by year-end 2025.

From 2022 through December 2024, we enrolled patients in a first-in-human clinical trial evaluating LAVA-1207 in patients with mCRPC in the United States and Europe. The open-label, multi-center, Phase 1 clinical trial was designed to evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity and preliminary anti-tumor activity of LAVA-1207.

In December 2024, we announced that after no patients remained on treatment, we would discontinue the first-in-human Phase 1 clinical trial for LAVA-1207, an investigational candidate that was designed to target PSMA-expressing cancers for patients with mCRPC.

As a result of the planned discontinuation of the LAVA-1207 clinical trial, we expensed $3.9 million of clinical trial, contract manufacturing, and bioanalytical costs during December 2024.

Recent Developments

In February 2025, we adopted a restructuring plan to extend our capital resources in connection with initiating a process to evaluate strategic alternatives. As part of the restructuring plan, we approved a reduction of approximately 30% of our global workforce to better align our resources with our focus on LAVA-1266. We expect approximately $1.0 million of expenses related to the restructuring to be incurred during the six months ended June 30, 2025, of which approximately $0.3 million of cash payments are expected to be made during 2025.

Financial Overview

Revenue

To date, we have not generated any revenues 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 candidates, 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 candidates, development candidates or collaborator candidates, or we enter into collaboration agreements with third parties for additional product candidates, may generate revenue from those product candidates.

Collaboration Agreement with Pfizer

In September 2022, we entered into an exclusive license agreement with Pfizer (formerly Seagen Inc.) (the “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 $50.0 million nonrefundable upfront payment in October 2022 and are eligible to receive up to approximately $650.0 million upon the achievement of development, regulatory and commercial milestones, as well as royalties ranging from the low teens to high mid-teens on future sales. The Pfizer Agreement also provided Pfizer with the opportunity to exclusively negotiate rights to apply our proprietary Gammabody platform on up to two additional tumor targets, which Pfizer did not exercise. In March 2024, Pfizer paid us $7.0 million for achieving a clinical 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 $35.0 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 “Item 1. Business – Pfizer” and Note 3 of the consolidated financial statements

Collaboration Agreement with J&J

In May 2020, we entered into a research collaboration and license agreement (the “J&J Agreement”) with Johnson & Johnson (J&J) (formerly Janssen Biotech, Inc.). As part of the J&J Agreement, we received a non-refundable upfront payment of $8.0 million, which we recognized on a straight-line basis over the two-year term of the research activities under the J&J Agreement. The straight-line method of recognition materially approximates the cost-to-cost method of revenue recognition. As of January 1, 2023, we had recorded the entirety of the $8.0 million upfront payment as revenue.

In December 2020, we achieved the first Research Milestone, as defined in the J&J 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 J&J Agreement, J&J 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. In October 2024, a milestone payment of $5.0 million from J&J was triggered under the terms of the J&J Agreement following filing with health authorities to start a Phase 1 clinical trial for JNJ-89853413. Each milestone payment was recorded as revenue when achieved, due to the variable consideration of the milestone payments no longer being constrained.

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 “Item 1. Business – Our Pipeline – Johnson & Johnson Partnered Program (JNJ-89853413)” and Note 3 of 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

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 compensation, employee benefits and share-based compensation for employees engaged in research and development;

- expenses incurred under agreements with contract manufacturing organizations, or CMOs, contract research organizations, or 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; 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.

General and Administrative Expenses

General and administrative expenses consist of costs incurred for operational expenses such as accounting, legal and insurance, and related activities. Our general and administrative expenses consist of:

- accounting, finance, insurance tax, legal and human relations;
- expenses for facilities, insurance and related costs;
- expenses and legal costs related to the protection of our intellectual property; and
- depreciation expenses and other corporate and operating expenses not included in research and development

General and administrative expenses are expensed as incurred.

Income Tax

We are subject to income taxes in the Netherlands, the United States, and Australia. A tax charge was recognized during the year ended December 31, 2024 due to profitable positions in the U.S. and Australia as a result of a cost plus intercompany remuneration in both jurisdictions. As of December 31, 2024, we had Dutch tax loss carryforwards of $106.5 million, which are fully offset by a valuation allowance. Furthermore, an amount of $16.1 million of IP development costs was amortized for tax purposes as of December 31, 2024. The 2024 taxable amount is not final as the 2024 Dutch corporate income tax return is still in draft form and has not been filed with the Dutch tax authorities yet. The 2023 Dutch corporate income tax return is final and has been filed on time. On the basis of the 2024 annual accounts, there are accounting-to-tax differences of $13.0 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 2024 for Dutch corporate income tax purposes and ASC 842 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 13 of the consolidated financial statements.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

The following table summarizes our results of operations for the year ended December 31, 2024 and 2023:

(in thousands)	Year Ended December 31, 2024	2023	Increase (Decrease)
Revenue:			
Revenue from contracts with customers	$ 11,982	$ 6,769	$ 5,213
Total revenue	11,982	6,769	5,213
Cost and expenses:			
Cost of revenue	-	(3,482)	(3,482)
Research and development	(28,450)	(32,559)	(4,109)
General and administrative	(13,225)	(14,122)	(897)
Total cost and expenses	(41,675)	(50,163)	(8,488)
Operating loss	(29,693)	(43,394)	(13,701)
Total other income, net	5,209	1,780	3,429
Net loss before taxes	(24,484)	(41,614)	(17,130)
Income tax expense, net	(630)	(257)	373
Net loss	$ (25,114)	$ (41,871)	$ (16,757)

Revenue from Contracts with Customers

Our revenue from contracts with customers was $12.0 million and $6.8 million for the years ended December 31, 2024 and 2023, respectively.

In connection with the Pfizer Agreement we entered into in September 2022, we recognized $7.0 million in revenue for the year ended December 31, 2024. This revenue was related to the achievement by Pfizer of a clinical development milestone for PF-08046052. For the year ended December 31, 2023 we recognized $4.3 million in revenue in connection with the Pfizer Agreement. Of that amount, $3.7 million related to the initial supply and manufacturing technology transfer related stability studies and $0.6 million related to reimbursement for additional services.

Additionally, we had revenue of $5.0 million and $2.5 million for the years ended December 31, 2024 and 2023, respectively, attributable to our J&J Agreement. The revenue for the year ended December 31, 2024 related to a $5.0 million milestone that was triggered under the J&J Agreement following J&J's filing with health authorities to start a Phase 1 clinical trial for JNJ-89853413. The revenue for the year ended December 31, 2023 related to a $2.5 million milestone that was triggered under the J&J Agreement following the selection of a lead bispecific antibody utilizing the Gammabody platform for an undisclosed tumor associated antigen.

Cost of Revenue

Our cost of revenue was $0.0 million and $3.5 million for the years ended December 31, 2024 and 2023, respectively. The cost for 2023 was related to the cost of the initial supply delivery and related stability studies under the Pfizer Agreement.

Research and Development Expenses

Below are our research and development expenses for the years ended December 31, 2024 and 2023:

(in thousands)	Year Ended December 31, 2024	2023	Increase (Decrease)
Pre-clinical and clinical trial expenses	$ 19,267	$ 20,374	$ (1,107)
Personnel-related expenses	5,322	6,660	(1,338)
Facilities and other research and development expenses	1,599	2,356	(757)
Share-based compensation expense	1,180	1,728	(548)
Research and development activities expenses	1,082	1,441	(359)
	$ 28,450	**$ 32,559**	**$ (4,109)**

Research and development expenses were $28.5 million for the year ended December 31, 2024, compared to $32.6 million for the year ended December 31, 2023. Pre-clinical and clinical trial expenses decreased by $1.1 million, primarily due to reduced manufacturing costs for LAVA-1266 and other product candidates offset by increased clinical trial activities for LAVA-1207, including shutdown costs of $3.9 million. Personnel-related expenses decreased $1.3 million primarily due to research and development headcount reductions which occurred in the second half of 2023. Facilities and other research and development expenses decreased by $0.8 million due to reduced office and laboratory leases, depreciation and related costs. Share-based compensation expense decreased by $0.5 million due to fewer options issued and a reduction in the Company's share price. Research and development activity expenses decreased by $0.4 million primarily due to a decrease in research project expenses driven by less headcount and a decrease in ongoing pre-clinical programs in 2024 as compared to 2023.

General and Administrative Expenses

Below are our general and administrative expenses for the years ended December 31, 2024 and 2023:

(in thousands)	Year Ended December 31, 2024	2023	Increase (Decrease)
Personnel-related expenses	$ 3,941	$ 3,812	$ 129
Professional and consultant fees	3,497	2,884	613
Insurance, facilities, fees and other related costs	2,580	2,877	(297)
Share-based compensation expense	2,046	3,311	(1,265)
Patent-related costs	1,161	1,238	(77)
	$ 13,225	**$ 14,122**	**$ (897)**

General and administrative expenses were $13.2 million for the year ended December 31, 2024, compared to $14.1 million for the year ended December 31, 2023. Personnel-related expenses increased $0.1 million due to an increase in temporary staffing offset by a decrease in headcount. Professional and consultant fees increased by $0.6 million due to increased audit, accounting, and finance compliance fees due to the transition to United States generally accepted accounting principles ("U.S. GAAP"). Insurance, facilities, fees and other related costs decreased by $0.3 million primarily due to reduced directors and officers insurance premiums and reduced office lease costs. Share-based compensation expense decreased by $1.3 million due to fewer options issued and a reduction in the Company's share price. Patent-related costs decreased by $0.1 million due to a reduction in the number of patent filings.

Other income, net

Other income, net was $5.2 million for the year ended December 31, 2024, compared to $1.8 million for the year ended December 31, 2023. The change of $3.4 million is primarily due to the impact of the fluctuation of the USD currency rate compared to the Euro, as both interest income and interest expense increased less than $0.1 million in 2024 as compared to 2023.

Liquidity and Capital Resources

Sources of Liquidity

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 administrative activities to support business operations.

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, 2024, we had $4.9 million in borrowings under the Innovation Credit, including accrued interest. In June 2023, we announced the discontinuance of the LAVA-051 program. This discontinuance ended the receipt of future installments. In October 2024, we received notice from the RVO requiring a payment of $0.6 million within six weeks of the notice date. Payment was made within the required period. The remaining balance of $4.9 million, which is inclusive of principal and accrued interest, has been conditionally waived with a further decision to be made within one year from the notice date. Upon satisfaction of certain conditions related to pledged assets in the conditional waiver, we may request a permanent waiver from the remaining payment obligations to the RVO. The liability will remain classified as current, as the waiver lasts one year from the notice date. We have submitted a request for permanent waiver in the first quarter of 2025 and we expect RVO to make their decision on repayment of the Innovation Credit by the third quarter of 2025. The potential repayment of principal and accrued interest is due on September 30, 2025.

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.

Under the Pfizer Agreement, we received a nonrefundable up-front payment of $50.0 million in October 2022 and a clinical milestone payment of $7.0 million in March 2024. Additionally, we were entitled to reimbursement of up to $6.5 million for certain agreed-to research, manufacturing, and supply activities under the Pfizer Agreement. We have received an aggregate amount of $6.4 million for agreed-to reimbursement services and do not anticipate receiving reimbursement for any additional agreed-to services at this time. Under the J&J Agreement, we received a nonrefundable up-front payment of $8.0 million in May 2020 and aggregate clinical milestone payments of $9.5 million to date.

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, 2024 and 2023, cash consists of cash deposited with four financial institutions and account balances exceeding the federally insured limits.

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

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2024, and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
(in thousands)	**Total**	**Less than 1 Year**	**1-3 Years**	**3 - 5 Years**	**More than 5 Years**
Operating lease commitments	$ 425	$ 343	$ 82	$ -	$ -

The commitment amounts in the table above primarily reflect the minimum payments due under our amended operating lease for office and laboratory space in the Netherlands and the United States. These commitments are also recognized as operating lease liabilities in our balance sheet at December 31, 2024. Refer to Note 5 to our audited consolidated financial statements and related notes included in this Annual Report on Form 10-K for additional discussion of the lease.

Funding Requirements

Based on our current operating plan, we believe that our existing cash, cash equivalents and investments as of December 31, 2024 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 candidates, including LAVA-1266 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 cGMP;
- seek regulatory and marketing approvals for LAVA-1266 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, Europe and Australia;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- complete our strategic review of our business and acquire or in-license additional product candidates and technologies, pursue a sale, merger or acquisition of the business, or other strategic alternatives;
- develop a potential companion diagnostic;
- incur additional legal, accounting and other expenses associated with the transition from foreign private issuer to U.S. domestic filer status;

- 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 the Russian invasion of Ukraine, the conflict in the Middle East 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.

Cash Flows

Comparison of the Years Ended December 31, 2024 and 2023

The following table summarizes our cash flows for each of the years presented:

	For the Year Ended December 31,		
(in thousands)	**2024**	**2023**	**Increase (Decrease)**
Net cash used in operating activities	$ (19,544)	$ (40,283)	$ 20,739
Net cash generated from (used in) investing activities	12,475	(17,636)	30,111
Net cash used in financing activities	(569)	—	(569)
Net decrease in cash and cash equivalents	**$ (7,638)**	**$ (57,919)**	**$ 50,281**

Operating Activities

Net cash used in operating activities for the year ended December 31, 2024 was $19.5 million, compared to net cash using in operating activities of $40.3 million for the year ended December 31, 2023. The decrease in net cash used in operating activities of $20.7 million was primarily driven by a decrease in net loss of $16.8 million, a foreign currency exchange gain of $0.8 million in 2024 as compared to a $0.8 million foreign currency exchange loss in 2023, a decrease in share-based compensation expense of $3.2 million in 2024 as compared to $5.0 million in 2023, and a net increase in other working capital accounts of $8.3 million in 2024 as compared to 2023.

Investing Activities

Net cash generated from investing activities for the year ended December 31, 2024 was $12.5 million compared to net cash used in investing activities of $17.6 million for the year ended December 31, 2023. During the year ended December 31, 2024, we received $109.5 million from the maturities of investments, offset by investment purchases of $97.1 million. 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.

Financing Activities

Net cash used in financing activities for the year ended December 31, 2024 of $0.6 million was due to repayments of $0.6 million to the RVO on the innovation credit offset by less than $0.1 million of proceeds from option exercises.

Critical Accounting Policies and Estimates

We prepare our consolidated financial statements in accordance with U.S. GAAP as issued by the Financial Accounting Standards Board (the "FASB"), 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 significant 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 significant 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 consolidated financial statements.

Clinical Trial Accruals

As part of the process of preparing our consolidated 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 consolidated 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 consolidated 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.

Recently Adopted Accounting Pronouncements

A description of recently issued and adopted accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our audited consolidated financial statements and related notes in this Annual Report on Form 10-K for the year ended December 31, 2024.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Item 10 of Regulation S-K and are not required to provide the information otherwise required under this item.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements for the years ended December 31, 2024 and 2023, together with the report of our independent registered public accounting firm, appear beginning on page F-1 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Exchange Act of 1934, as amended) as of December 31, 2024. Based on that evaluation, management, including our Chief Executive Officer and Chief Financial Officer, have concluded that as of December 31, 2024, our disclosure controls and procedures were effective at a reasonable assurance level.

The Company’s disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms; and (ii) accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely discussions regarding required disclosure. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures included in such controls may deteriorate. Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control - Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that, as of December 31, 2024, our internal control over financial reporting was effective.

Remediation of Previously Identified Material Weakness

A "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. Prior to the completion of our IPO in March 2021, we had been a private company and therefore had not designed or maintained internal controls over financial reporting commensurate with the financial reporting requirements of an SEC registrant. We previously disclosed in our 2023 Annual Report on Form 20-F the following material weaknesses:

- we did not design and maintain effective general controls over information technology, including the lack of change management and software development life cycle (SDLC) procedures and insufficient level of user access controls to key financial systems, and
- we did not design and maintain effective controls over appropriate segregation of duties.

With the oversight of the Audit Committee of our Board of Directors, we dedicated significant resources and efforts during the year ended December 31, 2024 to improve our control environment and remediate our material weaknesses identified above by implementing and maintaining changes to our internal control over financial reporting.

Remediation Actions Completed During Current Year

The following remediation efforts were established during the year ended December 31, 2024:

- hired additional accounting resources, including a full-time director with U.S. GAAP expertise, third-party internal control advisors and external 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, including IT policies and procedures, and IT general controls, including change management, SDLC, and user access; and

- performed testing and assessment of internal controls to evaluate the design and operating effectiveness of key controls.

We completed the design, testing and evaluation of new and enhanced internal controls and determined that, as of December 31, 2024, the controls were designed and had operated effectively for a sufficient period of time for our management to conclude that the material weakness previously identified had been remediated.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm due to an exemption provided by the JOBS Act for "emerging growth companies."

Changes in Internal Control Over Financial Reporting

Other than the applicable remediation efforts described in "Remediation of Previously Identified Material Weaknesses" above, Management determined that, as of December 31, 2024, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f)) that occurred during the year ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Adoption, Modification and Termination of Rule 10b5-1 Plans and Certain Other Trading Arrangements

During the quarter ended December 31, 2024, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement" (as each term is defined in Item 408 of Regulation S-K).

Amended and Restated Employment Agreement with Stephen Hurly

On March 27, 2025, we entered into an amended and restated employment agreement with Stephen Hurly (the "Hurly Employment Agreement"), which amended his existing employment agreement from 2021.

New Change

Pursuant to the Hurly Employment Agreement, in the event of a Change in Control (as defined therein) Mr. Hurly is entitled to, among other things, a lump-sum payment equal to 1.5 times his target bonus. Under Mr. Hurly's prior employment agreement, in the event of a Change of Control he was entitled to, among other things, a lump-sum payment equal to 1.5 times his target bonus, pro-rated for the portion of the year he was employed in the event of a Change in Control.

Terms of Original Employment Agreement

Other than amending the Change in Control benefits as described above, the Hurly Employment Agreement did not alter any other aspects of Mr. Hurly's employment with the Company. A description of the material terms of the Hurly Employment Agreement is set forth below.

The Hurly Employment Agreement provides for an annual base salary, which may be increased by the Company in its sole discretion. Mr. Hurly is also eligible to earn an annual incentive cash bonus based upon the achievement of individual and corporate goals determined by the Company's board of directors, with a target bonus amount equal to 50% of his then-current annual base salary, subject to adjustment by

the Company in its sole discretion. Mr. Hurly is also eligible to participate in the Company's employee benefit plans and programs and to receive reimbursement for reasonable business expenses in accordance with the Company's standard expense reimbursement policy. In the event of a Change in Control (as defined in Hurly Employment Agreement), 100% of the then unvested portion of those equity awards granted to Mr. Hurly prior to the effective date of the amended and restated employment agreement and subject to a time based vesting schedule will accelerate and vest in full immediately prior to the effective time of such Change in Control.

Under the terms of the Hurly Employment Agreement, upon execution and effectiveness of a separation agreement including a general release of claims in favor of the Company, its officers, directors and employees, Mr. Hurly will be entitled to severance payments if the Company terminates his employment without Cause (as defined in the Hurly Employment Agreement), or if he resigns his employment with the Company for Good Reason (as defined in the Hurly Employment Agreement). If such termination occurs other than during the period of 3 months prior or 12 months after a Change in Control, Mr. Hurly will be eligible to receive the following severance benefits: (a) an amount equal to 12 months of continued base salary, payable on the Company's regular payroll dates; (b) payment of applicable COBRA premiums for up to 12 months following termination; and (c) a lump-sum payment equal to his target bonus, pro-rated for the portion of the year he was employed. If such termination occurs during the period of 3 months prior or 12 months after a Change in Control, Mr. Hurly will be eligible to receive the following enhanced severance benefits: (a) an amount equal to 18 months of continued base salary, payable on the Company's regular payroll dates; (b) payment of applicable COBRA premiums for up to 18 months following termination; (c) a lump-sum payment equal to 1.5 times his target bonus; and (d) to the extent Mr. Hurly's equity awards have been continued, assumed, or substituted by the surviving entity in the Change in Control, then those equity awards subject to a time based vesting schedule will accelerate and vest in full effective as of his termination without Cause or resignation for Good Reason.

The foregoing summary of the Hurly Employment Agreement is not complete and is qualified in its entirety by reference to the full text of the Hurly Employment Agreement, a copy of which is attached hereto as Exhibit 10.11.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

We will file a definitive Proxy Statement for our 2025 Annual General Meeting of Shareholders, or the 2025 Proxy Statement, with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2025 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated by reference to the information set forth in the sections titled “Board of Directors and Corporate Governance” and “Executive Officers,” in our 2025 Proxy Statement.

We have adopted an insider trading policy, which governs the purchase, sale and/or other dispositions of our securities by our directors, officers and employees, their immediate family members and entities owned or controlled by them as well as consultants that have access to material nonpublic information, which we believe is reasonably designed to promote compliance with insider trading laws, rules and regulations as well as the listing standards of The Nasdaq Stock Market LLC applicable to us.

Item 11. Executive Compensation

The information required by this item is incorporated by reference to the information set forth in the sections titled “Executive Compensation” and “Director Compensation” in our 2025 Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item is incorporated by reference to the information set forth in the sections titled “Executive Compensation – Equity Compensation Plan Information” and “Security Ownership of Certain Beneficial Owners and Management” in our 2025 Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated by reference to the information set forth in the sections titled “Certain Relationships and Related Party Transactions” and “Board of Directors and Corporate Governance – Director Independence; Executive Sessions” in our 2025 Proxy Statement.

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated by reference to the information set forth in the sections titled “Board of Directors and Corporate Governance – Principal Accountant Fees and Services” and “Board of Directors and Corporate Governance – Pre-Approval Policies and Procedures” in our 2025 Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(1) For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

(3) Exhibits:

		Incorporation by Reference			
Exhibit number	**Description of Document**	**Form**	**Exhibit**	**File Date**	**File Number**
3.1*	Amended and Restated English translation of Articles of Association of LAVA Therapeutics N.V.				
4.1*	Description of Securities.				
10.1^	Restated and Amended License and Assignment Agreement, dates as of February 25, 2021 by and among LAVA Therapeutics B.V. and Stichting VUmc.	Form F-1	10.1	3/2/2021	**333-253795**
10.2^	Research Collaboration and License Agreement, dated as of May 13, 2020, by and among LAVA Therapeutics, B.V., and Janssen Biotech, Inc.	Form F-1	10.2	3/2/2021	**333-253795**
10.3+	Exclusive License Agreement, dated as of September 23, 2022, by and between LAVA Therapeutics, Inc. and Seagen, Inc.	Form 6-K	10.1	9/30/2022	**001-40241**
10.4+	Clinical Supply Agreement, dated as of January 27, 2023, by and between LAVA Therapeutics, Inc. and Seagen, Inc.	Form 20-F	4.4	4/11/2023	**001-40241**
10.5#	Form of Indemnification Agreement for executive directors and executive officers.	Form F-1/A	10.3	3/18/2021	**333-253795**
10.6#	Form of Indemnification Agreement for non-executive directors.	Form F-1/A	10.4	3/18/2021	**333-253795**
10.7#	2018 Stock Option Plan.	Form F-1/A	10.5	3/18/2021	**333-253795**
10.8#	2020 U.S. Stock Option Plan.	Form F-1/A	10.6	3/18/2021	**333-253795**
10.9*#	2021 Long Term Incentive Plan and form of Award Agreement.				
10.10#	2021 Employee Share Purchase Plan.	Form F-1/A	10.8	3/18/2021	**333-253795**
10.11*#	Employment agreement with Stephen Hurly				

10.12*#	Employment agreement with Fred Powell
10.13*#	Employment agreement with Charles Morris
19.1*	Insider Trading Policy
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (included on the signature page to this report)
31.1*	Certification of Principal Executive Officer Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
31.2*	Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
32.1*†	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*†	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1*	Incentive Compensation Recoupment Policy.
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Presentation Linkbase Document.
104	Cover Page Interactive Data File (the cover page iXBRL tags are embedded within the Inline XBRL document)

* Filed herewith

# Indicates a management contract or compensatory plan, contract or arrangement

^ Confidential treatment has been requested for portions of this agreement
+ Certain confidential information in this exhibit has been omitted and replaced with "[***]" because it is not material and is information that the company treats as private or confidential
† These certifications are being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

LAVA Therapeutics N.V.

Date: March 28, 2025

By: /s/ Stephen Hurly
Stephen Hurly
President and Chief Executive Officer

Date: March 28, 2025

By: /s/ Fred Powell
Fred Powell
Chief Financial Officer

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Stephen Hurly and Fred Powell, and each of them, as his or her true and lawful agents, proxies and attorneys-in-fact, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Stephen Hurly Stephen Hurly	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 28, 2025
/s/ Fred Powell Fred Powell	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	March 28, 2025

/s/ Kapil Dhingra Kapil Dhingra	Chair of the Board of Directors	March 28, 2025
/s/ Jay Backstrom Jay Backstrom	Director	March 28, 2025
/s/ Peter Kiener Peter Kiener	Director	March 28, 2025
/s/ James Noble James Noble	Director	March 28, 2025
/s/ Christy Oliger Christy Oliger	Director	March 28, 2025
/s/ Mary Wadlinger Mary Wadlinger	Director	March 28, 2025
/s/ Karen Wilson Karen Wilson	Director	March 28, 2025

LAVA Therapeutics N.V.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of LAVA Therapeutics N.V.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of LAVA Therapeutics N.V. and its subsidiaries (the “Company”) as of December 31, 2024 and 2023, and the related consolidated statements of operations and comprehensive loss, of shareholders’ equity and statements of cash flows for the years then ended, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers Accountants N.V.
Eindhoven, The Netherlands
March 28, 2025

We have served as the Company's auditor since 2018.

LAVA Therapeutics N.V.
Consolidated Balance Sheets
(In thousands, except par value and share data)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 35,015	$ 44,231
Short-term investments	41,561	51,340
Prepaid expenses	1,072	1,627
Other current assets	1,649	1,699
Total current assets	**79,297**	**98,897**
Property and equipment, net	1,002	1,602
Operating lease right-of-use assets	441	855
Other non-current assets	91	319
Total assets	**$ 80,831**	**$ 101,673**
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 2,722	$ 4,446
Accrued expenses and other current liabilities	10,083	4,751
Borrowings	4,886	5,282
Current portion of operating lease liabilities	315	415
Total current liabilities	**18,006**	**14,894**
Non-current portion of deferred revenue	35,000	35,000
Non-current portion of operating lease liabilities	80	415
Total liabilities	**53,086**	**50,309**
Commitments and contingencies (Note 10)		
Shareholders' equity:		
Common stock, $0.14 par value; 90,000,000 and 45,000,000 shares authorized as of December 31, 2024, and December 31, 2023, respectively; 26,305,295 and 26,289,087 shares issued and outstanding as of December 31, 2024, and December 31, 2023, respectively	3,717	3,715
Additional paid-in capital	211,656	208,405
Accumulated deficit	(174,973)	(149,859)
Accumulated other comprehensive loss	(12,655)	(10,897)
Total shareholders' equity	27,745	51,364
Total liabilities and shareholders' equity	**$ 80,831**	**$ 101,673**

The accompanying notes are an integral part of these consolidated financial statements.

LAVA Therapeutics N.V.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2024	**2023**
Revenue:		
Revenue from contracts with customers	$ 11,982	$ 6,769
Total revenue	**11,982**	**6,769**
Cost and expenses:		
Cost of revenue	—	(3,482)
Research and development	(28,450)	(32,559)
General and administrative	(13,225)	(14,122)
Total cost and expenses	**(41,675)**	**(50,163)**
Operating loss	**(29,693)**	**(43,394)**
Other income (expense), net		
Interest income	3,758	3,672
Interest expense	(515)	(470)
Foreign currency exchange gain (loss), net	1,966	(1,422)
Total other income, net	**5,209**	**1,780**
Net loss before taxes	**(24,484)**	**(41,614)**
Income tax expense, net	(630)	(257)
Net loss	**$ (25,114)**	**$ (41,871)**
Other comprehensive (expense) income:		
Foreign currency translation adjustment	(1,758)	2,075
Comprehensive loss	**$ (26,872)**	**$ (39,796)**
Net loss per share, basic and diluted	$ (0.94)	$ (1.57)
Weighted-average common shares outstanding, basic and diluted	26,834,422	26,732,556

The accompanying notes are an integral part of these consolidated financial statements.

LAVA Therapeutics N.V.
Consolidated Statements of Shareholders' Equity
(In thousands, except for share amounts)

	Common Shares		Additional	Accumulated	Accumulated other comprehensive	
	Shares	Amount	paid-in capital	deficit	loss	Total
Balance as of January 1, 2023	26,289,087	$ 3,715	$ 203,366	$ (107,988)	$ (12,972)	$ 86,121
Share-based compensation expense	—	—	5,039	—	—	5,039
Foreign currency translation adjustment	—	—	—	—	2,075	2,075
Net loss	—	—	—	(41,871)	—	(41,871)
Balance as of December 31, 2023	26,289,087	3,715	208,405	(149,859)	(10,897)	51,364
Exercise of share options	16,208	2	25	—	—	27
Share-based compensation expense	—	—	3,226	—	—	3,226
Foreign currency translation adjustment	—	—	—	—	(1,758)	(1,758)
Net loss	—	—	—	(25,114)	—	(25,114)
Balance at December 31, 2024	26,305,295	$ 3,717	$ 211,656	$ (174,973)	$ (12,655)	$ 27,745

The accompanying notes are an integral part of these consolidated financial statements.

LAVA Therapeutics N.V.
Consolidated Statements of Cash Flows
(In thousands, except for share amounts)

	Year Ended December 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (25,114)	$ (41,871)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	467	612
Non-cash operating lease expense	371	423
Foreign currency exchange (gain) loss, net	(746)	820
Share-based compensation expense	3,226	5,039
Accrued interest on borrowings	515	470
Amortization of premium on short-term investments	(2,636)	(1,900)
Deferred income taxes	(10)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	424	4,537
Other non-current assets	228	497
Accounts payable	(1,569)	352
Accrued expenses and other current liabilities	5,703	(4,004)
Operating lease liabilities	(403)	(535)
License liabilities	—	(4,723)
Net cash used in operating activities	**(19,544)**	**(40,283)**
Cash flows from investing activities:		
Purchases of property and equipment	(23)	(731)
Proceeds from sale of property and equipment	88	—
Purchases of investments	(97,090)	(90,082)
Maturities of investments	109,500	73,177
Net cash generated from (used in) investing activities	**12,475**	**(17,636)**
Cash flows from financing activities:		
Proceeds from option exercises	27	—
Repayment of borrowings	(596)	—
Net cash used in financing activities	**(569)**	**—**
Net decrease in cash and cash equivalents	**(7,638)**	**(57,919)**
Cash and cash equivalents at beginning of year	44,231	100,333
Effects of exchange rate changes	(1,578)	1,817
Cash and cash equivalents at end of year	**$ 35,015**	**$ 44,231**
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 283	$ 355
Cash paid for interest	—	—
Operating right-of-use assets obtained in exchange for operating lease liabilities	—	(1,180)
Adjustment to operating lease right-of-use assets from lease modification	—	475

The accompanying notes are an integral part of these consolidated financial statements.

1. Organization and Description of Business

Description of the Business

LAVA Therapeutics N.V. (the "Company") was founded in 2016 and is incorporated and domiciled in the Netherlands. The Company is a clinical-stage immuno-oncology company focused on developing its proprietary Gammabody® platform of bispecific gamma delta ($\gamma\delta$) T cell engagers to transform the treatment of cancer. Using its Gammabody platform, the Company is developing a portfolio of novel bispecific antibodies designed to engage and leverage the potency and precision of $\gamma\delta$ T cells to orchestrate a robust, natural 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.

Liquidity and Going Concern

In accordance with Accounting Standards Codification ("ASC") 205-40, *Going concern*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the consolidated financial statements are issued. The Company has incurred net losses since inception, and the Company expects to continue to generate operating losses in the foreseeable future. As of December 31, 2024, the Company had an accumulated deficit of $175.0 million. Management expects to incur additional losses in the foreseeable future.

Through December 31, 2024, the Company has funded its operations with proceeds from sales of equity financings, collaboration and licensing agreements, government grants, and borrowings under various agreements. The Company will need to raise additional capital to support the completion of its research and development activities or other strategic alternatives. Future capital requirements will depend on many factors, including the timing and extent of spending on research and development, including costs for preclinical and nonclinical studies, clinical trials, and clinical trial material manufacturing.

Additional funds may not be available when needed on terms that are acceptable to the Company, or at all. If adequate funds are not available on a timely basis, the Company may be required to delay, limit, scale back or cease our research and development activities, preclinical studies and clinical trials for its product candidates.

As of the issuance date of the consolidated financial statements, the Company believes that its cash and cash equivalents and short-term investments will be sufficient to fund its operations for at least the next twelve months.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company prepared these consolidated financial statements and accompanying notes in accordance with United States ("U.S.") generally accepted accounting principles ("GAAP"). Unless otherwise noted, the Company presents the consolidated financial statements in thousands of U.S. dollars (except share and per share data).

The Company has historically been classified as a foreign private issuer ("FPI"). However, as of June 30, 2024, the Company determined that, pursuant to the definition provided in Rule 405 of the Securities Act of 1933, it no longer satisfied the criteria to be considered an FPI. As such, beginning on January 1, 2025, the Company was required to begin reporting with the U.S. Securities and Exchange Commission on domestic forms and comply with domestic company rules in the United States. The Company retrospectively made the transition from International Financial Reporting Standards ("IFRS") to U.S. GAAP for all periods from the Company's inception.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Lava Therapeutics, Inc. and Lava Therapeutics Pty Ltd. All intercompany accounts and transactions have been eliminated in consolidation.

Foreign Currency

The Company measures items included in the consolidated financial statements of each of its entities using the currency of the primary economic environment in which the entity operates. The Company presents these consolidated financial statements in USD. The parent company, LAVA Therapeutics N.V., has a functional currency of EUR. Lava Therapeutics, Inc. has a functional currency of USD. Lava Therapeutics Pty Ltd. has a functional currency of AUD.

The Company translates foreign currency transactions into the functional currency using the exchange rates prevailing at the dates of the transactions. The Company recognizes 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 within foreign currency exchange gain (loss), net, in the consolidated statements of operations and comprehensive loss.

For presentation purposes, the Company translates all assets and liabilities denominated in foreign currencies into USD using exchange rates in effect as of the date of the balance sheet date. The Company translates revenue and expense transactions at the monthly average exchange rates, and the Company translates certain specific equity transactions at the exchange rate in effect at the time of the transaction. The Company recognizes all resulting exchange differences within currency translation adjustment in the consolidated statements of operations and comprehensive loss and as a separate component of shareholders' equity.

Segment Reporting

The Company identifies operating segments based on whether the Company's Chief Executive Officer, who is the Chief Operating Decision Maker ("CODM"), regularly reviews the allocation of resources and/or the assessment of performance of a particular component of the Company's activities. The Company has one reportable segment – the development of the Gammabody platform of bispecific $\gamma\delta$ T cell engagers for the treatment of cancer.

The CODM assesses performance for the segment and decides how to allocate resources based on net loss that also is reported on the consolidated statements of operations and comprehensive loss. Significant expenses within the consolidated statements of operations and comprehensive loss, as well as within net loss, include cost of revenue, research and development, and general and administrative expenses, which are each separately presented on the Company's consolidated statements of operations and comprehensive loss. Other segment items within net loss include other income (expense), net, and income tax expense, net. In the context of considerations around significant segment expenses, as the expense information that is regularly provided to the CODM is aligned with the consolidated expenses as presented on the statements of operations and comprehensive loss, such expense disclosures are not replicated here.

Net loss is used to monitor budget versus actual results. The monitoring of budgeted versus actual results are used in assessing performance of the segment and in part determining management's compensation. The CODM also analyzes forecasted general and administrative and research and development expenses when assessing the performance of the segment.

All assets, liabilities, cash flows, revenue and expenses are reported on the Company's one reportable segment.

Use of Estimates

The Company prepares its consolidated financial statements in conformity with U.S. GAAP, which requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingencies as of the balance sheet date and the reported amounts of revenues and expenses during the reporting periods. When preparing an estimate, management determines the amount based upon the consideration of relevant internal and external information, which includes historical experience and various other assumptions that the Company believes to be reasonable under the circumstances. Actual results may differ from these estimates if the assumptions prove incorrect. To the extent there are material differences between actual results and these estimates, future results could be materially and adversely affected. Significant estimates and assumptions which form the basis of amounts reported in the consolidated financial statements include the identification of performance obligations in contracts with customers; estimating variable consideration, determination and allocation of standalone selling prices of the Company's performance obligations; timing of revenue recognition; application of the cost-to-cost model in revenue recognition, accrual of clinical trial expenses, and valuation of deferred tax assets. The Company believes that the accounting policies described below require the Company to make significant judgments and estimates in the preparation of its consolidated financial statements.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, risks associated with completion and success of preclinical studies and clinical testing, dependence on key personnel, protection of proprietary technology, compliance with applicable governmental regulations, development by competitors of new technological innovations, protection of proprietary technology, and the ability to secure additional capital to fund operations. Drug candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing, prior to regulatory approval and commercialization. These efforts require significant amounts of additional capital, adequate personnel, and infrastructure and extensive compliance-reporting capabilities. Even if the Company’s drug development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product.

Clinical Trial Expenses

As part of the process of preparing its consolidated 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 contract research organizations (“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 consolidated 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 consolidated 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. The Company has not had any material adjustments to this estimate.

Concentrations of Credit Risk

The Company's cash is potentially subject to concentration of credit risk. The Company's cash accounts in financial institutions exceed the Federal Depository Insurance Coverage ("FDIC") limit. The Company has not experienced losses on these accounts.

Fair Value Measurements

The Company's financial instruments consist primarily of cash and cash equivalents, short-term investments, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities, and the Rijksdienst voor Ondernemend Nederland ("RVO") Innovation Credit.

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value, and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as the price that would be received from the sale of an asset or paid to transfer a liability in the principal or most advantageous market in an orderly transaction between market participants on the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

As a basis for considering such assumptions, the accounting guidance establishes a three- tier fair value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

> ***Level 1*** — Inputs are unadjusted, such as quoted prices in active markets for identical assets or liabilities;
>
> ***Level 2*** — Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and
>
> ***Level 3*** — Unobservable inputs that are significant to the measurement of the fair value of the asset or liabilities which there is little or no market data and require the Company to develop its own assumptions.

The fair value hierarchy gives the highest priority to Level 1 inputs and the lowest priority to Level 3 inputs. A financial instrument's fair value classification is based on the lowest level of any input that is significant in the fair value measurement hierarchy. Valuation methods and assumptions used to estimate fair value, when Level 1 inputs are not available, are subject to judgments, and changes in these factors can materially affect fair value estimates. At the end of each reporting period, the Company reviews the fair value hierarchy, including whether transfers have occurred between levels.

Financial instruments measured on a recurring basis are those that the Company adjusts each time it prepares a financial statement. Financial instruments measured on a nonrecurring basis are those that the Company adjusts only when a significant event occurs. The Company carries the RVO Innovation Credit at amortized cost, which approximates fair value. The carrying values of the prepaid expenses, other current assets, accounts payable, and accrued expenses and other current liabilities approximate their fair values due to the short-term nature of these assets and liabilities.

Cash and Cash Equivalents

The Company's cash equivalents consist of highly liquid investments with remaining maturities at the date of purchase of three months or less.

The Company makes short-term deposits for varying periods of between one day and three months, depending on the Company's immediate cash requirements. The deposits earn interest at the respective short-term deposit rates. The Company's cash and cash equivalents balances as of December 31, 2024, and December 31, 2023, included $35.0 million and $44.2 million, respectively, of short-term bank deposits.

The Company did not have any restricted cash as of December 31, 2024, or December 31, 2023.

Short-term Investments

The Company's investments consist only of holdings in U.S. Treasury debt securities with maturities ranging from three months to one year. Accordingly, the Company classifies these investments as current assets in its consolidated balance sheets. Because the Company has the intent and ability to hold these investments until maturity, the Company classifies its short-term investments in U.S. Treasury debt securities as held to maturity ("HTM") and thus measures the investments at amortized cost, which approximates fair value.

The Company estimates the allowance for credit losses on its HTM debt securities using a current expected credit loss methodology. The Company deducts any expected credit loss on its HTM debt securities from the amortized cost basis of the securities so that the consolidated balance sheets reflect the net amount the Company expects to collect. All of the Company's HTM debt securities are issued by the U.S. Treasury, a department of the U.S. government. U.S. Treasury debt securities are either explicitly or implicitly guaranteed by the U.S. government, are highly rated by major rating agencies, and have a long history of no credit losses. Accordingly, the Company has a zero-credit loss expectation on these securities. Therefore, as of December 31, 2024, and December 31, 2023, the Company did not record an allowance for credit losses on its short-term investments. The amortized cost basis of the Company's HTM debt securities is $41.6 million and $51.3 million as of December 31, 2024 and December 31, 2023, respectively. As of December 31, 2024, and December 31, 2023, the difference between the amortized cost basis and fair value is less than $0.1 million.

The Company records the amortization of premiums or discounts in the consolidated statements of operations and comprehensive loss within interest income and interest expense, respectively.

Property and Equipment, Net

The Company states its property and equipment at cost less accumulated depreciation and accumulated impairment losses, if any. The Company records depreciation on a straight-line basis over an asset's estimated useful life as follows:

Leasehold improvements	Shorter of estimated useful life and lease term
Building improvements	10 years
Laboratory equipment	5 years
Office equipment	5 years
Information and communication equipment ("ICT")	5 years

The Company records the depreciation of laboratory equipment and ICT equipment within research and development expenses in the consolidated statements of operations and comprehensive loss. The Company allocates the depreciation of leasehold improvements and office equipment between research and development expenses and general and administrative expenses in the consolidated statements of operations and comprehensive loss.

The Company records maintenance and repair expenses when incurred, with the Company recording these expenses within general and administrative expenses in the consolidated statements of operations and comprehensive loss. The Company capitalizes additions and improvements that increase the useful life of the asset.

Impairment of Long-Lived Assets

The Company reviews its long-lived assets, primarily comprised of property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. If indicators are present, the Company will perform a recoverability test by comparing the sum of the estimated undiscounted future cash flows attributable to the asset or asset group to the related carrying amounts. If the undiscounted cash flows used in the test for recoverability are less than the asset or asset group's carrying amount, the Company will recognize an impairment loss equal to the amount by which the carrying amount of the asset or asset group exceeds its fair value. The Company has not recognized any impairment losses for the years ended December 31, 2024 or 2023.

Leases

The Company determines whether an arrangement is, or contains, a lease at contract inception. An arrangement contains a lease if the Company has the right to direct the use of and obtain substantially all of the economic benefits of an identified asset. Right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The Company recognizes lease liabilities at lease commencement based on the present value of lease payments over the lease term. Unless the rate implicit in the lease is known, the Company utilizes its incremental borrowing rate as the discount rate to calculate the present value of lease payments. The Company bases its incremental borrowing rate on the lease term and the economic environment of the applicable country or region, as if it is collateralized. The Company recognizes ROU assets based on the measurement of the lease liability, adjusted for any lease payments made prior to or on lease commencement, lease incentives, and initial direct costs incurred, as applicable.

The Company considers leases with an initial term of twelve months or less to be short-term leases. The Company does not record short-term leases on its balance sheet and records the cash payments as short-term lease expense.

Certain leases have renewal options or options to terminate prior to lease expiration. The Company includes these options in the measurement of right-of-use assets and lease liabilities when it is reasonably certain that the options will be exercised. The Company has elected to account for lease and non-lease components as a single lease component for its offices. Some lease arrangements include payments that are adjusted periodically based on actual charges incurred for common area maintenance, utilities, taxes and insurance, or changes in an index or rate referenced in the lease. The Company includes the fixed portion of these payments in the measurement of right-of-use assets and lease liabilities at lease commencement, while the Company records the variable portion as variable lease expense. The Company's leases do not contain material residual value guarantees or restrictive covenants.

For operating leases where the Company is the lessee, the Company includes the operating lease ROU assets and the current and non-current portions of the operating lease liabilities in the Company's consolidated balance sheets. The Company recognizes operating lease expense for its operating leases on a straight-line basis over the term of the lease. The Company allocates operating lease expense between research and development expense and general and administrative expense using employee headcount. The Company does not have any finance leases.

Debt

The Company initially recognizes its debt at consideration received, adjusted for transaction costs. The Company subsequently measures the debt at amortized cost using the effective interest method. The Company includes interest expense within other income (expense) in the consolidated statements of operations and comprehensive loss.

The Company's debt consists only of the RVO Innovation Credit. Refer to Note 9, Borrowings, for further information.

Collaboration Agreements

The Company has determined that its collaborative agreements do not meet the criteria for accounting under ASC Topic 808, *Collaborative Agreements* ("ASC 808") and as such are accounted for under ASC Topic 606, *Revenue from contracts with customers* ("ASC 606"). The agreements do not specifically designate each party's rights and obligations to each other under the collaborative arrangements. Expenses incurred under these collaborative agreements are included in research and development expenses and funding received from grants are recorded as net revenues in the consolidated statements of operations.

Revenue Recognition

The Company recognizes revenue in accordance with ASC 606. The Company determines revenue recognition through the following steps:

- Identification of the contract, or contracts, with a customer;
- Identification of the performance obligation(s) in the contract;
- Determination of the transaction price, including potential constraints on variable consideration;
- Allocation of the transaction price to the performance obligation(s) in the contract; and
- Recognition of revenue when, or as, a performance obligation is satisfied.

The Company has entered into licensing and collaboration agreements that primarily includes the following: (i) upfront cash consideration; (ii) payments associated with achieving certain development, regulatory, and commercial milestones and (iii) royalties based on specified percentages of net product sales, if any. At the initiation of an agreement, the Company analyzes each unit of account within the contract to determine if the counterparty is a customer in the context of the unit of account.

At contract inception, the Company assesses the goods or services promised and enforceable in a contract with a customer and identifies those distinct goods and services that represent a performance obligation. If a promised good or service is not distinct, the Company combines that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct. The Company assesses optional goods or services that are exercisable at a customer's discretion to determine if the additional goods or services provide a material right to the customer and, if so, the additional goods or services are performance obligations.

The transaction price is the amount of consideration to which the Company expects to be entitled in exchange for transferring promised goods or services to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. The Company considers non-refundable upfront payments to be fixed consideration and includes the amount in the transaction price. At the inception of arrangements that include variable consideration, including milestones and royalties, the Company uses judgment to estimate the amount of variable consideration to include in the transaction price using the most likely amount method. If the Company determines that it is probable that a significant cumulative revenue reversal will not occur, the Company includes the estimated amount in

the transaction price. The Company does not include milestone payments that are not within the Company's or the licensee's control, such as regulatory approvals, in the transaction price until those approvals are received and actions are taken by 3rd parties. For arrangements with licenses of intellectual property that include sales-based royalties, including milestone payments based on the level of sales, if the Company deems the license to be the predominant item to which the royalties relate, the Company recognizes royalty revenue and sales-based milestones at the later of (i) when the related sales occur, or (ii) when the Company satisfies the performance obligation to which the royalty has been allocated. At the end of each reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint and, as necessary, adjusts the estimate of the overall transaction price. The Company records any adjustments on a cumulative catch-up basis, which affects revenues and earnings in the period of adjustment. The Company considers the existence of any significant financing component within its arrangements based on whether a substantive business purpose exists to support the payment structure other than to provide a significant benefit of financing.

If the Company determines that multiple performance obligations exist, the Company allocates the transaction price at the inception of the agreement to all identified performance obligations based on the relative standalone selling prices, unless the consideration is variable and meets the criteria to be allocated entirely to one or more, but not all, performance obligations in the contract. The Company allocates other components of the transaction price based on the relative standalone selling price, over which the Company applies significant judgment. The Company develops assumptions that require judgment to determine the standalone selling price for license-related performance obligations under the adjusted market assessment approach, which may include forecasted revenues, development timelines, discount rates, and probabilities of success. In certain circumstances, the Company may apply the residual method to determine the standalone selling price of a good or service if the standalone selling price is considered highly variable or uncertain.

The Company recognizes revenue when, or as, the Company satisfies a performance obligation which occurs upon the transfer of control of the promised goods or services to the customer. The Company recognizes revenue over time by measuring the progress toward complete satisfaction of the relevant performance obligation using an appropriate input method based on the nature of the good or service promised to the customer. The Company uses judgment to assess the nature of the performance obligation to determine whether the performance obligation is satisfied over time or at a point in time. The selection of the method to measure progress towards completion requires judgment and is based on the nature of the products or services to be provided. The Company recognizes revenue net of expected refunds and net of any sales taxes or indirect taxes collected from customers, which the Company subsequently remits to governmental authorities.

The Company records accounts receivable when its right to consideration becomes unconditional. Contract assets relate to our rights to consideration for services provided that they are conditioned on satisfaction of future performance obligations. If a customer pays consideration, or the Company has an unconditional right to the consideration, before the Company has satisfied the revenue recognition criteria, the Company records the amounts as deferred revenue (a contract liability) in the consolidated balance sheets. The current portion of deferred revenue represents the amount of the performance obligation that the Company expects to satisfy within the next twelve months.

The Company presents a net contract asset or liability for each contract with a customer. The Company presents contract assets separately from accounts receivable in the consolidated balance sheets.

Refer to Note 3, *Revenue*, for further information.

Cost of Revenue

The Company's cost of revenue consists primarily of costs of product materials and stability studies.

Research and Development Expenses

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. Government grants are recorded as a reduction of the related expense or cost of the asset acquired. Government grants are recognized when there is reasonable assurance that the Company has met the requirements of the approved grant program and there is reasonable assurance that the grant will be received. The Company 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. The Company accounts for a governmental research and development tax incentive from the Austalian Government as a reduction of research and development expenses. The Company recognizes the grants when there is reasonable assurance that the Company has met the requirements of the assistance and there is reasonable assurance that the grant will be received. The Company recognized government grants of $1.5 million and $2.0 million during the years ended December 31, 2024, and 2023, respectively.

The Company expenses research and development expenses as incurred.

The Company estimates clinical research expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and research services on its behalf. The Company records the costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and includes these costs in accrued expenses and other current liabilities in the consolidated balance sheets. These costs are a component of the Company's research and development expenses. The Company accrues these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers under the service agreements. The Company makes significant judgments and estimates in determining the accrued expenses and other current liabilities balance. As actual costs become known, the Company adjusts its accrued expenses. The Company has not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed may vary from the Company's estimates, resulting in adjustments to expense in future periods. Changes in these estimates that result in material changes to the Company's accrued costs could materially affect the Company's results of operations.

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, and costs associated with use by these functions of facilities and equipment, such as depreciation expenses, premises maintenance expenses, and other general corporate expenses. Costs to secure and prosecute patent applications and other legal costs related to the protection of the Company's intellectual property are expensed as incurred and are classified as general and administrative expenses in the Company's consolidated statements of operations and comprehensive loss. The Company expenses general and administrative expenses as incurred.

Income Taxes

The Company calculates the income tax expense included in the consolidated financial statements using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of assets and liabilities and their respective tax basis and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences or operating loss and tax credit carryforwards are expected to

be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that includes the enactment date. The Company has estimated and recorded a valuation allowance against certain of its deferred tax assets based on the history of losses incurred in certain jurisdictions and will maintain the valuation allowance until it is more likely than not the deferred tax assets will be realized. If required, the Company would include accrued tax interest and penalties within the related liability lines in the consolidated balance sheets, and the Company would record these items as a component of income tax expense in the consolidated statements of operations and comprehensive loss.

The Company presents tax liabilities net of any related tax loss carryforwards on a jurisdictional basis.

Share-based Compensation

Share-based compensation represents the cost related to share-based awards granted to directors, employees, and non-employees. The Company measures share-based compensation cost at the grant date, based on the estimated fair value of the award. The Company recognizes the expense over the vesting period. For awards with service-only conditions and graded-vesting features, the Company recognizes compensation cost using the accelerated method (also known as the graded-vesting method). Under this method, the Company recognizes compensation expense over the requisite service period for each separately vesting tranche of the award as though the award was in substance multiple awards, resulting in accelerated expense recognition over the vesting period. The Company accounts for forfeitures when they occur. All outstanding share-based awards are equity classified in the consolidated balance sheets.

The Company allocates share-based compensation expense between research and development expense and general and administrative expense based upon the employee's function in the consolidated statements of operations and comprehensive loss.

Restructuring and Other Costs

Restructuring and other costs consist of employee separation costs, asset impairments, and other associated costs primarily related to implementing a restructuring plan. Employee separation costs principally consist of one-time termination benefits and contractual termination benefits for severance, other termination benefit costs, and share-based compensation expense for the acceleration of share awards.

The Company records restructuring charges based on whether the termination benefits are provided under an on-going benefit arrangement or under a one-time benefit arrangement. The Company accounts for one-time employment benefit arrangements in accordance with ASC Topic 420, *Exit or Disposal Cost Obligations* ("ASC 420"). In accordance with ASC 420, the Company expenses one-time termination benefits at the date the Company notifies the employee, unless the employee must provide future service, in which case the Company expenses the benefits ratably over the future service period. The Company recognizes other associated costs in the period in which it incurs the liability.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued Accounting Standards Update ("ASU") *No. 2023-07, Segment Reporting (Topic 280)*: *Improvements to Reportable Segment Disclosures* ("ASU 2023-07"), which modifies the disclosure and presentation requirements of reportable segments. The amendments in the update require the disclosure of significant segment expenses that are regularly provided to the CODM and included within each reported measure of segment profit and loss. The amendments also require disclosure of all other segment items by reportable segment and a description of its composition. Additionally, the amendments require disclosure of the title and position of the CODM and an explanation of how the CODM uses the reported measure(s) of segment profit or loss in assessing segment performance and deciding how to allocate resources. This update is effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15,

2024. The Company adopted ASU 2023-07 on January 1, 2024 for annual disclosures for the year ended December 31, 2024, with no material effect on its consolidated financial statements, except for the related disclosures.

New Accounting Pronouncements – Not Yet Adopted

In December 2023, the FASB issued ASU *No. 2023-09, Income Taxes (ASC Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"), which establishes incremental disaggregation of income tax disclosures pertaining to the effective tax rate reconciliation and income taxes paid. The amendments in this update apply to all entities that are subject to ASC Topic 740, *Income Taxes*. For public business entities, the amendments in this update are effective for annual periods beginning after December 15, 2024, and early adoption is permitted. The Company is currently evaluating the provisions of the amendments and the impact on its income tax disclosures.

In November 2024, the FASB issued *ASU 2024-03, Disaggregation of Income Statement Expenses (DISE)* ("ASU 2024-03"), requiring additional disclosure of the nature of expenses included in the income statement. The new standard requires disclosures about specific types of expenses included in the expense captions presented on the face of the income statement as well as disclosures about selling expenses. The amendment in this update applies to all public business entities and is effective for annual reporting periods beginning after December 15, 2026 and interim reporting periods beginning after December 15, 2027. The Company is currently evaluating the provisions of the amendments and the impact on its disclosures.

3. Revenue

The Company does not currently have any commercial sales. The Company has entered 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 contain multiple promised goods and services, such as (i) licenses, (ii) research and development activities, and (iii) the manufacturing of certain materials. Payments pursuant to these arrangements include non-refundable payments upon the achievement of significant regulatory, development and commercial milestones, sales of product at certain agreed-upon amounts, and royalties on product sales.

The following table presents the components of the Company's revenues:

	Year Ended December 31,	
(in thousands)	**2024**	**2023**
Pfizer Inc. - Pfizer Agreement - Agreed-to reimbursement activities	$ 24	$ 3,666
Pfizer Inc. - Pfizer Agreement - Development milestones	6,960	—
Pfizer Inc. - Additional services	8	613
Johnson & Johnson Inc. - J&J Agreement	4,990	2,490
Total revenue from contracts with customers	**$ 11,982**	**$ 6,769**

Pfizer Agreement

In September 2022, the Company entered into a license agreement with Pfizer (formally Seagen Inc.) ("Pfizer") to develop, manufacture, and commercialize PF-8046052 (formerly LAVA-1223), an advanced preclinical asset that utilizes the Company's proprietary Gammabody technology to target EGFR-expressing solid tumors (the "Pfizer Agreement"). Under the terms of the Pfizer Agreement, the Company 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 Pfizer Agreement also provided Pfizer with the opportunity to exclusively negotiate rights to apply the Company's proprietary Gammabody platform on up to two additional tumor targets, although these rights expired during the year ended December 31, 2024. In March 2024, Pfizer achieved a clinical development

milestone for EGFRd2 (PF-08046052), resulting in the first milestone payment of $7.0 million to the Company under the Pfizer Agreement. The Company recognized the achievement of the milestone as revenue during the year ended December 31, 2024 as there are no remaining performance obligations under the contract.

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 the Company 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, the Company is entitled to receive increased future royalty percentages to a range of low teens to high mid-teen percentages on future sales, and certain future milestones will be decreased by 30%.

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 was 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. For the year ended December 31, 2024, the Company recognized less than $0.1 million related to the reimbursement of additional agreed-to services requested by Pfizer. For the year ended December 31, 2023, the Company recognized $4.3 million of revenue from the Pfizer Agreement, of which $3.7 million relates to the agreed-to reimbursement agreement and $0.6 million relates to reimbursement of additional other services requested by Pfizer. The Company does not anticipate receiving reimbursement for any additional agreed-to services at this time.

The Company determined that the Pfizer Agreement and the research, manufacturing, and supply activities and materials transfer fall within the scope of ASC 606. In calculating the transaction price, the Company 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 then allocated the transaction price to the performance obligations based upon the standalone selling price.

For each of the performance obligations identified 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, the Company immediately transferred ownership of the license 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 transferred license. As such, the Company has no significant continued involvement in the transferred license. Therefore, the transferred license is distinct from the other performance obligations in the agreement. Pfizer can begin to use and benefit from the license after the effective date of the Pfizer Agreement, as Pfizer is now the sole ‘owner’ of the underlying patents and know-how. $15.0 million of consideration was allocated to the license based upon the standalone selling price. See below for further discussion on the considerations of the buy-up fee. The $15.0 million consideration that was allocated to the license was recognized in 2022. The transaction price that was allocated to the license performance obligation is based upon the residual value approach due to the uniqueness of and lack of observable data related to the license.

- **License variable consideration restraint (Buy-up fee):** The Company determined that the one-time buy-up fee of $35.0 million represents variable consideration and not a performance obligation, for which it has deferred revenue recognition until such time the option expires or the Company exercises the option. The Company allocated the variable consideration from the buy-up fee to the license performance obligation as it aligns with the economic substance of the Pfizer Agreement. The Company received the non-refundable upfront payment of $50.0 million in October 2022, and recorded the variable consideration of $35.0 million as a deferred revenue liability. As of December 31, 2024, and December 31, 2023, the deferred revenue liability balance remained $35.0 million. If the Company does not exercise the buy-up option and the option expires, the Company will recognize the revenue related to the license performance obligation as there are no remaining performance obligations. If the Company does exercise the buy-up option, the Company will account for this amount 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.
- **Manufacturing technology transfer activities:** The Company recognizes manufacturing technology transfer activities over time. The Company performs these activities under the Pfizer Agreement at the direction of Pfizer. As such, the Company records revenue related to these activities over time as they occur, measured based on a cost-to-cost input method. The transaction price of $2.2 million that was allocated to the manufacturing technology transfer activities is based upon the estimated cost of providing the manufacturing technology transfer plus a margin. For manufacturing technology transfer activities performed, the Company recognized less than $0.1 million and $0.2 million of revenue for the years ended December 31, 2024, and 2023, respectively.
- **Initial supply:** The Company developed an initial supply of drug product, which it was obligated to transfer to Pfizer after entering into a separate supply and materials transfer agreement executed with Pfizer 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 of transfer. The transaction price of $3.6 million that was allocated to the initial supply of the drug is based upon the estimated cost of providing the initial supply of the drug product. After this transfer to Pfizer, the Company has no further rights or ownership to the drug product. For the years ended December 31, 2024, and 2023, the Company recognized $0.0 million and $3.4 million of revenue from the initial supply of drug product.
- **Research activities:** The Company recognizes research activities over time. The Company performs these activities under the Pfizer Agreement at the direction of Pfizer. As such, the Company records revenue related to these activities over time as they occur, measured based on a cost-to-cost input method. The transaction price of $0.8 million that was allocated to the research activities is based upon the estimated cost of providing the activities plus a margin. For the manufacturing and supply activities performed, the Company recognized $0.0 million and less than $0.1 million of revenue for the years ended December 31, 2024, and 2023, respectively.

Deferred Revenue

The Company's deferred revenue balance relates to amounts received but not yet earned under the Pfizer Agreement as described above. As of December 31, 2022, the Company established a deferred revenue balance related to the Pfizer Agreement buy-up option as described above. The balance as of December 31, 2024 is $35.0 million and there have been no changes during the years ended December 31, 2024 and 2023.

J&J Agreement

In May 2020, the Company entered into a research collaboration and license agreement (the "J&J Agreement") with Johnson & Johnson ("J&J") (formerly Janssen Biotech, Inc.). As part of the J&J Agreement, the Company received a non-refundable upfront payment of $8.0 million, which the Company recognized on a straight-line basis over the two-year term of the research activities under the J&J Agreement. The straight-line method of recognition materially approximates the cost-to-cost method of

revenue recognition. As of January 1, 2023, the Company had recorded the entirety of the $8.0 million upfront payment as revenue.

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. The Company is eligible to receive a research milestone and further payments upon the achievement of certain development and commercial milestones.

Development Milestones

In May 2023, upon selection of a lead bispecific antibody utilizing the Gammabody platform for an undisclosed tumor associated antigen for the treatment of cancer, the Company earned a milestone payment of $2.5 million from J&J under the terms of the J&J Agreement. Due to the variable consideration no longer being constrained as there are no remaining performance obligations, the Company recognized the $2.5 million milestone amount as revenue in May 2023 upon achievement of the milestone. The Company received this payment of the $2.5 million milestone amount in July 2023.

In October 2024, a milestone payment of $5.0 million from J&J was triggered under the terms of the J&J Agreement following filing with health authorities to start a Phase 1 clinical trial. Due to the variable consideration no longer being constrained as there are no remaining performance obligations, the Company recognized the $5.0 million milestone amount as revenue in October 2024 upon achievement of the milestone. The Company received this payment of the $5.0 million milestone amount in November 2024.

4. Property and Equipment, Net

The following table presents the components of the Company's property and equipment, net:

(in thousands)	As of December 31, 2024	2023
Leasehold improvements	$ 357	$ 378
Laboratory equipment	2,290	2,598
Office equipment	60	67
ICT equipment	301	294
Total property and equipment, gross	$ 3,008	$ 3,337
Less: accumulated depreciation	(2,006)	(1,735)
Total property and equipment, net	$ 1,002	$ 1,602

For the years ended December 31, 2024, and 2023, depreciation expense was $0.5 million and $0.6 million, respectively.

5. Leases

The Company leases various office equipment and laboratory and office space. The laboratories and offices are located in the Netherlands and the United States. The laboratory and office operating leases have various expiration dates through March 2026, and the office equipment has an expiration date of May 2028. These leases require periodic lease payments that may be subject to annual increases throughout the lease term. The Company has not included the periods associated with any renewal and extension options in the determination of the operating lease assets or lease liabilities associated with these leases, as the Company did not consider it reasonably certain that it would exercise the options.

The Company executed various operating lease arrangements during the years ended December 31, 2024, and 2023, summarized as follows:

LSI Lease

In November 2022, the Company commenced an operating lease arrangement for laboratory and office space on the first floor at Yalelaan 62 in Utrecht, the Netherlands. At the time of commencement, the lease had a term of 3.3 years. The lease contained a renewal option and a break option. At the time of commencement, total lease payments under the lease arrangement were $0.4 million.

In March 2023, the Company commenced an operating lease arrangement for laboratory and office space on the third and fourth floors at Yalelaan 62 in Utrecht, the Netherlands. At the time of commencement, the lease had a term of 3.2 years. The lease contained a renewal option for both floors and a break option for the fourth floor. As of the lease commencement date, the Company has determined that it is not reasonably certain to exercise the options and has not included the renewal option in the lease commencement term. At the time of commencement, total lease payments under the lease arrangement were $1.8 million. Upon commencement, the Company recorded an operating lease liability and a corresponding operating right-of-use asset of $1.4 million.

In August 2023, the Company executed its break option on the lease and informed the landlord that it would be terminating the lease of the first and fourth floors in February 2024. As a result of the termination, the Company reduced the lease operating lease liability and operating lease right-of-use asset by $0.5 million. The Company incurred no costs related to the lease termination.

Lease Disclosures

The weighted-average remaining lease term for the Company's operating leases was 1.20 years and 2.12 years at December 31, 2024, and December 31, 2023, respectively. The weighted-average discount rate for the Company's operating leases was 15.50% and 15.55% at December 31, 2024, and December 31, 2023, respectively.

The following table presents the components of lease expense recognized in operating expenses in the statements of operations:

	For the Year Ended December 31,	
(in thousands)	**2024**	**2023**
Operating lease expense	$ 468	$ 628
Variable lease expense	62	195
Short-term lease expense	44	98
Total lease expense	$ 574	$ 921

The variable lease expense consists of utility, common area maintenance, and real estate tax charges.

The following table presents the future minimum commitments under the Company's non-cancelable operating leases:

(in thousands)	December 31, 2024
2025	$ 343
2026	77
2027	3
2028	2
Total lease commitments	425
Less: imputed lease interest	(30)
Present value of operating lease liabilities	395
Less: current portion of operating lease liabilities	(315)
Non-current portion of operating lease liabilities	$ 80

For the years ended December 31, 2024, and 2023, the Company paid cash for the amounts included in the measurement of the lease liabilities of $0.5 million and $0.6 million, respectively.

6. Accrued Expenses and Other Current Liabilities

The following table presents the components of the Company's accrued expenses and other current liabilities:

	As of December 31,	
(in thousands)	2024	2023
Research and development external project costs	$ 7,138	$ 2,293
Personnel-related expenses	1,398	1,475
Professional fees	598	523
Other	949	460
	$ 10,083	$ 4,751

7. Restructuring

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 the redesigned focus on research and development. In connection with the reduction in force, the Company expensed $0.5 million during the year ended December 31, 2023. The Company completed the implementation of headcount reductions, including cash payments, by December 31, 2023.

8. Discontinuation of Clinical Trials

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 ("AML") was no longer recruiting and would be discontinued after no patients remain on treatment. The Company was evaluating LAVA-051 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 Company made the decision to discontinue the LAVA-051 clinical trial following 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 accrued $1.4 million in June 2023 for costs associated with contract manufacturing and bioanalytical activities for LAVA-051. Of the accrual, the Company paid $1.0 million in the year ended December 31, 2023 and $0.3 million in the year ended December 31, 2024. The Company reviewed the relevant items of its consolidated balance sheets 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 December 2024, the Company announced that the clinical trial of LAVA-1207 targeting prostate specific membrane antigen("PSMA")-expressing cancers for patients with metastatic castration resistant prostate cancer ("mCRPC") was no longer recruiting and would be discontinued after no patients remain on treatment. The Company was evaluating LAVA-1207 in an open-label, multi-center Phase 1 clinical trial to evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity and preliminary anti-tumor activity of LAVA-1207 and to determine recommended Phase 2a dose(s) for optimization in Phase 2a clinical trial. The Company made the decision to discontinue the LAVA-1207 as the Phase 1 study did not reach its internal benchmarks and the decision was made to discontinue the development program. The decision was not due to safety concerns. As a result of the discontinuation, the Company accrued $3.9 million in December 2024 for costs associated with contract manufacturing and bioanalytical activities for LAVA-1207. The Company expects to pay the $3.9 million in the year ending December 31, 2025. The Company reviewed the relevant items of its consolidated balance sheets and did not identify any asset that would be subject to impairment as a result of the discontinuation of the clinical trial of LAVA-1207.

9. Borrowings

The following table presents the current components of the Company's Innovation Credit debt:

			As of December 31,	
			2024	2023
(in thousands)	Stated interest rate	Maturity	Amount, including accrued interest	Amount, including accrued interest
Innovation Credit	10.0 %	9/30/2025	$ 4,886	$ 5,282
Current			$ 4,886	$ 5,282
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 the Company pledged certain assets of that project 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.

As of December 31, 2024, and December 31, 2023, the Company had $4.9 million and $5.3 million, respectively, in borrowings under the Credit, all of which was classified as short-term, and includes accrued interest. As of December 31, 2024, and December 31, 2023, the fair value of the Credit is $4.9 million and $5.3 million, respectively, and is based on Level 2 inputs. The Company determined the carrying value of the Credit is approximately equal to its fair value due to the nature of the Credit, and the Company's evaluation of estimated market prices of the Credit agreement.

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, and October 2022. In April 2023, the reporting dates for the last three reporting periods were extended by eighteen months.

The June 2023 discontinuance of the LAVA-051 program (see Note 8) ended the receipt of future installments of the Innovation Credit. The Company filed the required Project Settlement Report in July 2024 because of the discontinuance of the LAVA-051 program. As the Company expected RVO to make its decision on repayment of the Credit in the second half of 2024, the Company has classified the Credit as a current liability as of December 31, 2023.

In October 2024, the Company received notice from the RVO requiring a payment of $0.6 million within six weeks of the notice date, which was subsequently paid in December 2024. The remaining balance of $4.9 million, which is inclusive of principal and accrued interest, has been conditionally waived by RVO with a further decision to be made within one year from the notice date. Upon satisfaction of certain conditions related to pledged assets in the conditional waiver, the Company may request a permanent waiver from its remaining payment obligations to the RVO. The liability will remain classified as current, as the waiver lasts one year from the notice date.

As of December 31, 2024, the Company was in compliance with all of the terms of the Credit.

The Company recognized interest expense related to the Credit of $0.5 million and $0.4 million for the years ended December 31, 2024, and 2023, respectively.

10. Commitments and Contingencies

The Company accrues for contingency liabilities, including those involving general liability, workers' compensation, and other matters, when it is probable that the Company will incur and can reasonably estimate future costs (including legal fees and expenses). The Company bases the accruals on developments to date, management's estimates of the outcomes of these matters, the Company's experience in contesting, litigating, and settling similar matters. The Company reviews its legal contingencies at each reporting period and adjusts the liabilities to reflect the current best estimate. The Company was not party to any pending legal proceedings or claims as of December 31, 2024 or December 31, 2023. Other than the Amsterdam UMC Agreement described below, the Company did not make any material commitments outside the normal course of business.

Amsterdam UMC Agreement

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 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 low single-digit tiered royalties on net sales of products covered by claims included in the assigned patent rights. The Company has not incurred or paid royalties to Amsterdam UMC at this time, as there have been no net sales of the products covered by the claims. 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 the Company having rights to such patent right.

11. Common Shares

As of December 31, 2024, the articles of association authorize the Company to issue 90.0 million common shares. Prior to the June 2024 annual meeting, the articles of association authorized the Company to issue 45.0 million common shares and 45.0 million preferred shares. As part of the June 2024 annual meeting, the Company's general meeting approved reallocation of part of the authorized share capital that was reserved for the potential issuance of preferred shares for the potential issuance of common shares.

Each common share is entitled to cast one vote at the general meeting. Common shareholders are entitled to dividends and other distributions if and when declared. As of December 31, 2024, the Company had not declared any dividends on common shares and had no preferred shares outstanding.

The following table sets forth the aggregate information on all share-based compensation plans as:

	As of December 31,	
Number	**2024**	**2023**
Shares available for future options grants under the 2021 LTIP	644,532	957,505
Share options issued and outstanding	6,608,846	5,260,518
Total	7,253,378	6,218,023

12. Share-based Compensation

Share Plans

In 2018, the Company established the 2018 Stock Option Plan (the "2018 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 (the "2020 Plan") that entitles employees, directors and consultants providing services 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 March 2021, the Company established the 2021 Long-Term Incentive Plan (the "2021 LTIP"), as an incentive for all employees, members of the 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 were terminated and ceased to have any future shares available. Initially, the maximum number of common shares that may be issued under the 2021 LTIP after it became effective was 2,535,226 shares. The number of common shares reserved for issuance under the 2021 LTIP automatically increases on January 1 of each calendar year, starting on January 1, 2022 and continuing through January 1, 2031, in an amount equal to 4% of the total number of shares of our issued share capital on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the Company's board of directors. The number of shares available for awards under the 2021 LTIP increased by 1,051,563 and 1,051,563 for the years 2024 and 2023, respectively.

Under the option plans, the options granted generally have a maximum term of ten 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.

In March 2021, the Company established the 2021 Employee Stock Purchase Plan (the "ESPP"). The ESPP authorizes the issuance of common shares under purchase rights granted to the Company's employees or to employees of any of the Company's designated affiliates. The ESPP initially provided participating employees with the opportunity to purchase up to an aggregate of 253,523 common shares. The number of common shares reserved for issuance automatically increases on January 1 of each calendar year, starting on January 1, 2022 and continuing through January 1, 2031, by the lesser of (i) 1 % of the total number of common shares outstanding on December 31st of the preceding calendar year and (ii) 760,000 shares, or a lesser number of shares determined by the Company's board of directors. As of the date hereof, none of our common shares have been purchased under the ESPP.

Share Options

During the years ended December 31, 2024, and 2023, the board of directors granted 1,602,290 and 879,771 share-based options, respectively.

The following table provides movement information about the Company's share-based awards issued under the 2018 Plan:

	Number of options	Weighted-average exercise price ($)	Aggregate intrinsic value (in thousands)	Weighted-average remaining contractual term (years)
Outstanding as of January 1, 2024	600,457	$ 0.01	$ 949	(*)
Granted	—	—		
Exercised	(6,630)	0.01		
Expired	—	—		
Forfeited	—	—		
Outstanding as of December 31, 2024	593,827	$ —	$ 565	(*)
Vested and expected to vest as of December 31, 2024	593,827	$ 0.01	$ 565	(*)
Exercisable and vested at December 31, 2024	574,186	$ 0.01	$ 546	(*)
(*) contract term does not have fixed end date				

The following table provides movement information about the Company's share-based awards issued under the 2020 Plan:

	Number of options	Weighted-average exercise price ($)	Aggregate intrinsic value (in thousands)	Weighted-average remaining contractual term (years)
Outstanding as of January 1, 2024	999,755	$ 4.46	$ —	7.04
Granted	—	—		
Exercised	—	—		
Expired	—	—		
Forfeited	—	—		
Outstanding as of December 31, 2024	999,755	$ —	$ —	5.79
Vested and expected to vest as of December 31, 2024	999,755	$ 4.46	$ —	5.79
Exercisable and vested at December 31, 2024	970,753	$ 4.47	$ —	5.78

The following table provides movement information about the Company's share-based awards issued under the 2021 LTIP:

	Number of options	Weighted-average exercise price ($)	Aggregate intrinsic value (in thousands)	Weighted-average remaining contractual term (years)
Outstanding as of January 1, 2024	3,660,306	$ 4.27	$ —	8.73
Granted	1,602,290	1.59		
Exercised	(9,578)	2.77		
Expired	(104,470)	4.38		
Forfeited	(133,284)	2.80		
Outstanding as of December 31, 2024	5,015,264	$ —	$ —	8.12
Vested and expected to vest as of December 31, 2024	5,015,264	$ 3.45	$ —	8.12
Exercisable and vested at December 31, 2024	2,367,280	$ 4.15	$ —	7.77

Prior to the IPO in March 2021, the Company granted options with a contractual exercise price in EUR. After the IPO, all options are granted with an exercise price in USD.

As of December 31, 2024, the Company's outstanding options had exercise prices ranging from $0.01 to $15.00.

There were 16,208 options exercised during the year ended December 31, 2024. For the year ended December 31, 2024, the weighted-average share price at the date of exercise was $2.60. For the years ended December 31, 2024, and 2023, the weighted-average grant date fair value of granted stock options was $1.22 per share and $2.39 per share, respectively.

Share-based Compensation Expense

For the years ended December 31, 2024, and 2023, the Company recognized share-based compensation expense of $3.2 million and $5.0 million, respectively.

The following table presents the Company's share-based compensation expense:

	For the Year Ended December 31,	
(in thousands)	**2024**	**2023**
General and administrative expenses	$ 2,046	$ 3,311
Research and development expenses	1,180	1,728
Total share-based compensation expense	$ 3,226	$ 5,039

As of December 31, 2024, there is $1.8 million of unrecognized share-based compensation expense, which the Company will recognize over a weighted-average remaining recognition period of 0.77 years.

The Company uses the Black-Scholes option-pricing model, which requires the use of subjective assumptions, to determine the fair value of the share-based options on the date of grant and to determine the related compensation expense. The following tables outlines the assumptions and inputs used in the measurement of the weighted-average fair value of the granted share options:

	For the Year Ended December 31,	
	2024	2023
Expected term (years)	6.08	6.08
Expected volatility	89.26%	88.40%
Risk-free interest rate	3.90% - 4.34%	3.46% - 4.98%
Dividend yield	0.00%	0.00%
Fair value of underlying common shares	$ 0.95 - 1.57	$ 1.06 - 2.92
Exercise price	$ 1.20 - 2.03	$ 1.40 - 3.86

Expected Term—The expected term represents the period that the Company's share-based awards are expected to be outstanding. The Company determined the expected term using the simplified method, which is based on the mid-point between the contractual term and vesting period.

Volatility— Since the Company was a private company until March 2021, there is limited available Company-specific historical and implied volatility information. The Company therefore estimates expected volatility 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 being estimated, as well as the Company's own limited historical share performance and its own share-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 with consideration to 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.

Risk-Free Interest Rate—The Company determines the risk-free interest rate by reference to the U.S. Treasury zero-coupon yield curve in effect at the time of grant of the award for the time period approximately equal to the expected term of the award.

Dividend Yield—The Company has never paid dividends on its common shares and does not anticipate paying any dividends on its common shares. Therefore, the Company uses an expected dividend yield of zero.

13. Income Taxes

The following table presents the domestic and foreign components of (loss) income before income taxes:

	For the Year Ended December 31,	
(in thousands)	2024	2023
United States	$ 1,006	$ 789
Netherlands	(26,099)	(42,403)
Australia	609	—
Total	$ (24,484)	$ (41,614)

The following table presents the expense from income taxes:

(in thousands)	For the Year Ended December 31, 2024	2023
Current:		
Federal - U.S.	$ 195	$ 138
State - U.S.	158	119
Netherlands	—	—
Australia	287	—
Total current	$ 640	$ 257
Deferred:		
Federal - U.S.	$ (6)	$ —
State - U.S.	(4)	—
Netherlands	—	—
Australia	—	—
Total deferred	$ (10)	$ —
Expense from income taxes	$ 630	$ 257

For the years ended December 31, 2024, and 2023, for tax purposes, the Company amortized capitalized IP development costs of $16.1 million and $14.8 million, respectively. As of December 31, 2024, the Company has capitalized a total of $52.0 million of IP development costs, which will reduce future taxable income due to future tax amortization of capitalized IP development costs.

As of December 31, 2024, the Company has tax loss carryforwards of $106.5 million, which can be carried forward indefinitely but utilization of the tax loss carryforwards is limited to 50% of the taxable amount to the extent this exceeds EUR 1.0 million.

The following table presents the gross net operating losses available for the year:

(in thousands)	For the Year Ended December 31, 2024	2023
United States	$ —	$ —
Netherlands	106,513	66,411
Australia	—	—
Total gross net operating loss carryforwards	$ 106,513	$ 66,411

The Company has differences between the financial reporting and tax treatment of its financial statement items. These differences primarily relate to the amortization of IP development costs capitalized in preceding years for Dutch corporate income tax purposes, the capitalization of IP development costs incurred in 2024 for Dutch corporate income tax purposes, ASC 842 lease amounts, non-deductible share-based payment expenses, expenses which were treated as non-deductible for Dutch corporate income tax purposes.

The Company accounts for income taxes under ASC Topic 740, *Income Taxes* (“ASC 740”). ASC 740 requires the recognition of deferred tax assets and liabilities for both the expected impact of differences between the consolidated financial statements and tax basis of assets and liabilities and for the expected future tax benefit to be derived from tax loss carry forwards. ASC 740 additionally requires a valuation allowance to be established when it is more likely than not that all or a portion of deferred tax assets will not be realized.

The Company has determined, based upon available evidence, that it is more likely than not that the net Netherlands deferred tax asset will not be realized and, accordingly, has provided a full valuation allowance against it.

The following table reflects the activity in the valuation allowance for the year:

	For the Year Ended December 31,	
(in thousands)	2024	2023
Balance, January 1	$ 37,048	$ 25,003
Increase as reflected in income tax expense	4,322	12,046
Balance, December 31	$ 41,371	$ 37,048

The following table presents the reconciliation of the statutory U.S. income tax rate to the Company's effective income tax rate:

	For the Year Ended December 31,	
	2024	2023
Expected tax	% 21.0	% 25.8
Foreign rate differential	5.0	0.0
State and local income taxes	(0.5)	(0.2)
Other non-deductible and permanent differences	(3.8)	(3.1)
Valuation allowance	(24.3)	(23.2)
Total	% (2.6)	% (0.7)

The Company's overall effective tax rate is affected by non-deductible expenses and permanent differences, difference in overseas tax rates, and changes in valuation allowance for unrecognized net deferred tax assets. The Company has made provisions for deferred taxes based on the differences between the basis of the assets and liabilities for financial statement purposes and the basis of the assets and liabilities for tax purposes using currently enacted tax rates and regulations that are expected to be in effect when the Company expects the differences to be recovered or settled. The components of the deferred tax assets and liabilities are as follows:

	For the Year Ended December 31,	
(in thousands)	2024	2023
Deferred tax assets:		
Net operating loss carryforward	$ 27,967	$ 18,440
Research and development	13,417	18,615
Lease liabilities	102	213
Accruals and other	23	—
Gross deferred tax assets	$ 41,509	$ 37,268
Less: Valuation allowance	(41,371)	(37,048)
Total deferred tax assets	$ 138	$ 220
Deferred tax liabilities:		
Operating right-of-use	$ (114)	$ (220)
Property, plant and equipment	(14)	—
Gross deferred tax liabilities	$ (128)	$ (220)
Total deferred taxes	$ 10	$ —

The Company follows authoritative guidance regarding accounting for uncertainty in income taxes, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company recognizes interest and penalties, if any, related to uncertain tax positions in income tax expense. There

are no uncertain tax positions as of December 31, 2024 and December 31, 2023. Therefore, there is no interest and penalties related to uncertain tax positions that were accrued at December 31, 2024 and December 31, 2023.

The Company does not have any unrecognized tax benefits.

The Company is subject to taxation in the Netherlands and foreign jurisdictions. The Company has operations and filing obligations in the United States, the Netherlands, and Australia. Typically, the period for the statute of limitations ranges from three to five years, but this period could be extended due to the Company's NOL carryforward position in a number of its jurisdictions. The tax authorities generally have the ability to review income tax returns for periods where the statute of limitations has previously expired and can subsequently adjust the NOL carryforward or tax credit amounts.

14. Earnings Per Share (EPS)

The Company calculates basic EPS by dividing the loss for the period attributable to common equity holders of the parent by the weighted average number of common shares outstanding during the period. The Company accounts for vested share-based awards that are issued little to no consideration, as issuable common shares. As the share options under the 2018 Stock Option Plan have an exercise price of little to no consideration, the Company considers these share options to be issuable common shares and therefore included these options in the common shares outstanding.

The Company calculates diluted EPS by dividing the 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, 2024, and 2023, the Company had potentially dilutive share-based options of 6,015,019 and 4,660,061, respectively. The Company excluded these awards 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 as the Company was in a net loss position in both periods.

The following table presents the loss and share data utilized by the Company in its basic and diluted EPS calculations:

	For the Year Ended December 31,	
(in thousands, except for share and per share amounts)	**2024**	**2023**
Loss for the year	$ (25,114)	$ (41,871)
Weighted average number of common shares	26,834,422	26,732,556
Basic and diluted loss per share	$ (0.94)	$ (1.57)

15. Segment Information

As of December 31, 2024, and 2023, the Company's long lived assets, net were domiciled in the following countries:

	For the Year Ended December 31,	
(in thousands)	**2024**	**2023**
Long-lived assets domiciled in the Netherlands	$ 951	$ 1,560
Long-lived assets domiciled in the US and Australia	51	42
Total long-lived assets, net	**$ 1,002**	**$ 1,602**

For the year ended December 31, 2024, and 2023, the Company's generated revenue in the following countries:

(in thousands)	For the Year Ended December 31, 2024	2023
Revenue in the Netherlands	$ 11,982	$ 6,769
Total revenue	**$ 11,982**	**$ 6,769**

16. Retirement Plans

The Company provides defined contribution plans to its employees. The Company expenses contributions to defined contribution plans as the 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. For the years ended December 31, 2024, and 2023, the Company incurred expenses associated with the servicing of defined contribution plans of $0.4 million and $0.6 million, respectively.

17. Subsequent Events

In February 2025, the Company adopted a restructuring plan to extend its capital resources in connection with initiating a process to evaluate strategic alternatives. As part of the restructuring plan, the Company approved a reduction of approximately 30% of the global workforce to better align the Company's resources with its focus on LAVA-1266. The Company expects approximately $1.0 million of expenses related to the restructuring to be incurred during the six months ended June 30, 2025, of which approximately $0.3 million of cash payments are expected to be made during 2025.