Table of Contents

As filed with the Securities and Exchange Commission on December 23, 2022

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

FORM 20-F/A
(Amendment No. 1)

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

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

For the fiscal year ended December 31, 2021

OR

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

For the transition period from to

OR

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

Date of event requiring this shell company report

Commission file number: 001-40241

LAVA Therapeutics N.V.
(Exact Name of Registrant as Specified in its Charter)

Not Applicable
(Translation of Registrant's Name into English)

The Netherlands
(Jurisdiction of Incorporation or Organization)

Yalelaan 60
3584 CM Utrecht, The Netherlands
+31 85 016 3100
(Address of principal executive offices)

Lava Therapeutics, Inc.
520 Walnut St, Suite 1150
Philadelphia, PA 19106
ir@lavatherapeutics.com
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be 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, par value $0.14 per share	**LVTX**	**NASDAQ Global Select Market**

Securities registered or to be registered pursuant to Section 12(g) of the Act: None
Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

As of December 31, 2021, the issuer had 25,775,538 common shares outstanding.

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

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. 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, or an emerging growth company.

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

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, 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. ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Explanatory Note

This Amendment No. 1 to Form 20-F (Form 20-F/A) is being filed by Lava Therapeutics N.V. (Company) to amend the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2021, filed with the Securities and Exchange Commission on March 24, 2022 (Original Filing). The Company is filing this Form 20-F/A to amend Item 15 of Part II of the Original Filing to include disclosure of management's assessment of the effectiveness of the Company's disclosure controls and procedures as of December 31, 2021.

This Form 20-F/A does not reflect events occurring after the filing of the Original Filing and does not modify or update disclosures in the Original Filing in any way other than as required to reflect the revisions described above. Among other things, forward-looking statements made in the Original Filing have not been revised to reflect events that occurred or facts that became known to us after the filing of the Original Filing, and any such forward looking statements should be read in their historical context.

TABLE OF CONTENTS

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" and "potential," among others. Forward-looking statements appear in a number of places in this annual report and include, but are not limited to, statements regarding our intent, belief or current expectations. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various important factors, including, but not limited to, those identified under the section titled "Risk Factors" in Item 3 of this annual report. Forward-looking statements include, but are not limited to, statements about:

- our operations as a biotechnology company with limited operating history and a history of operating losses;
- our plans to develop and commercialize our 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 expectations regarding the impact of the COVID-19 pandemic on our business, our industry and the economy;
- 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 such product candidates;
- our continued reliance on third parties to conduct clinical trials of our product candidates and manufacture our product candidates for preclinical studies and clinical trials;
- our ability to fund our working capital requirements and expectations regarding the sufficiency of our capital resources;
- the implementation of our business model and strategic plans for our business and product candidates;
- our ability to establish sales, marketing and distribution capabilities;
- our intellectual property position and the duration of our patent rights;
- our estimates regarding expenses, future revenues, capital requirements and our needs for additional financing;
- the impact of government laws and regulations on our business;
- our need to hire additional personnel and our ability to attract and retain such personnel;
- our ability to compete in the markets we serve;
- developments relating to our competitors and our industry; and
- other risk factors discussed under "Risk Factors."

Forward-looking statements speak only as of the date they are made, and we do not undertake any obligation to update them in light of new information or future developments or to release publicly any revisions to these

statements in order to reflect later events or circumstances or to reflect the occurrence of unanticipated events, except to the extent required by applicable law.

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISORS

Not required for annual reports.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not required for annual reports.

ITEM 3. Key Information

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 5: Operating and Financial Review and Prospects." The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. In such an event, the market price of our common shares could decline, and you may lose all or part of your investment.

Summary Risk Factors

Risks related to our financial position and capital needs

- We anticipate incurring substantial operating losses for the foreseeable future and may never achieve or maintain profitability.
- We have a limited operating history, which makes it difficult to assess our future viability.
- We will require substantial additional funding to finance our operations to complete the development and commence commercialization of our product candidates.

Risks related to the development and commercialization of our product candidates

- Our product candidates and related technologies are novel approaches to cancer treatment, which makes it difficult to predict the time and cost of development and subsequent regulatory approval.
- We are dependent on the successful clinical development and regulatory approval of our product candidates. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates.
- Success in preclinical studies or early-stage clinical trials may not be indicative of results in future clinical trials.
- 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.
- 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.
- 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 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.

- The COVID-19 pandemic could continue to adversely impact our business, including our clinical trials, supply chain and business development activities.
- Interim, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.
- We face significant competition, and many of our competitors have substantially greater experience and resources than we have.

Risks related to manufacturing

- 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 product candidates.
- To date, we have relied on a single-source supplier for bulk drug substance and drug manufacturing. 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 candidates or otherwise delay the development process, which could adversely affect our business.

Risks related to our intellectual property

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

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

- We plan to expand our organization, and we may experience difficulties in managing this growth.
- There are risks inherent in our business that may subject us to potential product liability suits and other claims.
- We rely and expect to continue to be dependent and rely on third parties for key aspects of our business and operations, including our existing and future research, manufacturing and supply.
- If the security of the personal information that we collect, store or process is compromised, we may be exposed to liability and loss of business.
- We may be classified as a passive foreign investment company (PFIC) for U.S. federal income tax purposes, which could result in adverse U.S. federal income tax consequences to U.S. investors in the common shares.

Risks related to regulatory compliance

- The regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our 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.
- Coverage and adequate reimbursement may not be available for our product candidates.
- Healthcare legislative reform measures may have a negative impact on our business and results of operations.

Risks related to ownership of our common shares

- The market price of our common shares has been, and may continue to be volatile.
- Shareholders may not be able to exercise pre-emption rights and, as a result, may experience substantial dilution upon future issuances of common shares.
- We have identified material weaknesses in our internal control over financial reporting.

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 $45.3 million and $15.5 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $78.7 million. To date, we have not recognized significant revenues, and 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, 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-051 and LAVA-1207;
- initiate, conduct and complete any ongoing, anticipated or future preclinical studies and clinical trials for our current and future product candidates;
- develop processes and scale manufacturing production for our current and future product candidates in accordance with current Good Manufacturing Practices (cGMP);
- seek regulatory and marketing approvals for LAVA-051, LAVA-1207 and any of our other product 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 (U.S.) and Europe;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;

- acquire or in-license additional product candidates and technologies;
- develop a potential companion diagnostic;
- incur additional legal, accounting and other expenses associated with operating as a public company; and
- address any ancillary effects of the COVID-19 pandemic on our business.

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 product candidates, our expenses could increase.

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.

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

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

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will eventually need to transition from a company with a research and clinical focus to a company capable of supporting commercial activities, if any of our 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 product candidates. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the Phase 1/2a clinical trials for LAVA-051 and LAVA-1207, initiate later-stage clinical development, and continue to research, develop and initiate clinical trials for other product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution.

Furthermore, our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations

and planned research and clinical development activities. Because the design and outcome of our ongoing and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. Although it is difficult to forecast all of our future liquidity requirements, based on our current research and development plans, we believe that our existing cash, cash equivalents and investments will be sufficient to fund our operations through at least the next 12 months. Moreover, we will need to obtain substantial additional funding in connection with our continuing operations and planned research and clinical development activities. Our future capital requirements will depend on many factors, including:

- the timing, progress, costs and results of the Phase 1/2a clinical trials for LAVA-051 and LAVA-1207 and any later-stage clinical trials for these product candidates, after accounting for any COVID-19-related delays or other effects on our development programs;
- the timing, progress, costs and results of our ongoing preclinical studies, laboratory testing and clinical trials of other product candidate we may pursue, after accounting for any COVID-19-related delays or other effects on our development programs;
- the costs involved in growing our organization to the size and expertise needed to allow for the research, development and potential commercialization of our current or any future product candidates;
- our ability to establish collaborations on favorable terms, if at all;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we may receive marketing approval;
- further development of our Gammabody platform;
- validation of commercial-scale cGMP manufacturing process for LAVA-051 and LAVA-1207 and additional product candidates;
- the revenue, if any, received from commercial sales of our product candidates for which we may receive marketing approval;
- the cost of any milestone and royalty payments with respect to any approved product candidates.
- the payment of the second and third Exit payment under the license and assignment agreement (VUmc Agreement) with Stichting VUmc (VUmc) to the extent we elect to pay either of such payments in cash;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims;
- the costs of operating as a public company; and
- the extent to which we acquire or in-license other product candidates and technologies.

Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. Disruptions in the financial markets in general and the COVID-19 pandemic may make equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. If we are unable to obtain sufficient funding in a timely manner or on commercially acceptable terms, we may have to delay, reduce the scope of, or eliminate one or more of our operating activities, and consider other cost reduction initiatives, such as downsizing our operations 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 and could reduce the price of our common shares and we may ultimately go into 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.

Risks related to the development and commercialization of our product candidates

Our product candidates and related technologies, including LAVA-051 and LAVA-1207, which are based on bispecific gamma delta T cell engagers, are novel approaches to cancer treatment, which makes it difficult to predict the time and cost of development and subsequent regulatory approval. Currently, there are no bispecific gamma delta T cell engagers which have been approved for cancer treatment by the 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 gamma delta bispecific T cell engager product candidates.

To date, gamma delta T cells and products that induce gamma delta T cell activation have only been evaluated in a limited number of early clinical trials. These clinical trials were primarily designed to evaluate safety and tolerability, and not designed to produce statistically significant results as to efficacy. Although prior clinical trials by other companies have shown early signs of gamma delta T cell efficacy, and other clinical trials have produced encouraging results regarding bispecifics, our Phase 1/2a clinical trials for LAVA-051 and LAVA-1207 are the only clinical trials conducted regarding our Gammabody platform. Even after the completion of our Phase 1/2a clinical trials for LAVA-051 and LAVA-1207, our Gammabody product candidates will have only been tested in a small number of patients. Results from these clinical trials may not necessarily 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-051, LAVA-1207 and additional product candidates, in particular, as a result of the limited amount of prior studies and clinical trials of gamma delta 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 our LAVA-051 and LAVA-1207 product candidates are in early stages of development and may never be commercialized. Although we intend to leverage our experience with LAVA-051 and LAVA-1207 in our preclinical and clinical development of other product candidates, we may be unable to reduce development timelines or costs for our other Gammabody programs. For instance, we may encounter unforeseen problems and delays for current and future product candidates that are either or both specific to a product candidate or extend to multiple product candidates. We also may experience unanticipated problems or delays in expanding our manufacturing capacity, which may prevent us from completing our clinical trials, meeting the obligations of our collaborations or commercializing our products on a timely or profitable basis, if at all.

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 be because 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, because the FDA, EMA or other regulatory body disagrees with how we interpret the data from these clinical trials, or they do not accept these therapeutic effects as valid endpoints in pivotal clinical trials necessary for market approval. We will also need to demonstrate that our product candidates are safe. 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.

Moreover, 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 developed by other companies have been observed to cause safety issues, including cytokine release syndrome (CRS), which have resulted in a delay or abandonment of those clinical programs. At present one bispecific T cell engager, blinatumomab, is approved. Our Gammabody class of

bispecific gamma delta T cell engager product candidates have been perceived as potentially having similar complications. These perceived complications have affected the clinical protocol design of our clinical trials in the United States and may have further impact in different jurisdictions. Because all of our product candidates 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 generally, 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 also be perceived to have additional complications, due to their unique mechanism of action (MoA). If our 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.

In light of the foregoing, 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.

We are dependent on the successful clinical development and regulatory approval of our product candidates. We cannot give any assurance that LAVA-051, LAVA-1207 or any of our future product candidates will receive regulatory approval, and if we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, which will adversely affect our ability to generate product revenue.

We are in early-stage clinical development with two lead product candidates, LAVA-051 and LAVA-1207. Our business is dependent on our ability to successfully complete development of, and obtain regulatory approval for, our product candidates in a timely manner. We may face unforeseen challenges in our product candidate development strategy, and we can provide no assurances that (i) our product candidates will prove to be effective, (ii) we will be able to take advantage of abbreviated regulatory pathways for any of our product candidates or (iii) we will ultimately be successful in our ongoing and future clinical trials.

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

Our ability to successfully complete clinical development and obtain regulatory approval 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;
- 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 current Phase 1/2a clinical trials for LAVA-051 and LAVA-1207 involve 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 trials for LAVA-051 and LAVA-1207 and other potential product candidates;
- delays or setbacks in patient identification, qualification and enrollment;
- clinical trials of our product candidates may produce negative or inconclusive results;
- 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;
- the impact of the ongoing COVID-19 pandemic, which has slowed enrollment, reduced the number of eligible patients for clinical trials, and may reduce the number of patients that remain in our trials;
- imposition of a clinical hold by regulatory authorities as a result of, among other reasons, a serious adverse event or a failed inspection of our clinical trial operations, trial sites or manufacturing facilities;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; and
- need to conduct additional clinical trials or abandon product development programs.

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

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

Results from preclinical studies or early-stage clinical trials are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. Our lead product candidates, LAVA-051 and LAVA-1207, are still in the early stages of development in their Phase 1/2a clinical trials. As a result, our product candidates may fail to show the desired safety and efficacy in clinical development despite demonstrating positive results in preclinical studies or having successfully advanced through initial clinical trials.

Furthermore, we have limited safety and limited clinical efficacy data for the use of LAVA-051 and LAVA-1207 in humans. There can be no assurance that the results seen in preclinical studies for any of our product candidates ultimately will result in success in clinical trials. In addition, there can be no assurance that we will be able to achieve the same or similar success in our preclinical studies and clinical trials of our other product candidates.

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

experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval.

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

We 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 trials for LAVA-051 and LAVA-1207 and future preclinical and clinical studies. 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.

Our CROs are required to comply with good laboratory practices (GLPs) and good clinical practices (GCPs) which are regulations and guidelines enforced by the FDA and comparable regulatory authorities in the form of International Council for Harmonization (ICH) guidelines 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 amount 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. As a result, 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. We cannot predict with any certainty the schedule for completion of clinical trials for LAVA-051 and LAVA-1207 or commencement and completion of future clinical trials. If we experience delays in the commencement or completion of 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 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 their ability to hire and retain key personnel as well as those resulting from the ongoing COVID-19 pandemic 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.

In 2020, in response to the COVID-19 pandemic, the FDA postponed most inspections of foreign manufacturing facilities, and the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based prioritization system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting regular inspections, reviews, or other

regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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

For LAVA-051 and LAVA-1207, we do not believe it will be necessary to use FDA-cleared or CE marked or FDA-approved diagnostic tests to diagnose patients or to assure the safe and effective use of product candidates in clinical trial patients. The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express the specific marker that the companion diagnostic was developed to detect.

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

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

We are developing LAVA-051 and LAVA-1207, which may be used in combination with approved therapies, which may present additional challenges. We have not studied the benefits and potential challenges or side effects of combination therapies. For example, the FDA, EMA or other comparable regulatory authority may require us to use more complex clinical trial designs in order 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. Moreover, 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-051 and LAVA-1207 clinical trials and future product candidates is critical to our success. We may encounter difficulties in enrolling a sufficient number of eligible patients to participate in our clinical trials, thereby delaying or preventing development and approval of our product candidates. For example, we have experienced challenges in identifying qualifying patients due to the impact of the ongoing COVID-19 pandemic. Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our clinical trials. Because our focus could include diseases with limited patient

populations, there may be limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner. If any such patient enrolled in any of our clinical trials has to drop out due to pre-existing 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. As such, 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;
- limitations caused by COVID-19 or governmental restrictions imposed in response to the pandemic;
- 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, including but not limited to, patients' unwillingness to participate due to the ongoing COVID-19 pandemic;
- 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 health care capacities are required to cope with natural disasters, epidemics or other health system emergencies, such as the ongoing COVID-19 pandemic.

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-051 or LAVA-1207 clinical trials 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 or undesirable or unexpected side effects of LAVA-051, LAVA-1207 or future product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their doctor. Often, it is not possible to determine whether or not 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 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 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 trials 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 LAVA-051 and LAVA-1207 in a limited number of patients with cancer and these clinical trial participants have only been observed for a limited period of time after dosing. As we continue developing LAVA-051 and LAVA-1207 and initiate clinical trials of our additional product candidates, serious adverse events (SAEs), undesirable or potentially fatal side effects, CRS, viral infections, relapse of disease or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the SAEs or undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective or in which efficacy is more pronounced or durable. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, and inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Should we observe SAEs 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, a number of potentially significant negative consequences could result.

Any of these 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.

The COVID-19 pandemic could continue to adversely impact our business, including our clinical trials, supply chain and business development activities.

In connection with the COVID-19 pandemic, governments have implemented significant measures, including closures of businesses, quarantines, travel restrictions and other social distancing directives, intended to control the spread of the virus. In response to these public health directives and orders, we have implemented certain travel restrictions and work-from-home policies for our employees, and as a result we have experienced limitations and impacts on employee resources. The effects of government actions and our own policies and those of third parties to reduce the spread of COVID-19 may negatively impact our productivity, including actions and policies that have slowed down and delayed our clinical trials, preclinical studies and research and development activities, and have caused disruptions to our supply chain, to the administrative functions of clinical trial sites and/or to the operations of our other partners. The result of such impacts may impair our ability to execute our programs and/or business development strategy. In the event that government authorities were to enhance current restrictions, our employees who currently are not

telecommuting may no longer be able to access our facilities, including our laboratories and our operations may be further limited or curtailed.

Our clinical trials for LAVA-051 and LAVA-1207 have been, and may continue to be affected, directly or indirectly, by the COVID-19 pandemic. To date, the spread of COVID-19 in the Netherlands, Spain and Italy has impacted the intensive care unit capacity at the hospitals participating in our clinical trials and has slowed the rate of patient enrollment. As the COVID-19 pandemic continues we may experience other disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving approval from local or federal regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling, treating and maintaining patients in clinical trials;
- delays or difficulties in shipping and delivering in a timely manner supplies, samples or products required for our clinical trials due to the impact of the COVID-19 pandemic on the United States Postal Service, FedEx, United Parcel Service and/or other commercial shipping organizations;
- delays or difficulties in clinical site initiation, including difficulties completing any required contracts, successfully completing IRB review in a timely manner, or in recruiting clinical site investigators and clinical site staff;
- disruptions in our supply chain that result in shortages of reagents, equipment or materials to conduct our laboratory experiments and/or clinical trials;
- changes in local regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or cause us to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- difficulties in recruiting and retaining principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19;
- difficulties in capital raising efforts to support our business;
- delays in the development of product candidates;
- delays or disruptions in manufacturing, pre-commercial and commercialization activities for our product candidates;
- interruption of clinical trial activities, such as clinical trial site monitoring, manufacturing and equipment maintenance due to limitations on travel or access imposed or recommended by federal or state governments, hospitals, employers and others, or interruption of clinical trial subject visits and study procedures;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could result in the reporting of an SAE, potentially including patient deaths, and impact the results of the clinical trial, including by increasing the number of observed adverse events; and
- refusal of the FDA to accept data from clinical trials in affected geographies.

These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

The spread of COVID-19 and actions taken to reduce its spread may also materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, there have recently been, and could in the future be, significant disruptions of global

financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position. As a result, we may face difficulties raising capital or such capital raises may be on unfavorable terms.

COVID-19 and actions taken to reduce its spread continue to rapidly evolve. The extent to which COVID-19 may impede the development of our product candidates, reduce the productivity of our employees, disrupt our supply chains, delay our clinical trials, reduce our access to capital or limit our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section, such as those relating to the timing and results of our clinical trials and our financing needs.

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

From time to time, we may publish interim, "top-line" or preliminary data from our clinical trials for LAVA-051 or LAVA-1207 or future clinical trials. Interim, "top-line" or preliminary data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim, "top-line" and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, "top-line," and preliminary data should be viewed with caution until the final data are available. Differences between interim, "top-line" and preliminary data and final data could significantly harm our business prospects and may cause the trading price of our common shares to fluctuate significantly.

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

Our competitors in the field of gamma delta T cell therapy include Adicet Bio, Inc., Editas Medicine, Inc., Takeda Pharmaceutical Company Ltd, ImCheck Therapeutics SAS, Immatics Biotechnologies GmbH, Leucid Bio Ltd, PhosphoGam Inc., Shattuck Labs Inc., Sandhill Therapeutics, Inc, Gadeta BV, Eureka Therapeutics, Inc., In8Bio, Inc., and TC BioPharm Limited. Our gamma delta T cell product candidates may also compete with other T cell and NK cell engaging therapies as well as NK cell-engaging therapies.

There are many other companies that have commercialized or are developing immuno-oncology therapies for cancer including large biotechnology and pharmaceutical companies, such as AstraZeneca, BMS, Eli Lilly and Company, MSD, Merck, EMD Serono, Novartis, Pfizer, Genentech, a subsidiary of Roche, Takeda and Sanofi. A number of companies, not limited to those above, are attempting to combine immuno-oncology antibody therapies in order to modulate two cancer pathways simultaneously. Others have developed bispecific antibodies or bispecific fusion proteins in order 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. A competing company developing or acquiring rights to a more effective therapeutic product for the same diseases targeted by us, or one that offers significantly lower costs of treatment, could render our products noncompetitive or obsolete. We may not be successful in marketing any product candidates we may develop against competitors.

Risks related to manufacturing

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 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-051, LAVA-1207 or our other 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; and

- compliance with cGMP requirements and other inspections by the FDA, EMA or other comparable regulatory authorities.

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-051, LAVA-1207 and our 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. If we experience any of the foregoing, we may not be able to meet market demand for any approved product. 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.

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

We currently depend on one single-source supplier for each of our product candidates. In the event we lose our single-source supplier, our ability to develop our product candidates will likely be adversely impacted and delayed, which could adversely affect our business. Although, we are in the process of transferring our manufacturing process for LAVA-051 to a second BDS supplier. There can be no assurance that we will be successful in transferring our manufacturing process or if we will be able to do so on a timely basis, which could adversely affect our business.

Although we have commenced the transfer of the manufacturing process for LAVA-051 to a second BDS supplier, it is expected that this second supplier will not become operational until the fourth quarter of 2022. In addition, there is no guarantee that we will successfully complete the transfer process by the fourth quarter of 2022 or at all.

Although we believe that we have a substantial reserve of BDS to support each of our current clinical trial programs, 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 the following:

- 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;
- 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 programs;
- delays caused by supply issues may harm our reputation, frustrate our customers and cause them to turn to our competitors for future projects; and
- our ability to develop our product candidates could be materially and adversely impacted if the supplier, and in some cases single-source supplier, upon which we rely were to experience a significant business

challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory or reputational issues.

The manufacturing of our 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 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 products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications as a result of defects or storage over an extended period of time, undertake costly remediation efforts or seek more costly manufacturing alternatives. Any of these occurrences could adversely affect our business, operations and revenues.

We currently store our Gammabody product candidates 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.

All of our Gammabody product candidates are 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 bsTCE 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 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 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.

Future clinical trials that we conduct, as well as any potential commercialization of our product candidates when 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 future product candidates, or if our intellectual property rights are inadequate, we might not be able to compete effectively.

We have entered into license agreements and agreements where we have received a contingent assignment to certain patent rights with third parties and we expect to enter into additional such agreements in the future to advance our research or allow commercialization of LAVA-051, LAVA-1207 or any future product candidates we may develop. These license agreements impose financial and other obligations that are relevant to our business and financial operations, and if we fail to comply with our obligations under these agreements, we could lose our rights, or face further liability, under such license agreements. For example, if

we fail to meet our obligations under the VUmc Agreement in any material respect and fail to cure such breach in a timely fashion, the VUmc may terminate the agreement, and we would be obligated to transfer back to VUmc 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 VUmc Agreement, see *"Item 4: Information on the Company."* If these agreements are terminated, we could lose intellectual property rights that are important to our business, be liable for damages to such licensors or be prevented from developing and commercializing our product candidates. Termination of these agreements or reduction or elimination of our rights under these agreements may also result in our being required to negotiate new or reinstated agreements with less favorable terms, and it is possible that we may be unable to obtain any such additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis.

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

In addition, the research resulting in certain of our in-licensed patent rights may have been funded in part by the U.S. federal or state governments. As a result, the government may have certain rights, including march-in rights, to such patent rights.

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 patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- 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 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 our product candidates and technology, or if the scope of protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and technology may be adversely affected.

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

We and our licensors have sought, and intend to seek, to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and our technology that are important to our business including LAVA-051 and LAVA-1207. We may also seek to protect our proprietary position by acquiring or in-licensing additional issued patents or pending patent applications from third parties.

As of December 31, 2021, we own, co-own or exclusively license two issued U.S. patents, six pending U.S. patent applications, five pending European regional-phase patent applications, four pending Patent Cooperation Treaty (PCT) patent applications, eight issued patents in other territories and 37 pending patent applications in other territories, which are important to the development of our business. For more information relating to our patent portfolio, see *"Item 4: Information on the Company."* If we or our licensors are unable to obtain and maintain intellectual property protection with respect to inventions and technology important to our business, our competitive position, financial condition, results of operations and prospects may be significantly harmed.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. Since patent applications in the United States and most other countries are confidential for a period of time 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. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Furthermore, we may develop, acquire or license intellectual property rights that have been generated through the use of U.S. government funding. As a result, the U.S. government may have certain rights, or march-in rights, to such patent rights and technology. The U.S. 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. The U.S. government also has 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 United States. 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. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could significantly harm our business, financial condition, results of operations and prospects.

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

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

Patent terms may be inadequate to protect our competitive position on our 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. In order 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 of 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, as a result of the 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, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to 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.

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

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

United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents, and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

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

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

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

Since we rely on third parties to help us discover, develop and manufacture our current and any future product candidates, or if we collaborate with third parties for the development, manufacturing or commercialization of our current or any future product candidates, we must, at times, share know-how or trade secrets with them. We may also conduct joint research and development programs that may require us to share know-how or trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our know-how or trade secrets. Despite the contractual provisions employed when working with third parties, the need to share know-how or trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations. In addition, from time to time, we may hire scientists or other employees or consultants who originate from jurisdictions, including China, which have a history of engaging in misappropriation or theft of trade secrets or other acts of trade secret espionage. If any such individuals are found to be engaging in such illegal behavior, it could have a material adverse effect on our ability to protect our intellectual property and our business prospects more generally.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our know-how or trade secrets. Despite our efforts to protect our know-how and trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and

disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third-party illegally or unlawfully obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

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

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

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

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

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

As of December 31, 2021, we had 58 employees (including 55 full time employees). As the clinical development of our product candidates progresses, we also expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, drug development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We rely and expect to continue to be dependent and rely 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 into new strategic relationships which such third parties, our business, financial condition, commercialization prospects and results of operations may be adversely affected.

We are and expect to continue to be, dependent and rely 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 a party to a research collaboration and license agreement (Janssen Agreement) with Janssen Biotech, Inc. (Janssen), for the potential discovery and development of multi-specific antibody products that are directed to a specified target in all fields of use. We also intend to explore other strategic partnerships in order to broaden 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. In addition, we have a commercial supply agreement for the manufacturing of LAVA-051 with a global contract manufacturer. Reliance on such third parties and other manufacturers and suppliers may pose a number of 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 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 of 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.

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 our 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 commission, customer incentive programs, and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of 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 of 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.

If the security of the personal information that we (or our vendors, collaborators, contractors, or consultants) collect, store or process is compromised or is otherwise accessed without authorization, or if we fail to comply with our commitments and assurances regarding the privacy and security of such information, our reputation may be harmed and we may be exposed to liability and loss of business.

Our internal computer systems, cloud-based computing services and those of our current and any future vendors, collaborators, contractors, or consultants, are vulnerable to damage or interruption from natural disasters, fire, power loss, telecommunications failures, server malfunction, software or hardware failures, traditional computer "hackers," malicious code (such as viruses and worms), phishing attacks, employee theft or misuse, denial-of-service attacks, adware, malware installation, sophisticated nation-state and nation-state supported actors and other cyberattacks. Cyberattacks and other malicious internet-based activity continue to increase in frequency, sophistication and intensity, and are becoming increasingly difficult to detect.

We have conducted information security audits or evaluations on our internal computer systems but we cannot guarantee that our or our vendors', collaborators', contractors', or consultants' security measures will be sufficient to protect against unauthorized access to, or other compromise of, our systems and our confidential, financial or proprietary data, including personal information, which is stored in or otherwise

processed by such systems. Due to the COVID-19 pandemic, most of our employees are temporarily working remotely, which may pose additional data security risks. While we have security measures in place designed to protect our confidential and proprietary information and prevent data loss and other security breaches, there can be no assurance that our security measures or those of our third-party service providers that store or otherwise process certain of our confidential, financial or proprietary data on our behalf will be effective in protecting against unauthorized access to our platform or such data, particularly given that our ability to monitor our third-party service providers' data security is limited.

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

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

Failure to prevent or mitigate cyberattacks could result in the unauthorized access to our confidential and proprietary data, including personal information. Most jurisdictions have enacted laws requiring companies to notify individuals, regulatory authorities, and others of security breaches involving certain types of data. In addition, our agreements with certain counterparties and partners may require us to notify them in the event of a security breach. Such mandatory disclosures are costly, could lead to negative publicity, may cause the public to lose confidence in the effectiveness of our security measures and require us to expend significant capital and other resources to respond to and/or alleviate problems caused by an actual or perceived security breach.

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

Unauthorized access to our platform, systems, networks, or physical facilities could result in litigation with or liabilities to our contractual counterparties or other relevant stakeholders, which may adversely affect our business. While we maintain cybersecurity insurance, we could still be required to spend money in defense or settlement, divert management's time or attention, fundamentally change our business activities and practices or modify our products and/or platform capabilities, which could have an adverse effect on our business. Litigation could also increase our costs of doing business or adversely affect our reputation

Our risks are likely to increase as we continue to expand, and process, store, and transmit increasingly large amounts of proprietary and sensitive data.

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 the 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 ending December 31, 2021. 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. 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 a common share, 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 dividends 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 product or 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 products. 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 our products. We obtained product liability insurance covering our 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. We cannot predict the impact of such changes and cannot be certain of our future compliance. 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 the FDA, EMA and other comparable foreign regulatory authorities are lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our 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-051, LAVA-1207 or our 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 abbreviated regulatory pathways for any of our product candidates, or that we will ultimately be successful in our future clinical trials. We may request regulatory approval of LAVA-051, LAVA-

1207 and 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-051, LAVA-1207 or our product candidates to additional regulatory authorities. It is possible that neither our current product candidates nor any 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.

Our product candidates could fail to receive regulatory approval from the FDA, EMA or comparable regulatory authority for many reasons, including, among others:

- disagreement with the design or conduct of any of our clinical trials;
- failure to demonstrate to the satisfaction of regulatory agencies that our Gammabody product candidates are safe and effective, or have a positive benefit/risk profile for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a Biologics License Application (BLA) with the FDA, marketing authorization application (MAA) with the EMA or other submission or to obtain regulatory approval;
- upon review of our clinical trial sites and data, the FDA, EMA or comparable foreign regulatory authorities may find our record keeping or the record keeping of our clinical trial sites or investigators to be inadequate;
- on a recommendation by the Data Safety Monitoring Committee;
- failure to obtain approval of our manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies or our own manufacturing facility; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

Additionally, any delay in, or termination of, our clinical trials will delay the submission of a BLA to the FDA, MAA to the EMA or other similar applications with other relevant regulatory authorities and, ultimately, our ability to commercialize our product candidates, if approved, and generate product revenue.

We may also experience delays in obtaining regulatory approvals, including but not limited to:

- obtaining regulatory authorization to begin a trial, if applicable;
- redesigning our study protocols and need to conduct additional studies as may be required by a regulator;
- governmental or regulatory delays and changes in regulation or policy relating to the development and commercialization of our product candidate by the FDA or other comparable foreign regulatory authorities;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, and other comparable foreign regulatory authorities;
- the availability of financial resources to commence and complete the planned trials;

- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- failure of third-party contractors, such as CROs, or investigators to comply with regulatory requirements, including GCPs;
- clinical sites deviating from trial protocol or dropping out of a trial;
- delay or failure in obtaining the necessary approvals from regulators or institutional review boards, or IRBs, in order to commence a clinical trial at a prospective trial site, or their suspension or termination of a clinical trial once commenced;
- Inability to recruit, qualify and enroll suitable patients to participate in a trial;
- having patients complete a trial, including having patients enrolled in clinical trials dropping out of the trial before the product candidate is manufactured and returned to the site, or return for post-treatment follow-up;
- addressing any patient safety concerns that arise during the course of a trial;
- inability to add new clinical trial sites;
- varying interpretations of the data generated from our preclinical or clinical trials;
- 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;
- problems with biopharmaceutical product candidate storage, stability and distribution resulting in global supply chain disruptions; or
- potential unforeseen business disruptions or market fluctuations that delay our product development or clinical trials and increase our costs or expenses, such as business or operational disruptions, delays, or system failures due to malware, unauthorized access, terrorism, war, natural disasters, strikes, geopolitical conflicts, restrictions on trade, import or export restrictions, or public health crises, such as the current COVID-19 pandemic.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our 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-051, LAVA-1207 or other product candidates, we will be subject to ongoing regulatory oversight.

Our 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-051, LAVA-1207 or other product candidates are approved. Any regulatory approvals that we receive for our product candidates may also be subject to a REMS to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may

include, among other things, a communication plan to health care 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 health care 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 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 a number of 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 our product candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business.

We have sought and may continue to 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.

We may seek orphan drug designation for one or more of our current or future product candidates. 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.

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 is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a 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 are unable to manufacture sufficient supply of our product.

We received orphan drug designation for LAVA-051 for chronic lymphocytic leukemia (CLL) and may seek orphan drug designation for our other indications for LAVA-051 or other 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 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.

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 is dependent upon 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 or not 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 designation is no longer supported by data from our clinical development program.

We expect the product candidates we develop will be regulated as biologics, and therefore they 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 generic 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 and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations. For additional information on the healthcare laws and regulations that we may be subject to, see section titled “Business—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 the Company, 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.

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. In particular, there have been and continue to be a number of initiatives at the federal and state levels 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 health care coverage for individuals. Since its enactment, there have been executive, judicial and Congressional challenges to the ACA. Most of the ACA survived such challenges but further healthcare reform measures of the Biden administration may impact the ACA or our business. Changes in control of Congress and the Presidential election in 2024 may bring further litigation and legislation, with unpredictable consequences. We continue to evaluate the effect that changes to the ACA and other 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.

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, with a temporary suspension from May 1, 2020 through March 31, 2021, 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.

The COVID pandemic also resulted in significant additional federal funding for healthcare systems, temporary regulatory waivers and other reforms to expedite regulatory approvals of new products beginning in 2020. In March, 2020, President Trump signed the Families First Coronavirus Response Act (FFCRA), which provided additional support for the U.S. domestic COVID-19 response, and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which provided temporary and limited relief to hospitals during the COVID-19 public emergency, including the appropriation of $100 billion under the Public Health and Social Services Emergency Fund (Provider Relief Fund) to reimburse providers for expenses and lost revenue attributable to COVID-19. Among other things, in an effort to blunt the pandemic financial impact on many health care facilities and providers, the CARES Act temporarily eliminated the 2% reduction in Medicare payments and delayed the $4 billion reduction in Medicaid funding for Medicare disproportionate share hospitals. In March, 2021, President Biden signed the American Rescue Plan Act (ARPA) into law, a $1.9 trillion coronavirus relief package. The ARPA appropriated $100 billion to support COVID-19 vaccinations and testing, including $10 billion for medical supplies and equipment through the Defense Production Act and $15 billion for vaccine distribution and administration. The ARPA also maintained Medicaid DSH payments during the public health emergency, increased access to healthcare coverage via expanded eligibility and federal support for coverage obtained on the health insurance marketplace, offered incentives for states to expand Medicaid eligibility, and extended Medicaid and CHIP coverage for COVID-19 vaccines. The ARPA triggered automatic spending cuts as a deficit control method and required a reduction of $36 billion in Medicare spending in fiscal year 2022. It remains unclear whether the massive relief funding provided under these laws will be sufficient to cover the significant revenue shortfalls and staffing crises that healthcare facilities nationwide have suffered since the beginning of the pandemic and whether future cuts in spending will be adopted to address the deficit spending. Whether some of the public health measures will become continue or be made permanent once the Federal Emergency Declaration ends is also unpredictable at this time.

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. At this time, it is unclear how the introduction of the Medicare quality payment program will impact overall physician reimbursement.

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 Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. 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. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, 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.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug, which could have an adverse effect on demand for our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. For additional information on healthcare reform, see the section titled “Business—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. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. 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 health care 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 in order 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.

We are subject to stringent and changing laws, regulations and standards, and contractual obligations related to data privacy and security. The actual or perceived failure to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

Data privacy and security has become a significant focus in the United States and abroad. The regulatory framework for privacy issues is rapidly evolving and is likely to remain uncertain for the foreseeable future. Many government bodies and agencies have adopted or are considering adopting laws and regulations regarding the collection, use, processing, storage, transmission, destruction, and disclosure of personal information and breach notification procedures. We are also required to comply with laws, rules and regulations relating to data security. Interpretation of these laws, rules and regulations in applicable jurisdictions is ongoing and cannot be fully determined at this time.

In the United States, there are state and federal laws relating to data privacy and security. As we expand our operations, these laws which vary from jurisdiction to jurisdiction, may increase our compliance costs and potential liability. In addition to California, Virginia and Maine, other states are beginning to propose similar laws, which may be the beginning of a trend toward more stringent privacy legislation in the United States that could increase our potential liability and adversely affect our business, results of operations and financial condition.

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

European data protection laws including the GDPR also generally prohibit the transfer of personal information from Europe to the United States and most other non-EEA countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. There is uncertainty regarding how to ensure that transfers of personal information from Europe to the United States comply with the GDPR. As such, any transfers by us, or our vendors, of personal information from Europe may not comply with European data protection laws; may increase our exposure to the GDPR's heightened sanctions for violations of its cross-border data transfer restrictions; and may reduce demand for our services from companies subject to European data protection laws. Loss of our ability to transfer personal information from

Europe may also require us to increase our data processing capabilities in those jurisdictions at significant expense.

Complying with the GDPR and other related foreign privacy laws and regulations may cause us to incur substantial operational costs or require us to change our business practices. Despite our efforts to bring our practices into compliance with these laws and regulations, we may not be successful in our efforts to achieve compliance either due to internal or external factors such as resource allocation limitations or a lack of vendor cooperation. Any inability to adequately address privacy concerns, even if unfounded, or comply with applicable privacy or data protection laws, regulations and policies, could result in additional cost and liability to us, damage our reputation, inhibit sales and adversely affect our business, results of operations and financial condition.

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, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries 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 government agencies and government-affiliated hospitals, universities and other organizations. In addition, we may engage third-party intermediaries to promote our clinical research activities abroad or 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 anti-corruption laws applicable to our business throughout the world. However, we cannot assure you 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

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

The market price of our common shares is volatile. The stock market in general and the market for biopharmaceutical and pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may lose all or part of your 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-051 or LAVA-1207, the commencement enrollment or results of our future product candidates or those of our competitors;
- the success of competitive products or therapies or announcements by potential competitors of their product development efforts;
- regulatory or legal developments in the United States, the Netherlands, Europe more broadly and other jurisdictions;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or shareholder litigation;
- market volatility due to the continued effects of and responses to the COVID-19 pandemic;
- 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 the course of 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.

We are incorporated under the laws of the Netherlands and substantially all of our assets are located outside the United States.

As a result, it may not be possible for shareholders to effect service of process within the United States upon us or our directors and executive officers or to enforce judgments against us or them in U.S. courts, including judgments predicated upon the civil liability provisions of the federal securities laws of the United States. In addition, it is not clear whether a Dutch court would impose civil liability on us or any of our directors and executive officers in an original action based solely upon the federal securities laws of the United States brought in a court of competent jurisdiction in the Netherlands.

As of the date of this annual report, the United States and the Netherlands do not have a treaty providing for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. With respect to choice of court agreements in civil or commercial matters, it is noted that the Hague Convention on Choice of Court Agreements entered into force for the Netherlands, but has not entered into force for the United States. Accordingly, a judgment rendered by a court in the United States, whether or not predicated solely upon U.S. securities laws, would 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 a foreign judgment if (i) the jurisdiction of the foreign court was based on a ground of jurisdiction that is generally acceptable according to international standards, (ii) the judgment by the foreign 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 foreign judgment is not contrary to Dutch public order (*openbare orde*) and (iv) the judgment by the foreign 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 foreign judgement is given binding effect, a claim based thereon may, however, still be rejected if the foreign judgment is not or no longer formally enforceable.

Based on the lack of a treaty as described above, U.S. investors may not be able to enforce against us or our directors, representatives or certain experts named herein who are residents of the Netherlands or countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

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

In the event of an issuance of common shares or a grant of rights to subscribe for common shares, subject to certain exceptions, each shareholder will have a pro rata pre-emption right in proportion to the aggregate nominal value of such holder's common shares. These pre-emption rights may be restricted or excluded by a resolution of the general meeting or by another corporate body designated by the general meeting. Our board of directors has been authorized until March 2026 to issue shares or grant rights to subscribe for shares up to our authorized share capital from time to time and to limit or prohibit 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 December 31, 2021, in the aggregate, beneficially own shares representing approximately 79.1% of our outstanding common shares. If our executive officers, directors and shareholders who own more than 5% of our outstanding common shares acted together, they may be able to significantly influence all matters requiring shareholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. The concentration of voting power and transfer restrictions could delay or prevent an acquisition of our company on terms that other shareholders may desire or result in the management of our company in ways with which other shareholders disagree.

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

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

property rights. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common share to decline and existing stockholders may not agree with our financing plans or the terms of such financings. Adequate additional financing may not be available to us on acceptable terms, or at all.

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

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

As a public company, and particularly after we are no longer an EGC or smaller reporting company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 (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 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.

When we are subject to Section 404 of the Sarbanes-Oxley Act (Section 404), we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an EGC or a smaller reporting company with less than $100 million in annual revenue, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We could be an EGC for up to five years. To achieve compliance with Section 404 within the prescribed period, 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 will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

We have identified material weaknesses in our internal control over financial reporting. If our remediation of the material weaknesses is not effective, or if we experience additional 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 certification or attestation requirement of Section 404 of the Sarbanes-Oxley Act, in connection with the preparation of our financial statements as of and for the year ended December 31, 2020, we identified control deficiencies that we concluded represented material weaknesses in our internal control over financial reporting across the principles for each component of the COSO framework at the entity level (*i.e*. control environment, risk assessment, monitoring, information & communication and control activities) and accordingly, across our business and IT processes. The material weaknesses that we identified related to:

- the lack of consistent and documented risk assessment procedures and control activities related to our financial reporting, among which are a sufficient level of (management) review and approval, manual processes, roles and responsibilities, and adequate application and controls over information technology; and
- our ability to: (i) design and maintain formal accounting policies, procedures and controls over the fair presentation of our financial statements; (iii) design and maintain controls over the preparation and review of journal entries and financial statements, including maintaining appropriate segregation of duties.

While we have taken measures during the year ended December 31, 2021 to remediate these material weaknesses and have enhanced our internal control over financial reporting in preparation for compliance with Section 404(a) of the Sarbanes-Oxley Act for the year ended December 31, 2022, such remediation measures have been operational for a limited period of time and have not been formally tested. As such, we cannot consider these material weaknesses as remediated as of December 31, 2021.

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

If we are not able to comply with the requirements of Section 404 in a timely manner, when required, or if we are unable to maintain proper and effective internal controls over financial reporting, or identify any material weakness, we may not be able to produce timely and accurate financial statements which could result in material misstatements in our financial statements and potentially require us to restate our financial statements. If we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, when required, our investors could lose confidence in the accuracy and completeness of our reported financial information, the market price of our shares could be materially adversely affected, we could face restricted access to the capital markets, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

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

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

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

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

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

ITEM 4. Information on the Company

History and Development of the Company

LAVA Therapeutics N.V., together with its subsidiary, is a clinical-stage immuno-oncology company dedicated to rapidly developing new cancer treatments that leverage the immune system to save patients' lives. We were incorporated in the Netherlands in February 2016 and are currently headquartered in Utrecht, the Netherlands. At the time of our incorporation in 2016, we acquired or exclusively in-licensed the development and commercial rights to certain clinical and preclinical programs and intellectual property from VUmc. We also have a research services agreement with VUmc in support of our preclinical and clinical stage programs.

In 2019, we established our wholly-owned U.S. subsidiary, which began business in January 2020. LAVA Therapeutics NV is a limited liability public company (naamloze vennootschap). The address of the Company's registered office is Yalelaan 60, 3584 CM Utrecht, the Netherlands, and its phone number is +31 85 016 3100.

Our business is primarily conducted in the European Union and we maintain our books and records in EUR and USD where applicable as functional currency. As of this annual report, we have changed our reporting currency for our financial statements and all other financial information included in this annual report to USD, having previously reported in EUR. We believe this presentation better conforms to the expectations of our investor base as a U.S. public company.

In March 2021, our management and board of directors approved and the general meeting of shareholders of the Company resolved to effect a share split. The effect of the share split was a 221:1 share split of the outstanding common and preferred shares held by the Company's shareholders and was effective on

March 17, 2021. All share, per-share and related information presented in this annual report have been retroactively adjusted, where applicable, to reflect the impact of the share split.

On March 29, 2021, we completed an initial public offering (IPO) of common shares in the United States pursuant to a Registration Statement on Form F-1, as amended (File No. 333-253795). The common shares are listed for trading under the symbol “LVTX” on The NASDAQ Global Select Market (“NASDAQ”). Pursuant to the registration statement, we issued and sold 6,700,000 shares of $0.14 par value common share at a price of $15.00 per share. Net proceeds from the IPO were approximately $89.0 million after deducting underwriting discounts and commissions of $7.0 million and offering costs of $4.5 million. In March 2021, we also received $56.6 million in proceeds from the Series C financing, net of repurchasing Series A Preferred and common shares.

On April 19, 2021, underwriters of the IPO consummated the exercise of their option to purchase an additional 425,712 common shares at the price of $15.00 per share resulting in additional IPO net proceeds of $5.9 million after deducting underwriting discounts and commissions of $0.4 million.

Prior to the IPO, all previously outstanding shares of preferred stock were converted to common share, and we changed from a private company with limited liability (besloten vennootschap met beperkte aansprakelijkheid), LAVA Therapeutics B.V., to a public company with limited liability (naamloze vennootschap), LAVA Therapeutics N.V.

The SEC maintains an Internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov. Our Company website is www.lavatherapeutics.com.

Business Overview

We are a clinical-stage immuno-oncology company dedicated to rapidly developing new cancer treatments that leverage the immune system to save patients’ lives. 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 (gd) T cells to elicit a robust, natural anti-tumor immune response and improve outcomes for cancer patients.

Gamma Delta T Cells

Gamma delta (gd) 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 (Vg9Vd2) T cells, the largest subpopulation of gamma delta T cells in 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-T) cells, have provided 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 CRS. CD3-based TCEs have additional limitations because of their indiscriminate activation of T cells, including both effector T cells and regulatory cells (Tregs). Activation of Tregs can dampen anti-cancer immunity, potentially resulting in decreased or no therapeutic efficacy. The therapeutic active dose and the toxic dose of CD3-based TCEs are often in close proximity, resulting in a very narrow therapeutic window which may preclude full exploitation of their therapeutic potential. Adoptive transfer of CAR-T cells is complex and costly, and has also been associated with significant risk of CRS an on-target off-tumor-related toxicities.

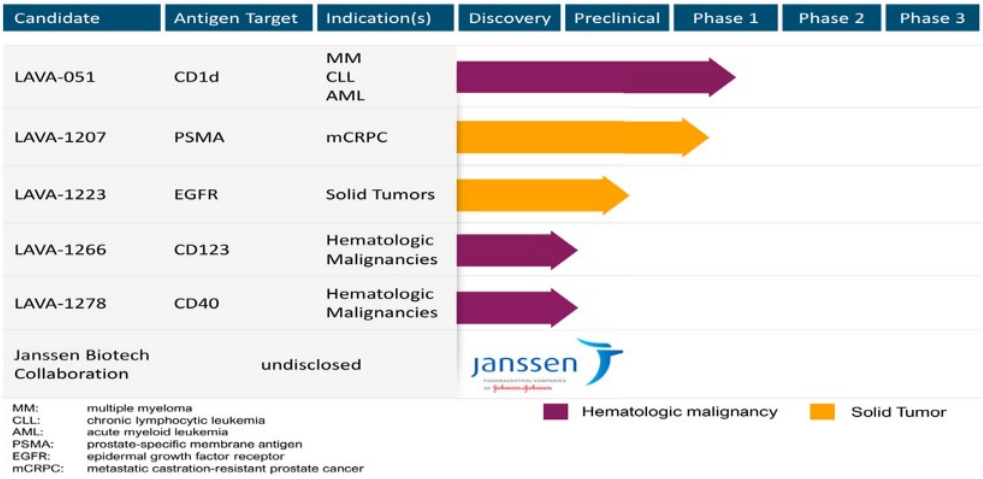
Our Proprietary Gammabody Platform

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 Vgamma9 Vdelta2 T cells resulting in tumor cell targeting and conditional cancer cell killing. One arm of the Gammabody recruits Vgamma9 Vdelta2 T cells, while the other arm recognizes and binds to a specific tumor target present on blood cancers or solid tumors. Our Gammabody drug candidates are designed to activate the Vgamma9 Vdelta2 T cells once the respective arms are bound to each 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 and may provide a superior therapeutic window compared to other approaches by reducing the risk of on target/off tumor mediated toxicity and avoid activation of Tregs and broad systemic activation resulting in 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. Studies in non-human primates, using surrogate Gammabody molecules, showed that our gamma delta T cell engagers were well tolerated and did not induce CRS.

Our Pipeline

We believe our Gammabody platform has the potential to develop treatments for patients with a wide variety of cancers, both as monotherapy and in combination with other therapies. Our lead clinical-stage candidates, LAVA-051 and LAVA-1207, are in Phase 1/2a clinical trials for blood cancers and solid tumors, respectively. LAVA-051 is a Gammabody designed to target CD1d-expressing blood cancers; including chronic lymphocytic leukemia (CLL), multiple myeloma (MM) and acute myeloid leukemia (AML). LAVA-1207 is a Gammabody designed to target prostate-specific membrane antigen (PSMA)-expressing cancers. We are developing the product candidate in metastatic castration-resistant prostate cancer (mCRPC). We are also developing other Gammabody drug candidates, including LAVA-1223, which targets the epidermal growth factor receptor (EGFR) for the treatment of selected solid tumors. We designed our Gammabody platform to be fully modular and compatible with existing anti-tumor antibodies to facilitate expedited discovery and development of novel compounds. We are currently advancing our Gammabody pipeline for the development of potential therapeutics in both hematologic malignancies and solid tumors.



LAVA-051

Our most advanced product candidate, LAVA-051, is a unique CD1d-targeting Gammabody in development for treating hematologic cancers including CLL, MM and AML. CD1d is expressed by tumor cells of most patients with CLL, MM and (myelo) monocytic subtypes of AML. LAVA-051 works via a dual mechanism of action, with engagement of Vgamma9 Vdelta2 T cells as the primary mechanism, and is designed to kill CD1d-expressing tumor cells.

LAVA-051 cross-links CD1d-expressing tumor cells and Vgamma9 Vdelta2 T cells, resulting in conditional Vgamma9 Vdelta2 T cell activation, the secretion of cytolytic molecules and cytokines and subsequent tumor cell killing. As published in 2020 in Nature Cancer, we preclinically demonstrated that the CD1d-binding moiety of the bsTCE is also uniquely able to enhance the interaction of CD1d and the T cell receptor of invariant NKT cells (iNKT) cells. These iNKT cells are a population of innate-like lymphocytes that play an important role in orchestrating immune responses in cancer. We found that this feature led to iNKT cell activation and anti-tumor activity by LAVA-051. LAVA-051 has shown activity against CD1d-positive CLL, MM and AML cells in *in vitro* functional assays. These results suggest that LAVA-051 may have a positive effect on clinical outcomes for patients with CLL, MM and AML. We believe the combined Vgamma9 Vdelta2 T cell and iNKT cell-activating properties and the resulting cascade response of downstream immune cell activation contribute to the potential of LAVA-051 to provide rapid tumor cell cytotoxicity as well as potentially long-term anti-tumor immune responses.

In July 2021, we dosed the first patient in a Phase 1/2a clinical trial evaluating LAVA-051 in patients with relapsed or refractory CLL and MM. AML patients will be included later in the study once biological relevant dose(s) have been reached. The open-label, multi-center clinical trial will evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity and preliminary anti-tumor activity of LAVA-051 (NCT04887259). The Phase 1 dose-escalation portion will determine an optimal Phase 2 dose of LAVA-051. The Phase 2a portion of the trial will enroll patients in disease specific cohorts, to confirm safety and evaluate preliminary anti-tumor activity in each disease cohort. The Phase 1/2a clinical trial for LAVA-051 is underway in Europe and we expect to file an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA), which, if accepted, will include patients in the United States. In October 2021, the FDA granted orphan drug designation for LAVA-051 for the treatment of CLL.

In March 2022, we announced preliminary clinical data from the first three single patient cohorts of the Phase 1 dose-escalation study, which demonstrated that the doses of LAVA-051 that were administered in these initial cohorts were safe and well tolerated with no dose limiting toxicities or CRS observed. Per the study protocol, the cohort three dose was 33-times that of the cohort one dose. Drug exposure and Vgamma9 Vdelta2 T cell receptor occupancy of LAVA-051 increased with LAVA-051 dose increases and peripheral blood Vgamma9 Vdelta2 T cells also expressed higher levels of activation markers after LAVA-051 dosing.

One CLL patient experienced multiple enlarged tender diseased lymph nodes 1 week after first dosing that subsequently regressed, reminiscent of tumor flare. Dosing in the study is continuing, with subsequent cohorts planned to enroll at least three patients per cohort. We currently expect to have additional data from the Phase 1 dose escalation phase of the trial in the second quarter of 2022 and clinical data from the Phase 2a expansion cohorts in the second half of 2022.

Disease Overview

Despite current treatment options, there remains an unmet need for patients with CLL, MM and AML, as the vast majority will become refractory to or develop resistance to existing therapies.

Chronic lymphocytic leukemia (CLL)

CLL is the most common leukemia in the U.S. and Europe. CLL has an incidence of approximately 4.7 cases per 100,000 people in the U.S., and an increasing incidence in Western Europe including up to 5.27 per 100,000 in the UK. The disease has a male predominance and a median age at diagnosis of approximately 70 years.

CLL starts in white blood cells, called lymphocytes, in the bone marrow, and is caused by the monoclonal expansion of mature-appearing, functionally incompetent neoplastic B lymphocytes. As a disease, CLL has a highly variable presentation and as such, a variable clinical course. Most patients with CLL are initially asymptomatic and are managed with a watch-and-wait approach. In time, about two-thirds of patients will require treatment.

There is standard front-line treatment regimen for all symptomatic CLL, mostly due to differences in patient age and frailty. In recent years, two new classes of drugs have been added to the primarily chemotherapy-based treatments: the BCL-2 inhibitor venetoclax and the Bruton's tyrosine kinase (BTK) inhibitors, which are now broadly evaluated at various stages of disease and in different patient segments and combinations. When disease progression occurs, especially after treatment with DNA-damaging agents and the two drug classes mentioned earlier, CLL cells serially accumulate adverse biological features and increasingly develop resistance to existing therapies. Novel and more effective therapeutic approaches with an alternative MoA and an acceptable safety profile are needed. Patients for whom no standard of care treatment currently exists are included in our clinical trial with LAVA-051.

Published studies have shown that CD1d levels are higher in more advanced stages of CLL, underscoring the potential of using CD1d as a target for Vgamma9 Vdelta2 T cells in CLL immunotherapy.

Multiple myeloma (MM)

MM is the second-most frequent blood cancer diagnosis in the U.S. and Western Europe, with an estimated incidence of about 4.5-6 per 100,000 people per year, with higher incidence in black male populations and lower incidence in Asian-Pacific populations. MM primarily affects elderly patients with a median age at diagnosis of 72 years.

MM is characterized by the neoplastic proliferation of plasma cells producing a monoclonal immunoglobulin known as M-protein. Plasma cells, a type of immune cell, are typically responsible for secreting antibodies to fight infection in a healthy person. In MM, the neoplastic plasma cells proliferate in the bone marrow and often result in extensive skeletal destruction with osteolytic lesions, osteopenia or pathologic fractures. Most patients with MM present with signs or symptoms related to the infiltration of plasma cells into the bone or other organs, or symptoms related to high levels of M-protein including reduced immune function.

Even though the treatment landscape for MM has evolved considerably, MM remains an incurable disease. Patients typically receive combination therapy consisting of two or more different classes of drugs, including Immunomodulatory imide drugs, proteasome inhibitors, anti-CD38 antibodies and anti-BCMA B-cell maturation agent drugs. Combinations of different drugs are used upon failure of the previous treatment and disease progression. Upon relapse, the disease typically becomes more aggressive with shortened subsequent progression-free intervals. There is a critical need to develop novel therapeutic approaches with a different MoA and an acceptable side-effect profile, particularly for relapsed refractory MM. LAVA-051 will initially be evaluated in MM patients who had progressive disease following treatment with the main drug classes used as standard therapy.

Several studies have demonstrated that patient MM cells express CD1d and that MM cells are susceptible to the cytolytic activity of both iNKT cells and gamma delta T cells. We believe that these data, combined with the demonstrated ability of LAVA-051 to trigger targeted anti-cancer activity of iNKT and gamma delta T cells in preclinical in vitro and in vivo MM models and against patient malignant cells ex vivo, supports the potential of targeting CD1d using LAVA-051 in MM.

Acute myeloid leukemia (AML)

AML is the most common form of acute leukemia in adults. The median age at diagnosis is 68 years and the age-adjusted incidence is about 4 per 100,000 people per year in the U.S. The incidence of AML increases, and its prognosis worsens, with age, ranging from a 5-year overall survival of 40-50% in patients under 50 years of age, to approximately 5-10% in older patients. Prognosis is also worse in patients with secondary AML.

AML is characterized by infiltration of the bone marrow, blood and other tissues by proliferative, clonal, abnormally differentiated, and occasionally poorly differentiated cells of the hematopoietic system.

The mainstay of AML treatment for patients under approximately 60 years of age and medically fit patients consists of intensive induction chemotherapy. For patients who are not eligible for intensive regimens, therapy includes best-supportive care, low-dose cytarabine and hypomethylating agents decitabine and azacitidine alone or in combination with venetoclax. In the case of relapsed and/or refractory AML, patients are offered intensive salvage therapy with the aim of achieving a complete response and subsequent allogeneic hematopoietic stem cell transplant when deemed sufficiently physically fit. In other cases, patients receive low-intensity therapy or best supportive care.

In recent years, several novel treatments have been approved for certain treatment settings and/or subsets of AML patients, including approaches involving FLT3 inhibitors, IDH-2 inhibitors, IDH-1 inhibitors, and anti-CD33 antibodies. Despite the improved and more effective therapeutic options available to patients with AML, resistance has been shown to develop for most of these drug classes, underscoring the urgent need for efficacious therapies with novel MoAs.

AML cells have been shown to be susceptible to lysis by iNKT cells as well as gamma delta T cells. Among AML patients, expression of CD1d was reported to be most pronounced in patients with the (myelo) monocytic subtypes, which was confirmed in the patient series that we studied. We believe these data, combined with the demonstrated activity of LAVA-051 in triggering relevant anti-cancer activity of iNKT and gamma delta T cells in preclinical *in vitro* and *in vivo* models and using *ex vivo* AML patient samples, support the potential of targeting CD1d using LAVA-051 in AML.

LAVA-1207

LAVA-1207 is a Gammabody that conditionally activates Vgamma9 Vdelta2 T cells upon crosslinking to PSMA to trigger the potent and preferential killing of PSMA-positive tumor cells. LAVA-1207 specifically targets and mediates activation of Vgamma9 Vdelta2 T cells against PSMA-expressing tumor cells. PSMA, a transmembrane protein, is expressed by the vast majority of prostate tumors, and its expression is further increased in poorly differentiated, metastatic, and hormone-refractory carcinomas. Its expression profile in prostate cancer has been clinically validated and makes PSMA an important target for therapies for this form of cancer. In preclinical experiments, LAVA-1207 has been demonstrated to be highly specific and potent in its ability to induce Vgamma9 Vdelta2 T cell-mediated killing of PSMA-positive tumor cells.

In February 2022, we dosed the first patient in a Phase 1/2a clinical trial evaluating LAVA-1207 in patients with metastatic castration-resistant prostate cancer (mCRPC). The open-label, multi-center, Phase 1/2a clinical trial will evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity and preliminary anti-tumor activity of LAVA-1207. The Phase 1 dose-escalation phase will determine a recommended Phase 2 dose of LAVA-1207. Once a recommended Phase 2 dose has been established, the trial will expand into the Phase 2a portion to confirm safety and evaluate preliminary anti-tumor activity of LAVA-1207 in patients with mCRPC.

The Phase 1/2a clinical trial for LAVA-1207 is initially being conducted in Europe and will later expand to sites in the United States. We received regulatory approval for our Clinical Trial Application (CTA) and clearance

from the FDA for a Phase 1/2a clinical trial for LAVA-1207. We currently expect to have data from the Phase 1 dose escalation phase of the trial in the second half of 2022 and clinical data from the Phase 2a expansion cohorts in the first half of 2023.

Disease Overview

Prostate cancer is the second most common cancer among men in the U.S., with nearly 200,000 new diagnoses in 2020. It is estimated that 50,000 men with mCRPC are treated every year in the U.S. Several treatments are approved for mCRPC, including chemotherapies (docetaxel and cabazitaxel), next generation androgen receptor directed therapeutics (e.g., enzalutamide and abiraterone) and PARP inhibitors (for a small subset of patients with certain DNA damage repair mutations), which have collectively improved the therapeutic options for patients with mCRPC. The long-term outcome for patients with mCRPC is highly variable and will depend on prognostic factors of the underlying disease, its responsiveness to the available therapies and the co-morbidities of this generally elderly population. However, there is no curative treatment available today and additional new therapies are needed. Once mCRPC has metastasized beyond regional lymph nodes, the 5-year survival rate is 30%, and it is estimated that more than 33,000 men have died of mCRPC in the U.S. in 2020.

Prostate cancer is well-known for its immunosuppressive tumor microenvironment and generally low tumor mutational burden. These characteristics are believed to hamper the efficacy of classical CD3-based TCEs and other immuno-oncology compounds. According to published literature, prostate cancer is the solid tumor indication with the highest relative abundance of tumor-infiltrating Vgamma9 Vdelta2 cells. This high relative abundance correlates with a lower biochemical recurrence (BCR) rate, which is related to an improved patient prognosis.

Future Programs

In addition to our two lead programs, we are developing a portfolio of earlier stage programs including LAVA-1223, a Gammabody directed at the epidermal growth factor receptor (EGFR) for the treatment of solid tumors, for which we intend to file a CTA and/or IND in late 2022. There is potential for targeting several EGFR-expressing tumors with LAVA-1223, including: colorectal cancer, head and neck squamous cell carcinoma, non-small cell lung cancer and pancreatic cancer. We are also investigating LAVA-1266, a CD123 Gammabody, and LAVA-1278, a CD40 Gammabody, as preclinical candidates for the treatment of several hematologic malignancies.

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 the recognition of 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 the treatment of cancer 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 makes use of 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 CD3ε in the T-CR/CD3 receptor complex and can trigger broad activation of CD3-expressing T cells. Thesecells 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. This is reflected in approximately 60 TCEs currently in clinical development for hematologic and solid tumor indications.

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

Challenges with current TCE approaches

Current TCE approaches, including CD3 TCEs and CAR-T approaches, have demonstrated anti-cancer activity inclinical 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.
- High variability in effectiveness: CD3 TCEs dampen the antitumor efficacy of cytotoxic T cells through activation of immune-suppressive Tregs which has resulted in variability of clinical efficacy.
- Patient preconditioning: For CAR-T, high doses of chemotherapy are typically needed to precondition the patient by lymphodepletion. Such lymphodepletion creates space for CAR-T cells and improves their homeostatic expansion and therapeutic efficacy, but it also results in side effects associated with both high-dose chemotherapy and leukopenia.
- Manufacturing and logistics complexity: CAR-T manufacturing complexities to date means that products cannot always be successfully produced for patients. Lengthy processes result in lag times for treatment administration, resulting in a long vein-to-vein time and a limited addressable patient population.

Gammabody (gamma delta bsTCEs): a potential new class of immuno-oncology treatments

The successes of current TCE approaches highlight the high 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 is further testimony to how this approach is, potentially the most promising from both a clinical and commercial perspective. We have identified the engagement of gamma delta T cells as the next-generation application of TCEs and believe our Gammabody platform will address limitations of current TCEs to improve patient outcomes in both hematologic malignancies and solid tumors.

Vgamma9 Vdelta2 (Vg9Vd2) T cells in cancer therapy

Background on Vgamma9 Vdelta2 T cells

T lymphocytes are divided into two main categories based on T cell receptor type: aß, or alpha beta, and gd, 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 (Vg) and Vdelta (Vd) receptor chains, with Vgamma9 Vdelta2 T cells representing about 90% of all gamma delta T cells in circulation. In addition, these Vgamma9 Vdelta2 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, gamma delta T cells typically recognize their ligands independent of classical antigen processing and MHC restriction. The gamma delta T cell population can be roughly divided into two large sub-populations: Vdelta1 (Vd1) and Vdelta2 (Vd2) TCR expressing gamma delta T cells. The Vdelta2 population of gamma delta T cells associate 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, Vdelta1 T cells constitute a heterogeneous population of cells in part because the Vdelta1 chain can pair with several Vgamma chains, such as Vgamma4,5,9, and also with alpha beta-TCR, and has more variability in TCR CDRs. Consequently, Vdelta1 T cell subsets recognize various antigen presenting molecules and can recognize various antigens. Vdelta1 T cells also have substantial functional diversity not only being able to exert cytotoxic effects, but also play a role in tissue homeostasis, repair and immune suppression. Both cell subsets can infiltrate tumors, but protumor functions related to IL-17 production and a regulatory phenotype have only been reported for tumor-infiltrating Vdelta1 T cells, and in various tumor types infiltration of Vdelta1 has in a number of studies been demonstrated to be related to poorer patient outcome, while Vdelta2 tumor infiltration has generally been shown to correlate to positive prognosis.

When these Vgamma9 Vdelta2 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 dendriticcells. Activated Vgamma9 Vdelta2 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 Vgamma9 Vdelta2 T cells for cancer treatments

As mentioned above, Vgamma9 Vdelta2 T cells have been observed to infiltrate tumors in a wide variety of cancer indications and can provide effective anti-tumor immune responses against both hematologic malignancies and solid tumors. These T cells contain a tumor recognition mechanism, allowing them to recognize and kill cancerous cells, while leaving healthy cells unharmed. Vgamma9 Vdelta2 T cells represent a potent and relatively homogeneous class ofproinflammatory immune effector cells with an immune surveillance function.

Because Vgamma9 Vdelta2 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 have the capability to 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 not only potent, but also durable responses.

Vgamma9 Vdelta2 T cells detect and kill tumor cells by indirectly detecting specific metabolites, called phosphoantigens, which often accumulate intracellularly at relatively high levels in tumorcells. These phosphoantigens bind to an intracellular domain of the cell-surface receptor, butyrophilin, triggering a conformational change and the recognition of butyrophilin receptors on tumor cells by Vgamma9 Vdelta2 cells. Upon this interaction with tumor cells, Vgamma9 Vdelta2 T cells are activated and release cytolytic molecules that can directly kill cancer cells and simultaneously 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 as compared with other leukocyte subpopulations present in tumors. Further, as reported in *Oncoimmunology* in 2017, infiltration of Vgamma9 Vdelta2 T cells was confirmed in a large set of different tumors, including cancers with a low incidence of alpha beta T cell infiltration (also called: cold tumors).

The unique anti-cancer potential of gamma delta T cells drove prior attempts to evaluate them in clinical trials. Various clinical trials were conducted utilizing either adoptive cell therapy of ex vivo expanded activated autologous or allogeneic gamma delta T cells or in vivo gamma delta 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 gamma delta 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 Vgamma9 Vdelta2 T cells. We believe a targeted approach utilizing a gamma delta bsTCE could materially improve clinical responses while maintaining a good safety profile.

Advantages of our Gammabody approach

Gamma delta bsTCEs represent an emerging new class of targeted immuno-oncology treatments. By engaging only Vgamma9 Vdelta2 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 the treatment of cancer. We believe our approach has the following advantages:

- Unique engager of gamma delta T cells. Our Gammabody molecules specifically engage the proinflammatoryimmune effector Vgamma9 Vdelta2 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 Vgamma9 Vdelta2 T cells to distinguish tumor cells from healthy cells.
- Conditional activation with high precision. Our Gammabody molecules only trigger activation of Vgamma9 Vdelta2 T cells upon simultaneous binding of the gamma delta 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 Vgamma9 Vdelta2 T cells. Tumor-targeted activation, by design, avoids systemic exhaustion, which is commonly observed after repeated generalized gamma delta T cell triggering in non-tumor targeted phosphoantigen-based, adoptive cell transfer or antibody-based approaches applied by others.
- Driving a cascade response that includes both innate and adaptive immune responses. Activated Vgamma9 Vdelta2 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 have demonstrated high antitumor potency in vitro and ex vivo using both cell lines and patient tumor samples with our Gammabody platform, with an average EC50 in the low picomolar range. This suggests that clinical antitumor activity may be triggered using relatively low doses.
- Low Risk of CRS. Our Gammabody molecules did not result in any CRS in non-human primate studies. This is consistent with earlier clinical studies of gamma delta Tcell-based therapeutic approaches, including those that triggered systemic activation of the entire Vgamma9 Vdelta2 T cell population. Therefore, our approach compares favorably to non-gamma delta T cell-based strategies, which often suffer from the excessive release of cytokines resulting in CRS.

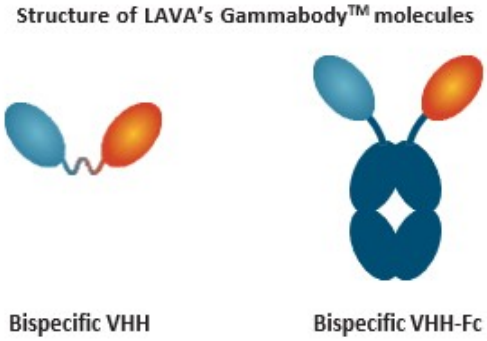
- Potential activity in hematologic malignancies and solid tumors, including immunologically “cold” tumors. Our Gammabody molecules can trigger activation of both peripheral blood and tumor-infiltrating Vgamma9 Vdelta2 T cells, allowing access to and activity against both hematologic malignancies and solid tumors, potentially including those that have not been successfully addressed using immune checkpoint inhibitors.
- Broad therapeutic window. Vgamma9 Vdelta2 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 well below the toxic dose. We believe that the high tumor selectivity and potency of our Gammabody molecules, in combination with the low risk of 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 Gammabody molecules are off-the-shelf products, which are 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 MoA and targeted nature, our Gammabody molecules have the potential to be combined with a variety of current standard-of-care therapies, including cytotoxic agents, anti-PD-1/PD-L1 agents, monoclonal antibodies and other cell therapy approaches, for the treatment of a wide range of cancer indications.

Our novel constructs

Our Gammabody molecules utilize fully 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 have been shown to be able to 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 use of VHH single domain antibody components and their therapeutic potential 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 two relatively small Gammabody formats: a bispecific format in which a Vgamma9 Vdelta2 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 a 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

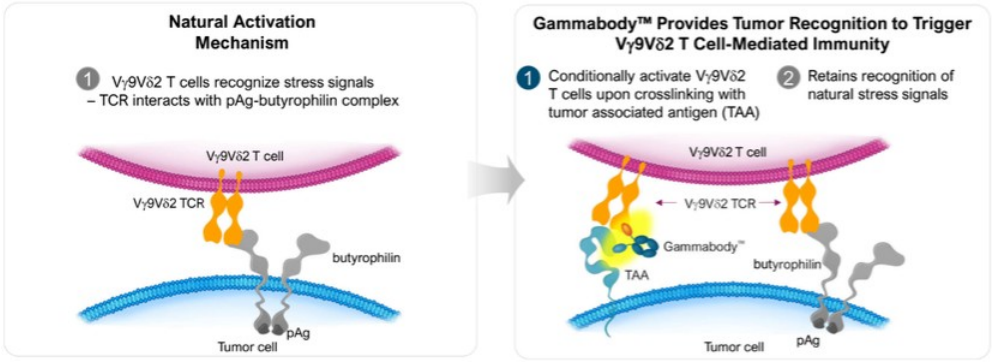
We have demonstrated that bispecific VHH antibodies can be produced in yeast, which allows for robust and low-cost production. Fc-domain-containing bispecific VHH-domain antibodies are produced using the widely used Chinese Hamster Ovary (CHO) manufacturing platform and knobs-into-holes (KiH) technology. 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. Bispecific VHH-Fc are thus produced in a single CHO cell line in which favored heterodimer pairing ensures high yields of the bispecific product.

Our Gammabody platform

We have developed a proprietary Gammabody platform that optimizes tumor-targeted activation of Vgamma9 Vdelta2 cells for tumor cell killing, retains and leverages the inherent tumor cell recognition and killing capabilities of thesecells and drives a downstream immune response cascade against tumor cells. Our platform combines the power and natural selectivity of Vgamma9 Vdelta2 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, as well as upon earlier strategies for recruiting gamma delta T cells for cancer therapy.

In the graphic below, the left panel shows the natural activation mechanism of Vgamma9 Vdelta2 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 Vgamma9 Vdelta2 T cells and a tumor-associated antigen of choice. Crosslinking via our Gammabody leads to activation of Vgamma9 Vdelta2 T cells and potent tumor cell killing. While our approach bypasses the requirement of interactions between the Vgamma9 Vdelta2 TCR and phosphoantigen-activated butyrophilins, Gammabody molecule bound Vgamma9 Vdelta2 T cells retain the inherent tumor specificity of Vgamma9 Vdelta2 T cells. We have shown in our preclinical work that this results in strong activityagainst tumor cells, but only limited activity against healthy cells expressing the same target.

LAVA's proprietary Gammabody platform engages Vgamma9 Vdelta2 T cells for targeted cancer treatment



Our approach targets antigens that are frequently expressed at higher levels on tumor cells as compared to healthy cells. In addition, our platform avoids 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 that have shown that Treg activation, as assessed by flowcytometric detection of the early activation-marker CD69, is induced by a CD3-based TCE, but not by our Gammabody. Since our platform does not activate immune suppressive cells like Tregs, we believe this dampening effect is unlikely to occur with our Gammabody molecules, increasing their potential efficacy compared to CD3-based TCEs.

We believe our Gammabody molecules drive a cascade response that potentially provides for enhanced anti-tumor efficacy. After the initial activation of Vgamma9 Vdelta2 T cells is mediated through our Gammabody molecules, the activated Vgamma9 Vdelta2 T cells are designed to rapidly kill tumor target cells, and also have the potential for:

- *Expansion.* The Vgamma9 Vdelta2 T cells proliferate, resulting in an increased number of anti-tumor Vgamma9 Vdelta2 T cells.
- *Broad immune activation.* The Vgamma9 Vdelta2 T cells trigger the activation and antitumor activity of other immunecells, such as NK cells, alpha-beta T cells and dendritic cells.
- *Antigen presentation.* The Vgamma9 Vdelta2 T cells process and present tumor antigens and acquire dendritic cell- like antigen presenting functions to trigger the development of "classical" naïve $CD4^+$ and $CD8^+$ alpha-beta Tcell responses against the tumor.

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

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. Anti-tumor activity has been shown in *in vivo* preclinical animal models and in *ex vivo* models using patient tumor and Vgamma9 Vdelta2 T cells. Our preclinical experiments have also shown that activation of the Vgamma9 Vdelta2 T cell population is conditional upon Gammabody crosslinking.

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

License agreements

Janssen Agreement

In May 2020, we entered into the Janssen Agreement for the discovery and development of novel bispecific antibody-based gamma delta T cell engagers for the treatment of cancer. Under the Janssen Agreement, we granted Janssen an exclusive, sublicensable, worldwide license under certain of our patents, materials, and know-how, including certain rights assigned to us pursuant to the VUmc Agreement, to exploit multi-specific antibody products which have variable domains specific to the licensed target or products which are directed to the licensed target, in all fields of use. We retain the right to use our technology to perform our obligations under the Janssen Agreement and for all purposes not granted to Janssen.

We are conducting 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. The parties have established a joint steering committee to oversee the research, information sharing, and potential amendments of the research plan. We are responsible for conducting research activities at our expense and are entitled to certain milestone payments from Janssen for product candidates that progress through all subsequent research stages. Janssen may elect to take over all or a portion of such research at any time. Following completion of such research, Janssen has the right to determine whether to bring one or more designated product candidates forward into further development. If Janssen so elects, Janssen is responsible for the development, manufacture, and commercialization of the licensed products at Janssen's sole cost and expense. Janssen is required to use commercially reasonable efforts to exploit one licensed product.

In May 2020, we received an upfront fee of $8.0 million and have achieved research milestones necessary to receive $2.0 million, $1.0 million received both in October of 2021 and December of 2020, and are eligible to receive further payments upon the achievement of certain development and commercial milestones. We also are entitled to receive tiered royalties based on commercial for a fixed period following the first commercial sale of such a licensed product.

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

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

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

VUmc agreement

In January 2017, we entered into the VUmc Agreement. Under the VUmc Agreement, VUmc 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 VUmc, effectively including research and other services provided in collaboration by VUmc since 2017 to develop, make, and sell licensed products. In March 2021, VUmc assigned all of the patent rights previously licensed by us under the VUmc Agreement for no additional consideration paid. VUmc 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 VUmc sub to low single-digit tiered royalties on net sales of products covered by claims included in the assigned patent rights. Royalties are payable on a country-by-country basis for a royalty term that expires upon the expiration of the last valid claim in the assigned patent rights in such country that would be infringed by the use, manufacture, or sale of a product in such country in the absence of us having rights to such patent right. In connection with our IPO, we issued to VUmc 235,664 of our common share and paid $0.3 million in cash. On each of the first and second anniversary of our IPO, we are required to pay $5.0 million. Such payment shall be made in cash or common shares, at the election of the Company, valued using the closing price of common shares on the date two trading days prior to the respective anniversary of our IPO. The Company and VUmc have been collaborating since 2017 and VUmc makes available certain employees to the Company who perform research and other activities for the benefit of the Company.

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

In January 2021, we entered into a master research services agreement with VUmc under which VUmc performs certain clinical research services and preclinical development for us under the direction of our CSO. Under this master research services agreement, we own all rights, title, ownership and interest in and to any inventions made, created or prepared by VUmc in connection with the Agreement. 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 agreement.

Manufacturing, sales and marketing

Given the stage of our lead programs, we are in the process of building our U.S. commercial, medical affairs and manufacturing infrastructure and intend to build, alone or with potential future partners, our global commercialization and distribution capabilities over time for our lead clinical candidates. We do not own or operate manufacturing facilities for the production of our clinical candidates, and we rely on third-party contract manufacturers for all of our required raw materials, manufacturing devices, active pharmaceutical ingredients and finished product for our preclinical research and clinical trials.

Our Strategy

Our goal is to rapidly develop new cancer treatments that leverage the immune system to save patients' lives. 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. Key components to our strategy include:

- Establish ourselves as the leader in the development of gamma delta T cell engagers for the treatment of cancer.
- Rapidly accelerate the clinical development of our lead candidates, LAVA-051 and LAVA-1207, to support proof-of-concept and other enabling activities for our investigational candidates.
- Achieve competitive excellence by leveraging the transformational potential of our platform to advance and expand our earlier stage pipeline while broadening the applications of the platform to additional targets and patient populations.
- Enhance our pipeline and platform through strategic partnership and collaboration opportunities.
- Leverage and continue to build our intellectual property portfolio in order to protect our Gammabody platform and our leadership position in gamma delta bsTCEs.

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 gamma delta T cell field.

Our competitors in the field of gamma delta T cell therapy include Adicet Bio, Inc., Editas Medicine, Inc., Takeda Pharmaceutical Company Ltd, ImCheck Therapeutics SAS, Immatics Biotechnologies GmbH, Leucid Bio Ltd, PhosphoGam Inc., Shattuck Labs Inc., Sandhill Therapeutics, Inc, Gadeta BV, Eureka Therapeutics, Inc., In8Bio, Inc., and TC BioPharm Limited. Our gamma delta 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 prove to 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 issued U.S. patents, six pending U.S. patent applications, five pending European regional-phase patent applications, four pending PCT patent application, eight issued patents in other territories and 37 pending patent applications in other territories that are important to the development of our business.

Our strategic initiative is to protect proprietary technology, inventions and improvements to inventions and other intellectual property that may be commercially important to the development of our business. We also intend to seek additional patent protection or rely upon trade secret rights to protect other technologies that may be used to manufacture and develop our gamma delta T cell products. We are a party to license and assignment agreements that grant us exclusive rights to use specific technologies in our gamma-delta T cell products and in the manufacturing and development of our products. For more information, see *"Item 4: Information on the Company."*

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, 2021, our patent portfolio included U.S. and foreign patents and patent applications. Our patent portfolio also includes in-licensed patents and patent applications that we have filed on our own technologies, including technologies related to our preclinical programs and our manufacturing technologies. The patents and patent applications in our patent portfolio cover technology used in our own development programs, as well as technology used in our collaboration with Janssen. We have granted Janssen an exclusive worldwide license for the development and commercialization of a confidential product candidate.

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

LAVA-051

For LAVA-051, LAVA's patent portfolio includes two issued U.S. patents and five U.S. pending patent applications, as well as, five pending European patent applications, eight foreign issued patents, 27 pending foreign patent applications. These patent and patent applications contain claims or supporting disclosures directed to the LAVA-051 composition of matter and to methods of treating diseases of interest using LAVA-051. These issued patents and patents issuing from these pending patent applications, if any, are expected to expire between 2035 and 2039, excluding any potential patent term extensions or patent term adjustments.

LAVA-1207

For LAVA-1207, LAVA's patent portfolio includes one issued U.S. patent, two U.S pending patent applications, and one pending European patent application, five foreign issued patents, eight foreign pending patent applications and two pending PCT patent applications containing claims or supporting disclosures directed to the LAVA-1207 composition of matter and to methods of treating diseases of interest using LAVA-1207. This issued patent and patents issuing from these pending patent applications, if any, are expected to expire between 2035 and 2041, excluding any potential patent term extensions or patent term adjustments.

LAVA-1223

For LAVA-1223, LAVA's patent portfolio includes one issued U.S. patent, two U.S pending patent applications, and one pending European patent application, five foreign issued patents, eight foreign pending patent applications and three pending PCT patent applications containing claims or supporting disclosures directed to the LAVA-1223 composition of matter and to methods of treating diseases of interest using LAVA-1223. This issued patent and patents issuing from these pending patent applications, if any, are expected to expire between 2035 and 2042, excluding any potential patent term extensions or patent term adjustments.

LAVA-1266

For LAVA-1266, LAVA's patent portfolio includes one issued U.S. patent, two U.S pending patent applications, and one pending European patent application, five foreign issued patents, eight foreign pending patent applications and four pending PCT patent 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 between 2035 and 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-051, LAVA-1207 and preclinical candidates.

LAVA-1278

For LAVA-1278, LAVA's patent portfolio includes one issued U.S. patent, three U.S pending patent applications, and two pending European patent applications, five foreign issued patents, eighteen foreign pending patent applications and two pending PCT patent applications containing claims or supporting disclosures directed to the LAVA-1278 lead composition of matter and to methods of treating diseases of interest using the CD40 lead compound. This issued patent and patents issuing from these pending patent applications, if any, are expected to expire between 2035 and 2040, excluding any potential patent term extensions or patent term adjustments.

Platform Technology

Our patent portfolio also includes patent families relating to our Gammabody platform, including three patent families that are generally relate to the antibodies that activate gamma delta T cells, dosing of such antibodies and uses of such antibodies for certain patient groups.

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 gamma delta T cells and modified gamma-delta 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 physical security of our premises and physical and electronic security of our information technology systems.

Government regulation

The FDA and other regulatory authorities at federal, state, and local levels, and in the European Union 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 various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA’s current Good Laboratory Practices regulation;
- submission to the FDA of an IND, 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 trial is commenced;
- performance of adequate and well controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA 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 an FDA 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
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and clinical development

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

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

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

Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points 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 BLA 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.

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.

BLA submission and review

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

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

requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

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

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

Expedited development and review programs

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

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of 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 take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

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

A new regenerative medicine advanced therapy, or RMAT, designation as part of its implementation of the 21st Century Cures Act. 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 on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites.

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

Orphan drug designation

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

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

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

Post-approval requirements

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

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

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

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

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

Biosimilars and reference product exclusivity

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

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

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

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

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

Clinical Trial Approval

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the applicant may only start a clinical trial at a specific study site after the independent ethics committee has issued a favorable opinion. The CTA must be accompanied by an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the member states and further detailed in applicable guidance documents.

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

Orphan Drug Designation and Exclusivity

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

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

Marketing Authorization

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

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

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting the assessment of a product to define its risk/benefit profile. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation may be granted by the CHMP in

exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

Periods of Authorization and Renewals

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

Regulatory Requirements after Marketing Authorization

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

Other healthcare laws and compliance requirements

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

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

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

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information on certain healthcare providers, healthcare clearinghouses, and health plans, known as covered entities, and independent contractors, or

agents of covered entities that receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity, known as a business associates, as well as their covered subcontractors. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions.

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

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

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) 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. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists and certified nurse-midwives.

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 be in compliance 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 a number of 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. In particular, obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. Limited coverage and less than adequate reimbursement may reduce the demand for, or the price of, any product for which we obtain regulatory approval. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Additionally, in the United States there is no uniform policy among third-party payors for coverage or reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

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

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

Healthcare reform

In the United States and some foreign jurisdictions, there have been, and continue to be, legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the ACA and its implementing regulations substantially changed healthcare financing and delivery by both governmental and private insurers. Among the ACA provisions of importance to the

pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

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

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.

Other regulations

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

Facilities

Our headquarters are at Yalelaan 60, 3584 CM Utrecht, the Netherlands, where we occupy approximately seven multiple office and laboratory spaces under a lease that, for certain spaces, has been entered into for an indefinite period and, for other spaces, expires December 31, 2021. We also occupy a small office space located at 520 Walnut Street, Suite 1150, Philadelphia, Pennsylvania 19106, U.S. 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 4A: Unresolved Staff Comments

None.

Item 5: Operating and Financial Review and Prospects

You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and the notes included elsewhere in this Annual Report. The following discussion contains forward-looking statements that involve certain risks and uncertainties. Our actual results could differ materially from those discussed in these statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report, particularly under the "Item 3. Key Information—Risk factors" and "Special Note Regarding Forward-Looking Statements" sections.

Our audited consolidated financial statements are included elsewhere in this Annual Report. These financial statements are in accordance with and comply with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). As permitted by the rules of the SEC for foreign private issuers, we do not reconcile our financial statements to accounting principles generally accepted in the U.S. (U.S. GAAP).

Operating Results

Impact from COVID-19 Pandemic

Our financial condition and results of operations are most affected by our capital resources, continued research and development expenses and general and administrative expenses. Although the COVID-19 pandemic has impacted the timing of onboarding investigational sites and enrolling patients in our ongoing Phase 1/2a clinical trial for LAVA-051, to date we have not experienced any material business disruption as a result of the COVID-19 pandemic.

Components of operating results

Revenue from research and license agreements

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 and our ability to finance operations. If our development efforts result in clinical success and regulatory approval or we enter into collaboration

agreements with third parties for our product candidates, we may generate revenue from those product candidates.

In May 2020, we entered into the Janssen Agreement. As part of the Janssen Agreement, we received a non-refundable upfront payment of $8.0 million. As of December 31, 2021, there was $1.5 million of unearned income related to this payment. The unearned income is being recognized as revenue on a straight-line basis over the remaining four-month term of the research activities under the Janssen Agreement. Including research and development milestone payments, we recognized revenue of $5.0 million and $3.5 million for the years ended December 31, 2021 and 2020, respectively. In December 2020, we achieved the first Research Milestone, as defined in the Janssen Agreement, triggering a milestone payment of $1.0 million. In September 2021, we achieved the second Research Milestone, triggering a milestone payment of $1.0 million. Each milestone payment was recorded as revenue when achieved, as each was linked to the completion of specific and separable research and development deliverables, rather than recorded over time like the upfront payment.

We are entitled to receive tiered royalties based on commercial sales levels from low to mid-single digit percentages of net sales of licensed products. Royalties are payable on a licensed product-by-licensed product and country-by-country basis beginning with the first commercial sale of such licensed product in such country of sale and expiring ten years after such sale, subject to specified and capped reductions for the market entry of biosimilar products, loss of patent coverage of licensed products, and for payments owed to third parties for additional rights necessary to commercialize licensed products in the territory. For additional information, see “License Agreements – Janssen Agreement” and Note 4 to the consolidated financial statements for the years ended December 31, 2021 and 2020.

Operating expenses

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

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

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

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

We expect that our research and development expenses will increase substantially in connection with our ongoing and planned preclinical and clinical development activities in the near term and in the future.

General and administrative expenses consist of personnel-related expenses for employees involved in general corporate functions, including accounting, finance, insurance, tax, legal and human relations, costs associated with outside professional fees such as legal counsel and auditors, costs associated with use by these functions of facilities and equipment, such as facility expenses, depreciation expenses, other operating

costs not included in research and development, and general corporate expenses. General and administrative expenses are expensed as incurred.

We expect general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development activities. We anticipate that we will incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance, and investor and public relations expenses associated with operating as a public company.

Income tax

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

A tax charge was recognized during the December 31, 2021 period due to the U.S. profitable position. As of December 31, 2021, we had Dutch tax loss carryforwards of $8.5 million. Furthermore, an amount of $59.8 million of IP development costs are capitalized for tax purposes. This amount can be offset against future income derived from this IP.

The 2021 taxable amounts are not final as the 2021 Dutch corporate income tax return is still in draft. The 2020 Dutch corporate income tax return is final and has been filed.

On the basis of the 2021 annual accounts according to IFRS, there are accounting-to-tax differences of $4.2 million. These differences primarily relate to non-deductible share-based payment expenses. Other differences relate to the IFRS 16 lease amounts and expenses which were treated as non-deductible for Dutch corporate income tax purposes and other non-deductible mixed expenses.

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

Comparison of the Years Ended December 31, 2021 and 2020:

Research and license revenue

Our research and license revenue increased to $5.0 million for the year ended December 31, 2021 compared to $3.5 million for the year ended December 31, 2020. Research and license revenue is solely attributable to our collaboration with Janssen, which we entered into in May 2020. In connection with this collaboration, we received a non-refundable upfront payment of $8.0 million that is being recognized on a straight-line basis over the two-year term of the research activities under the agreement, as this method of recognition matches the pattern in which we provide research services to Janssen. As of December 31, 2021, we had $1.5 million of unearned income related to this payment. We achieved milestone payments of $1.0 million during each of the years ended December 31, 2021 and 2020. Each milestone payment was recorded as revenue when achieved, as each was linked to the completion of specific and separable research and development deliverables, rather than recorded over time like the upfront payment.

Research and development expenses

Below are our research and development expenses for the years ended December 31, 2021 and 2020 (in thousands):

	For the Year ended December 31,		
	2021	2020	Variance
VUmc license expenses	$ 14,357	$ 203	$ 14,154
Pre-clinical and clinical trial expenses	14,188	11,325	2,863
Personnel-related expenses	4,955	2,276	2,679
Research and development activities expenses	1,843	1,022	821
Share-based compensation expense	1,036	232	804
Facilities and other research and development expenses	814	643	171
	$ 37,193	**$ 15,701**	**$ 21,492**

Research and development expenses were $37.2 million for the year ended December 31, 2021, compared to $15.7 million for the year ended December 31, 2020. The increase was primarily due to a VUmc license fees liability of $14.4 million triggered by our IPO. Pre-clinical and clinical trial expenses increased by $2.9 million primarily due to the start of the clinical trial for LAVA-051, clinical development preparations for LAVA-1207 and expenditures in connection with our Janssen collaboration. Personnel-related expenses increased by $2.7 million and non-cash share-based compensation expense increased by $0.8 million due to the increased research and development headcount and associated granting of stock option awards.

General and administrative expenses

Below are our general and administrative expenses for the years ended December 31, 2021 and 2020 (in thousands):

	For the Year ended December 31,		
	2021	2020	Variance
Personnel-related expenses	$ 3,800	$ 1,474	$ 2,326
Share-based compensation expense	3,261	326	2,935
Professional and consultant fees	2,593	683	1,910
Insurance, facilities, fees and other related costs	2,506	236	2,270
	$ 12,160	**$ 2,719**	**$ 9,441**

General and administrative expenses were $12.2 million for the year ended December 31, 2021, compared to general and administrative expenses of $2.7 million for the year ended December 31, 2020. The increase was primarily due to increases in personnel-related expenses of $2.3 million and noncash share-based compensation expense of $2.9 million, due to the increased general and administrative headcount and associated granting of stock option awards. Professional and consultant fees increased by $1.9 million due to increased legal and assurance services primarily due to becoming a publicly traded company. Insurance, facilities, fees and other related costs increased by $2.3 million primarily due to directors' and officers' insurance costs and other costs associated with being a publicly traded company.

Interest expense, net

Interest expense, net was $0.6 million for the year ended December 31, 2021, compared to $0.3 million for the year ended December 31, 2020. Interest expense, net includes interest on borrowings associated with our Innovation Credit from Rijksdienst voor Ondernemend Nederland, lease interest and negative interest on cash deposits held at financial institutions, net of interest income.

Foreign currency exchange loss, net

Our foreign currency exchange loss was $0.2 million for both years ended December 31, 2021 and 2020. The activity was primarily due to our USD denominated cash and investment accounts, foreign exchange cash activity with our U.S. subsidiary as well as transactions with vendors whose functional currency is not the EUR, the functional currency of LAVA Therapeutics N.V.

Comparison of the Years Ended December 31, 2020 and 2019

Research and license revenue

Our research and license revenue was $3.5 million for the year ended December 31, 2020. We had no research and license revenue for the year ended December 31, 2019. Research and license revenue is solely attributable to our collaboration with Janssen, which we entered into in May 2020. In connection with this collaboration, we received a non-refundable upfront payment of $8.0 million that is being recognized on a straight-line basis over the two-year term of the research activities under agreement. We achieved milestone payments of $1.0 million during the year ended December 31, 2020, which were recorded as revenue when achieved, as each was linked to the completion of specific and separable research and development deliverables, rather than recorded over time like the upfront payment.

Research and development expenses

Below are our research and development expenses for the years ended December 31, 2020 and 2019 (in thousands):

	For the Year ended December 31,		
	2020	2019	Variance
Pre-clinical and clinical trial expenses	$ 11,325	$ 5,118	$ 6,207
Personnel-related expenses	2,276	1,360	916
Research and development activities expenses	1,022	1,624	(602)
Facilities and other research and development expenses	643	64	579
Share-based compensation expense	232	181	51
VUmc license expenses	203	—	203
	$ 15,701	**$ 8,347**	**$ 7,354**

Research and development expenses were $15.7 million for the year ended December 31, 2020, compared to $8.3 million for the year ended December 31, 2019. Pre-clinical and clinical trial expenses increased by $6.2 million primarily due to our lead products' clinical manufacturing costs. Personnel-related expenses increased by $0.9 million and non-cash share-based compensation expense increased by $0.1 million primarily due to the increased research and development headcount and associated granting of stock option awards. Facilities and other research and development expenses increased by $0.6 million primarily due to expansion of our facilities in the Netherlands. An additional increase of $0.2 million was due to expenses associated with our VUmc license. These increases were offset by a decrease of $0.6 million due to fewer scientific advisory consultants, research and development consultants and laboratory supplies.

General and administrative expenses

Below are our general and administrative expenses for the years ended December 31, 2020 and 2019 (in thousands):

	For the Year ended December 31,		
	2020	2019	Variance
Personnel-related expenses	$ 1,474	$ 477	$ 997
Professional and consultant fees	683	674	9
Share-based compensation expense	326	11	315
Insurance, facilities, fees and other related costs	236	74	162
	$ 2,719	**$ 1,236**	**$ 1,483**

General and administrative expenses were $2.7 million for the year ended December 31, 2020, compared to general and administrative expenses of $1.2 million for the year ended December 31, 2019. The increase was primarily due to increases in personnel-related expenses of $1.0 million and noncash share-based compensation expense of $0.3 million, due to the increased general and administrative headcount and associated granting of stock option awards. Insurance, facilities, fees and other related costs increased by $0.2 million primarily due to the addition of office space in the U.S.

Interest expense, net

Interest expense, net was $0.3 million for the year ended December 31, 2020, compared to $0.1 million for the year ended December 31, 2019. Interest expense, net includes interest on borrowings associated with our Innovation Credit from Rijksdienst voor Ondernemend Nederland, lease interest and negative interest on cash deposits held at financial institutions, net of interest income.

Foreign currency exchange loss, net

Our foreign currency exchange loss was $0.2 million for the year ended December 31, 2020, compared to no foreign currency exchange loss for the year ended December 31, 2019. The activity was primarily due to our

USD denominated cash and investment accounts, foreign exchange cash activity with our U.S. subsidiary as well as transactions with vendors whose functional currency is not the EUR, the functional currency of LAVA Therapeutics N.V.

Liquidity and Capital Resources

As of December 31, 2021, we had cash, cash equivalents and investments totaling $133.2 million, compared to cash and cash equivalents of $15.8 million as of December 31, 2020. We have historically funded our operations primarily through issuance of preference shares prior to our IPO and from the sale of common shares in our IPO. Our expenditures are primarily related to research and development activities and general and administrative activities to support business operations.

In March 2021, we closed 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, we received $56.6 million in net proceeds from our Series C financing, net of repurchasing Series A Preferred and common shares.

Based on our current operating plan, we believe that our existing cash, cash equivalents and investments as of December 31, 2021 are sufficient to meet our projected cash requirements for at least 12 months from the date of this 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-051 and LAVA-1207;
- initiate, conduct and complete any ongoing, anticipated or future preclinical studies and clinical trials for our current and future product candidates;
- develop processes and scale manufacturing production for our current and future product candidates in accordance with cGMP;
- seek regulatory and marketing approvals for LAVA-051, LAVA-1207 and any of our other product candidates that successfully complete clinical trials;
- discover and develop additional bispecific gamma delta engagers and make further investments in our Gammabody platform to identify additional product candidates;
- maintain, protect and expand our intellectual property portfolio; including costs associated with opposing and invalidating competitor patents and licensing other technologies for our product candidates;
- establish a sales, marketing, manufacturing and distribution, supply chain and other commercial infrastructure in the future to commercialize any current or future product candidate for which we may obtain marketing approval;
- expand our operations in the United States and Europe;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- acquire or in-license additional product candidates and technologies;
- develop a potential companion diagnostic;
- incur additional legal, accounting and other expenses associated with operating as a public company; and
- address any ancillary effects of the COVID-19 pandemic on our business.

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

The following table summarizes our cash flows for each of the years ended December 31, 2021, 2020 and 2019 (in thousands):

	For the Year ended December 31,		
	2021	2020	2019
Net cash used in operating activities	$ (28,647)	$ (9,307)	$ (8,615)
Net cash used in investing activities	(43,545)	(502)	(792)
Net cash provided by financing activities	151,160	18,969	1,176
Net increase (decrease) in cash and cash equivalents	**$ 78,968**	**$ 9,160**	**$ (8,231)**

Cash Flows Used in by Operating Activities

Net cash used in operating activities for the year ended December 31, 2021 was $28.6 million, compared to net cash used in operating activities of $9.3 million for the year ended December 31, 2020. The increase was primarily due to an increase in loss before income tax of $29.7 million, partially offset by an increase of $4.3 million of increased non-cash operating expenses including share-based compensation, depreciation, lease amortization, foreign currency exchange and amortization of investment bond premiums, and an increase in changes in working capital of $6.1 million.

Net cash used in operating activities for the year ended December 31, 2020 was $9.3 million, compared to net cash used in operating activities of $8.6 million for the year ended December 31, 2019. The increase was primarily due to an increase in loss before income tax of $5.8 million, partially offset by an increase of $1.0 million of increased non-cash operating expenses including share-based compensation, depreciation, lease amortization and foreign currency exchange, and an increase in changes in working capital of $4.1 million.

Cash Flows Used in Investing Activities

Cash flows used in investing activities for the year ended December 31, 2021 were $43.5 million, compared to $0.5 million for the year ended December 31, 2020. During the year ended December 31, 2021, we purchased $45.3 million in investments in debt securities and received proceeds from maturities of investments of $2.5 million. We also made equipment purchases of $0.8 million and $0.5 million for the years ended December 31, 2021 and 2020, respectively.

Cash flows used in investing activities for the year ended December 31, 2020 were $0.5 million, compared to $0.8 million for the year ended December 31, 2019. We made equipment purchases of $0.5 million and $0.8 million for the years ended December 31, 2020 and 2019, respectively.

Cash Flows Provided by Financing Activities

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

Cash flows provided by financing activities for the year ended December 31, 2020 of $19.0 million was primarily related to net proceeds from our Series C preferred financing of $22.0 million and proceeds from debt borrowings of $2.0 million, offset by Series A preferred payments and common share repurchases of $4.8 million and repayments of lease liabilities of $0.2 million.

Cash flows provided by financing activities for the year ended December 31, 2019 of $1.2 million was primarily related to proceeds from debt borrowings of $1.3 million, offset by repayments of lease liabilities of $0.1 million.

Off-Balance Sheet Arrangements

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

Critical accounting policies and significant judgments, estimates and assumptions

We prepare our financial statements in accordance with IFRS as issued by the IASB, which requires us to make judgments, estimates and assumptions that affect the reported amounts of our assets and liabilities and the disclosure of our contingent assets and liabilities at the end of each fiscal period and the reported amounts of revenue and expenses during each fiscal period. Critical accounting policies are defined as those policies that are reflective of 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 financial statements.

Clinical trial expenses

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

We determine accrual estimates based on estimates of the services received and efforts expended that take into account discussion with applicable personnel and outside service providers as to the progress or state of completion of trials. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from our estimates. We make estimates of our accrued expenses and prepaid assets as of each balance sheet date in our financial statements based on the facts and circumstances known to us at that time. Our clinical trial accrual and prepaid assets are dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Although we do not expect our estimates to differ materially from amounts we actually incur, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low for any particular period.

Deferred tax assets

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

A tax charge was recognized during the reporting periods due to the U.S. profitable position. We have tax loss carryforwards of $8.5 million as of December 31, 2021. As a result of the Dutch corporate income tax

law, tax loss carryforwards are not subject to a time limitation and remain available for offset indefinitely. Actual offset of these losses is however limited to 50% of the taxable amount that exceeds EUR 1 million (previously losses carry forward were subject to a time limitation of six years whereas losses from 2018 and prior years were subject to a time limitation of nine years – all losses that were still available for offset on 1 January 2022 became available for offset indefinitely).

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

In order to promote innovative technology development activities and investments in new technologies, a corporate income tax incentive has been introduced in Dutch tax law called the “Innovation Box.” Profits from self-developed qualifying intangible assets are effectively subject to a 7% income tax rate for 2020 and a 9% income tax rate for 2021 and future years, instead of the general headline rate of 25% (25.8% as of 2022). Lava Therapeutics N.V. believes it qualifies for the Innovation Box and is in this respect currently in a process for obtaining advance certainty from the Dutch tax authorities. For further information, please refer to Note 9 in our consolidated financial statements.

Item 6: Directors, Senior Management and Employees

A. Directors and Senior Management

Non-Executive Directors

The following table lists the current composition of the non-executive directors serving on the board of directors, including the ages of the directors, their current terms of service and year of expiry of their term, and their position:

Name	Age	Term served	Year in which term expires	Position
Kapil Dhingra	61	February 2021—Present	2024	Chairperson and Non-Executive Director
Erik J. van den Berg	49	January 2017—Present	2022	Non-Executive Director
Joël J.P. Jean-Mairet	49	September 2019—Present	2022	Non-Executive Director
Nanna L✔neborg	45	September 2020—Present	2023	Non-Executive Director
Stefan Luzi	37	January 2018—Present	2023	Non-Executive Director
Guido Magni	67	May 2018—Present	2023	Non-Executive Director
Karen J. Wilson	58	March 2021—Present	2024	Non-Executive Director

The following is a brief summary of the business experience of our supervisory board members. Unless otherwise indicated, the current business address for each director is the same as our business address: Yalelaan 60, 3584 CM Utrecht, the Netherlands.

Kapil Dhingra, M.B.B.S. has served as Chairperson of our board and as a non-executive director since February 2021. He has served as Managing Member of KAPital Consulting, LLC, which he also co-founded, since August 2008. He has served on the boards of directors of several publicly traded and privately held companies, including Black Diamond Therapeutics, Inc. since January 2021, Replimune Group since July 2017 and Autolus Ltd. since August 2014. He also served on the board of directors at Five Prime Therapeutics from December 2015 to April 2021, Exosome from 2012 to August 2018, where he also served as Chairman, at Advanced Accelerator Applications from April 2014 to January 2018, at EpiTherapeutics ApS from January 2014 to May 2015, Algeta ASA from 2010 to March 2014, YM Biosciences from 2012 to February 2013, Coferon from January 2009 to June 2012, Micromet AG from 2009 to March 2012 and BioVex from 2009 to 2011. Dr. Dhingra previously served as Vice President, Head of the Oncology Disease Biology Leadership Team and Head of Oncology Clinical Development at Hoffman-La Roche from May 1999 to August 2008. He received a M.B.B.S. from the All India Institute of Medical Sciences. We believe that Dr. Dhingra is qualified to serve on our board of directors because of his extensive experience in executive

positions with several pharmaceutical companies and in the clinical development of pharmaceuticals in several therapeutic areas, including in oncology, and his experience serving on the boards of several publicly traded life science companies.

Erik J. van den Berg has served as a non-executive director since January 2017 and as Chairperson of our non-executive board from March 2018 to February 2021. He currently serves as the Chief Executive Officer of AM-Pharma. Prior to joining AM-Pharma in 2007, where he also previously served as Chief Business Officer, Mr. van den Berg served as a Senior Executive at Organon, where he was responsible for global biotechnology business development. He currently serves on the boards of directors at Heatmatrix Group, Lead Pharma and Step Pharma. He received his Master's in Chemistry from the University of Utrecht and an MBA from the Manchester Business School. We believe that Mr. van den Berg is qualified to serve on our board of directors due to his experience as a senior executive and director of clinical-stage biotechnology and life sciences companies, his extensive experience as a director of multiple companies and his investment experience in the life sciences industry.

Joël J.P. Jean-Mairet, Ph.D., has served as a non-executive director since 2019. He has served as Managing Partner at Ysios Capital, which he also co-founded, since November 2007. He has served on the boards of directors of several privately held companies, including Aura Biosciences, Sanifit Therapeutics, Ona Therapeutics, SpliceBio and Inbiomotion, where he also serves as Chairman. He also served on the board of directors at Cellerix/Tigenix (now Takeda). Dr. Jean-Mairet previously served as Chief Executive Officer of Glycart Biotechnology from 2001 to 2005. He received a M.S. and Ph.D. in Biotechnology from the Swiss Federal Institute of Technology (ETH). We believe that Dr. Jean-Mairet is qualified to serve on our board of directors because of his extensive experience in our industry, including his strategic management and operational experience, as well as his significant experience as an investor in life sciences companies.

Nanna L✓neborg, Ph.D., has served as a non-executive director since September 2020. She is currently a General Partner of Forbion, since September 2021. She has previously been employed in various roles at Novo Holdings A/S since March 2012, including as Partner, Principal, Investment Director. She currently serves on the boards of directors of several other privately held companies, including ReViral, NodThera, Epsilon3-Bio and Stargazer. She has previously served on the boards of publicly traded and privately held companies, including ObsEva, NBE Therapeutics, Inthera, IO Biotech, MinervaX, Pcovery, Inventiva, and Orphazyme. Dr. L✓neborg previously served as an Associate at Apposite Capital. She received a B.A. in Physiology and Psychology from the University of Oxford, a Ph.D. in Neuroscience from University College London and an MBA from the University of Cambridge. We believe that Dr. L✓neborg is qualified to serve on our board of directors due to her experience serving on the board of directors of clinical-stage biotechnology companies, including public companies, and her investment experience within the life science industry.

Stefan Luzi, Ph.D., has served as a non-executive director since January 2018. He has also served on the board of directors at Lumicks B.V. (observer) and Draupnir Bio ApS (director). Dr. Luzi has served in various roles at Gilde Healthcare since April 2015, including Associate and then Partner. Dr. Luzi previously worked at Merck KGaA from March 2013 to February 2015. He received a B.Sc. in Biology and M.Sc. in Biotechnology from the Swiss Federal Institute of Technology Zurich (ETH) and his MPhil in Bioscience Enterprise and his Ph.D. in Molecular Biology from the University of Cambridge. We believe that Dr. Luzi is qualified to serve on our board of directors due to his business and investment experience within the life science industry, particularly with biotechnology companies.

Guido Magni, M.D., Ph.D., has served as a non-executive director since May 2018. He is currently a Partner at Versant Ventures. Prior to joining Versant in 2012, Dr. Magni previously served as a Managing Director of EuroVentures, a Versant incubator, where he was intimately involved in several biotech investments including Synosia (sold to Biotie Therapies), Flexion and Okairos. He currently serves on the boards of directors of several privately held companies, including Nouscom and Tarveda Therapeutics. He also previously served on the boards of directors of Aprea and Gensight Biologics, both publicly held companies. Dr. Magni previously served as the Global Head of Medical Science and of Global Drug Development at Roche. He received his M.D. and Ph.D. in neuropharmacology from the University of Padua. We believe that Dr. Magni is qualified to serve on our board of directors due to his experience serving on the board of directors of clinical-stage biotechnology companies, his experience as a director of public companies and his investment experience in the life sciences industry.

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

Board Diversity

The table below provides certain information regarding the diversity of members of our Board as of the date of this Annual Report:

Board Diversity Matrix

Country of Principal Executive Offices	The Netherlands
Foreign Private Issuer	Yes
Disclosure Prohibited Under Home Country Law	No
Total Number of Directors	8

	Female	Male	Non-Binary	Did not disclose
Part I: Gender Identity				
Directors	2	6	—	—
Part II: Demographic Background				
Underrepresented Individual in Home Country			—	
LGBTQ+			—	
Did Not Disclose Demographic Background			1	

Management director and executive officers

The following table presents information about our current management director and executive officers, including their ages as of the date of this annual report:

Name	Age	Year in which term expires	Position
Stephen Hurly	53	2024	Management Director and Chief Executive Officer
Edward F. Smith	50	—	Chief Financial Officer
Benjamin Winograd	65	—	Chief Medical Officer
Paul W.H.I Parren	57	—	EVP and Head of Research and Development
Hans van der Vliet	48	—	Chief Scientific Officer
Ton Adang	60	—	Chief Development Officer
Amy Garabedian	46	—	General Counsel and Corporate Secretary

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

Stephen Hurly has served as our President, Chief Executive Officer and as our management director since June 2019. Prior to joining LAVA Therapeutics, he served as President and Chief Executive Officer of Sesen Bio, a Nasdaq listed late-stage oncology firm, from September 2016 to August 2018. From August 2015 to September 2016, he served as the President and Chief Executive Officer of Viventia Bio Inc., a specialty pharmaceutical company acquired by Sesen Bio Inc in September 2016. He has served on the board of directors of PHusis Therapeutics Inc., a private targeted small molecule therapeutics company, since May 2011. Previously, he was the Chief Executive Officer of Burrill & Co.'s Merchant Banking Division, a

finance business for life science companies, from June 2011 to August 2015. From June 2008 to June 2011, he was also the head of the Life Sciences Investment Banking Practice at Boenning & Scattergood, a securities asset management and investment banking firm. He graduated from Swarthmore College with a B.A. degree in Engineering and earned an M.B.A. from the University of Chicago.

Edward F. Smith has served as our Chief Financial Officer since March 2021. Since April 2020, he has served on the board of directors of Benitec Biopharma, Inc., a publicly traded company. From November 2013 to March 2021, Mr. Smith served as the Chief Financial Officer of Marinus Pharmaceuticals, Inc., a publicly traded company. Mr. Smith previously served as the Chief Financial Officer of PolyMedix, Inc. from January 2006 to April 2013 and the executive director of finance at InKine Pharmaceutical Company, Inc. from September 2000 to December 2005. He received his B.S. in Business Administration from the University of Hartford.

Benjamin Winograd, M.D., Ph.D., has served as our Chief Medical Officer since July 2020. Prior to joining Lava Therapeutics, he served in various roles at Celgene from 2007 to 2020, including as Clinical R&D Therapeutic Area Head for Multiple Myeloma, where he led landmark studies resulting in the registration of lenalidomide (Revlimid) and pomalidamide (Pomalyst/Imnovid). Before that, Dr. Winograd served as Executive Director of Clinical Oncology at Bristol-Myers Squibb from 1990 to 1999, as VP of Global Medical Affairs (Oncology) at Pharmacia from 1999 to 2003, and as VP of Global Medical Affairs (Oncology) at Schering-Plough from 2004 to 2007. He received his MD and PhD in 1982 from the Technical University of Munich, Germany, and began his career as part of the EORTC Cooperative Group at the VU University in Amsterdam.

Paul W.H.I. Parren, Ph.D., has served as our Executive Vice President and Head of Research and Development and as a management director since May 2018. Since January 2015, he has served as a professor of molecular immunology at the Leiden University Medical Center. Since 2013, Dr. Parren has served as a board member of The Antibody Society. He has also served as Operational Partner at Gilde Healthcare since December 2017 and as Owner and Chief Executive Officer of Sparring Bioconsult BV since November 2017. From 2002 to 2017, Dr. Parren served in the positions of Vice President, Senior Vice President and Scientific Director heading Genmab's preclinical R&D and he was an Associate Professor at The Scripps Research Institute in La Jolla, CA in 2001, where he previously was a Postdoctorate and Assistant Professor. From May 2013 to May 2018, he served as Adjunct Professor of Translational Cancer Research at the University of Southern Denmark. He received his PhD in Molecular Immunology and M.Sc. in Molecular Biology & Immunology from the University of Amsterdam.

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

Ton Adang, Ph.D., has served as our Chief Development Officer since July 2017, initially as a consultant through his management consultancy company, PMC Biopartners B.V., and then full-time beginning in August 2019. Prior to joining Lava Therapeutics, he served as Chief Operating Officer at EnCare Biotech from August 2014 to December 2017, as Chief Operating Officer at Fast Forward Pharmaceuticals from October 2012 to October 2017, as Project Director at AM-Pharma from August 2014 to September 2016 and as Chief Operating Officer at SimiBio BV from July 2011 to June 2014. Dr. Adang also previously served in various roles at Merck, including as Site Scientific Operations Lead from March 2010 to July 2011 and as Senior Director of Project & Pipeline Management from November 2009 to March 2010. He received his PhD in Bioorganic Chemistry and Biopharmaceutical Sciences from the University of Leiden at the Divisions of Bio-Pharmaceutical Sciences and Bio-Organic Chemistry, and his MSc in Life Sciences from Wageningen University.

Amy Garabedian has served as our General Counsel and Corporate Secretary since July 2021. During her more than 15 years practicing law, she has advised pharmaceutical & biotech companies from start-ups to

multi-national public companies on the complex legal issues facing industry today. Ms. Garabedian most recently served as associate general counsel of Spark Therapeutics (Roche), where she served as a strategic and innovative advisor, playing an instrumental role in the successful U.S. launch of the first gene therapy for a genetic disease, led key business development transactions, and enabled pre-clinical, clinical and commercial product development. Earlier in her career, Ms. Garabedian held positions of increasing responsibility at Sandoz (Novartis) and as a business and finance attorney at Ballard Spahr LLP. She holds a B.S. in genetics and developmental biology from Penn State University, a M.S. in regulatory affairs from Temple University and a J.D. from Widener University Delaware School of Law.

B. Compensation

As a foreign private issuer, in accordance with Nasdaq listing requirements, we comply with home country compensation requirements and certain exemptions thereunder rather than complying with Nasdaq compensation requirements. Dutch law does not provide for limitations with respect to the aggregate annual compensation paid to our directors, provided that such compensation is consistent with our compensation policy.

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

For so long as we qualify as a foreign private issuer, we are not required to comply with the proxy rules applicable to U.S. domestic companies, including the requirement applicable to emerging growth companies to disclose the compensation of our chief executive officer and other two most highly compensated executive officers on an individual, rather than an aggregate, basis. The aggregate compensation, including benefits in kind, accrued or paid to members of our Board and Senior Management with respect to the year ended December 31, 2021 for services in all capacities was approximately $6.4 million.

The following table sets forth the compensation paid or accrued, including benefits in kind, to members of our Board for the year ended December 31, 2021:

		Total compensation
Stephen Hurly	$	746,894
Kapil Dhingra	$	54,750
Erik J. van den Berg	$	35,625
Joël J.P. Jean-Mairet (1)	$	—
Nanna L✔neborg	$	23,500
Stefan Luzi (2)	$	34,875
Guido Magni	$	36,750
Karen J. Wilson	$	41,250

(1) Dr. Jean-Mairet waived any director fees he was entitled to for his service on our Board during the year ended December 31, 2021.
(2) Compensation for Dr. Luzi is paid to Gilde Healthcare.

The following table sets forth the number of stock options granted to members of our Board during the year ended December 31, 2021:

	Number of Options	Exercise Price	Expiration date
Stephen Hurly	310,000	$ 5.10	12/20/2031
Kapil Dhingra	207,740	$ 8.69	3/2/2031
Kapil Dhingra	20,000	$ 5.10	12/20/2031
Erik J. van den Berg	12,428	$ 15.00	3/24/2031
Erik J. van den Berg	20,000	$ 5.10	12/20/2031

Joël J.P. Jean-Mairet (1)	—	$ —	—
Nanna L✔neborg	20,000	$ 5.10	12/20/2031
Stefan Luzi (2)	20,000	$ 5.10	12/20/2031
Guido Magni	20,000	$ 5.10	12/20/2031
Karen J. Wilson	24,261	$ 15.00	3/24/2031
Karen J. Wilson	20,000	$ 5.10	12/20/2031

(1) Dr. Jean-Mairet voluntarily waived the receipt of stock options that were granted to members of our Board in December 2021.
(2) Pursuant to a Nominee and Indemnity Agreement between Stefan Luzi and Gilde Healthcare, Dr. Luzi holds the legal title of these awards, however Gilde Healthcare holds full economic ownership of these awards.

Equity Incentive Plans

In 2018, the Company established a share option plan (2018 Stock Option Plan) that entitles employees, directors, and consultants providing services to purchase depository receipts for common shares of the Company. 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 a U.S. share option plan (2020 U.S. Stock Option Plan) that entitles employees, directors and consultants providing services to give the right to acquire a number of common shares. Under this plan, holders of vested options are entitled to purchase common shares at the exercise price determined at the date of the grant.

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

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

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

C. Board Practices

Board Structure

In connection with our IPO, we transitioned from a two-tier board structure to a one-tier board structure consisting of executive and non-executive directors. There are no family relationships among any of our directors.

Board of Directors Composition

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

- Erik van den Berg and Joël Jean-Mairet with terms expiring at the annual general meeting of shareholders in 2022;

- Stefan Emanuel Luzi, Nanna L✔neborg, and Guido Magni with terms expiring at the annual general meeting of shareholders in 2023; and
- Kapil Dhingra, Stephen Hurly, and Karen Wilson with terms expiring at the annual general meeting of shareholders in 2024.

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

Board Committees

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

Audit Committee

The Audit Committee consists of Karen J. Wilson, Stefan Luzi and Erik J. van den Berg. The Audit Committee assists the board of directors in overseeing our accounting and financial reporting processes and the audits of our financial statements. Ms. Wilson serves as chairperson. In addition, the Audit Committee is responsible for the appointment, compensation, retention and oversight of the work of our independent registered public accounting firm. Our board of directors has determined that Ms. Wilson and Mr. van den Berg satisfy the "independence" requirements set forth in Rule 10A-3 under the Exchange Act and Ms. Wilson qualifies as an "audit committee financial expert," as such term is defined in the rules of the SEC. Mr. Luzi did not qualify as independent since he is a partner at Gilde Healthcare, a significant shareholder of the company. In order to maintain audit committee membership at three members as required by Nasdaq rules and to maintain continuity of our audit committee, the board of directors has determined that it is in the best of the company and its shareholders that Mr. Luzi continue serving on the Audit Committee for a limited time until the company's 2022 annual general meeting. The audit committee is governed by a charter that complies with applicable Nasdaq rules, which charter is posted on our website.

Compensation Committee

The Compensation Committee consists of Guido Magni, Karen J. Wilson and Erik J. van den Berg. The Compensation Committee assists the board of directors in determining compensation for our executive officers and our directors. Dr. Magni serves as chairperson.

Under SEC and Nasdaq rules, there are heightened independence standards for members of the Compensation Committee, including a prohibition against the receipt of any compensation from us other than standard director fees. As permitted by the listing requirements of Nasdaq, we have opted out of Nasdaq Listing Rule 5605(d), which requires that a Compensation Committee consist entirely of independent directors. The Compensation Committee is governed by a charter that is posted on our website.

Nomination and Corporate Governance Committee

The Nomination and Corporate Governance Committee consists of Nanna L✔neborg, Stefan Luzi and Joël J.P. Jean-Mairet. The Nomination and Corporate Governance Committee assists our board of directors in identifying individuals qualified to become our directors consistent with criteria established by us and in developing our code of business conduct and ethics. Dr. L✔neborg serves as chairperson.

As permitted by the listing requirements of Nasdaq, we have opted out of Nasdaq Listing Rule 5605(e), which requires independent director oversight of director nominations. The Nomination and Corporate Governance Committee is governed by a charter that is posted on our website.

D. Employees

As of December 31, 2021, we had 58 employees (including 55 full time employees). In the Netherlands 40 of our employees work in research and development and 6 work in general and administrative areas. In the

United States 5 of our employees work in research and development and 7 work in general and administrative areas. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union and we consider our employee relations to be good. We also use outside consultants and contractors for limited engagements.

E. Share Ownership

The following table sets forth the share ownership of our Board and Senior Management as of December 31, 2021:

	Number of Common Shares	Percentage of Shares Outstanding	Voting Rights
Stephen Hurly	5,000	(1)	(2)
Edward F. Smith	—	(1)	
Benjamin Winograd	7,140	(1)	(2)
Hans van der Vliet	77,350	(1)	(2)
Ton Adang	800	(1)	(2)
Paul Parren	3,500	(1)	(2)
Amy Garabedian	—	(1)	
Kapil Dhingra	30,000	(1)	(2)
Erik J. van den Berg	60,145	(1)	(2)
Joël J.P. Jean-Mairet	—	(1)	
Nanna L✔neborg	—	(1)	
Stefan Luzi	—	(1)	
Guido Magni	10,000	(1)	(2)
Karen J. Wilson	10,000	(1)	(2)

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

The following table sets forth the stock option ownership of our Board and Senior Management as of December 31, 2021:

	Number of Options	Exercise Price	Percentage of Shares Outstanding	Expiration date
Stephen Hurly	232,934	$ 2.76	0.9 %	2/11/2030
Stephen Hurly	494,819	$ 2.76	1.9 %	12/16/2030
Stephen Hurly	310,000	$ 5.10	1.2 %	12/20/2031
Edward F. Smith	249,509	$ 15.00	1.0 %	3/24/2031
Edward F. Smith	125,000	$ 5.10	0.5 %	12/20/2031
Benjamin Winograd	259,896	$ 2.76	1.0 %	12/16/2030
Benjamin Winograd	115,000	$ 5.10	0.4 %	12/20/2031
Hans van der Vliet	68,289	$ —	0.3 %	n.a.
Hans van der Vliet	125,000	$ 5.10	0.5 %	12/20/2031
Ton Adang	7,072	$ —	— %	n.a.
Ton Adang	24,310	$ —	0.1 %	n.a.
Ton Adang	6,630	$ —	— %	n.a.
Ton Adang	8,619	$ —	— %	n.a.
Ton Adang	99,008	$ —	0.4 %	n.a.
Ton Adang	60,000	$ 5.10	0.2 %	12/20/2031
Paul Parren	89,726	$ —	0.3 %	n.a.
Paul Parren	43,316	$ —	0.2 %	n.a.
Paul Parren	178,789	$ —	0.7 %	n.a.
Paul Parren	100,000	$ 5.10	0.4 %	12/20/2031
Amy Garabedian	125,000	$ 10.33	0.5 %	7/8/2031
Kapil Dhingra	207,740	$ 8.69	0.8 %	3/2/2031
Kapil Dhingra	20,000	$ 5.10	0.1 %	12/20/2031
Erik J. van den Berg	12,428	$ 15.00	— %	3/24/2031
Erik J. van den Berg	20,000	$ 5.10	0.1 %	12/20/2031
Joël J.P. Jean-Mairet (1)	—	$ —	— %	—
Nanna L✔neborg	20,000	$ 5.10	0.1 %	12/20/2031
Stefan Luzi (2)	20,000	$ 5.10	0.1 %	12/20/2031
Guido Magni	20,000	$ 5.10	0.1 %	12/20/2031
Karen J. Wilson	24,261	$ 15.00	0.1 %	3/24/2031
Karen J. Wilson	20,000	$ 5.10	0.1 %	12/20/2031

(1) Dr. Jean-Mairet voluntarily waived the receipt of stock options that were granted to members of our Board in December 2021.
(2) Pursuant to a Nominee and Indemnity Agreement between Stefan Luzi and Gilde Healthcare, Dr. Luzi holds the legal title of these awards, however Gilde Healthcare holds full economic ownership of these awards.

Item 7: Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table presents information relating to the beneficial ownership of our common shares as of December 31, 2021 by: (i) each person, entity or group of affiliated persons, known by us to own beneficially 5% or more of our outstanding common shares; (ii) each member of our Board and Senior Management; and (iii) our Board and Senior Management as a group.

The number of common shares beneficially owned by each person, entity, or group of affiliated persons is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any common shares over which the person, entity, or group of affiliated persons has sole or shared voting power or investment power as well as any common shares that the person, entity, or group of affiliated persons has the

right to acquire within 60 days of December 31, 2021 through the exercise of any option, warrant or other right.

This information in the table relating to 5% or greater shareholders is based upon information from Schedules 13D and 13G filed with the SEC and our Senior Management's understanding of each person, entity or group of affiliated persons beneficial ownership. The percentage of outstanding common shares is computed on the basis of 25,775,538 common shares outstanding as of December 31, 2021. All major shareholders listed below have the same voting rights. Unless otherwise indicated below, the address for each beneficial owner listed is c/o LAVA Therapeutics, at Yalelaan 60, 3584 CM Utrecht, the Netherlands.

	As of December 31, 2021	
Name of beneficial owner	Number of shares	Percentage of class
5% or greater shareholders		
Cooperative Gilde Healthcare IV UA (1)	5,421,170	21.0 %
Versant Ventures (2)	4,587,837	17.8 %
Novo Holdings A/S (3)	3,327,312	12.9 %
Redmile Group, LLC (4)	2,774,409	10.8 %
Sanofi Foreign Participations B.V. (5)	1,919,455	7.4 %
Ysios Capital Partners, SGECR,S.A.U. (6)	1,590,527	6.2 %
Board and Senior Management		
Stephen Hurly (7)	218,855	*
Paul Parren (8)	138,989	*
Kapil Dhingra (9)	89,117	*
Hans van der Vliet (10)	85,163	*
Benjamin Winograd (11)	71,203	*
Erik J. van den Berg (12)	65,145	*
Ton Adang (13)	54,611	*
Karen J. Wilson (14)	23,087	*
Guido Magni (15)	15,000	*
Edward F. Smith (16)	7,813	*
Nanna L✔neborg (17)	5,000	*
Stefan Luzi (18)	5,000	*
Amy Garabedian	—	*
Joël J.P. Jean-Mairet	—	*
All board members and senior management as a group (14 persons)	783,983	3.0 %

* Represents less than 1% of our shares outstanding.

(1) All shares are held of record by Cooperative Gilde Healthcare IV U.A. ("Gilde Healthcare"). Gilde Healthcare IV Management B.V. is the manager of Gilde Healthcare and may be deemed to have voting, investment and dispositive power with respect to these securities. Gilde Healthcare IV Management B.V. is fully owned by Gilde Healthcare Holding B.V. The managing partners of Gilde Healthcare Holding B.V. are Edwin de Graaf, Marc Olivier Perret and Martemanshurk B.V. The address for Gilde is Newtonlaan 91, 3584 BP Utrecht, the Netherlands.

(2) Represents holdings of Versant Venture Capital VI, L.P. ("Versant VI"), Versant Ventures VI GP, L.P. ("GP VI"), Versant Ventures VI GP-GP, LLC ("LLC VI"), Versant Vantage I, L.P. ("Vantage LP"), Versant Vantage I GP, L.P. ("Vantage GP") and Versant Vantage I GP-GP, LLC ("Vantage LLC" and, with Versant VI, GP VI, LLC VI, Vantage LP and Vantage GP, collectively, the "Reporting Persons"). LLC VI is the general partner of GP VI, which is the general partner of Versant VI. Each of LLC VI and GP VI share voting and dispositive power over the shares held by Versant VI. Vantage LLC is the general partner of Vantage GP, which is the general partner of Vantage LP. Each of Vantage LLC and Vantage GP share voting and dispositive power over the shares held by Vantage LP. ese shares are held by Versant VI. LLC VI is the general partner of GP VI, which is the general partner of Versant VI. Each of LLC VI and GP VI share voting and dispositive power over the shares held by Versant VI and as a result may be deemed to have beneficial ownership over such securities. The address for the Versant Funds is One Sansome Street, Suite 3630, San Francisco, CA 94104.

(3) Novo Holdings A/S is a Danish limited liability company that is wholly owned by Novo Nordisk Foundation (the "Foundation"), a Danish commercial foundation. Novo Holdings A/S is the holding company in the group of Novo companies (currently comprised of Novo Nordisk A/S and Novozymes A/S) and is responsible for managing the Foundation's assets, including its financial assets. Based on the governance structure of Novo Holdings A/S and the Foundation, the Foundation is not deemed to have any beneficial ownership of the securities of the Issuer held by Novo Holdings A/S. Nanna L✔neborg, Ph.D. was formerly employed as a partner at Novo Ventures (US), Inc., which provides certain consultancy services to Novo Holdings A/S. Dr. L✔neborg is not deemed to hold any beneficiary ownership or reportable pecuniary interest in the shares held by Novo Holdings A/S. The address for Novo is Tuborg Havnevej 19, DK-2900 Hellerup, Denmark.

(4) Redmile Group, LLC's beneficial ownership is comprised of shares owned by certain private investment vehicles managed by Redmile Group, LLC, including Redmile Biopharma Investments II, L.P., which shares may be deemed beneficially owned by Redmile Group, LLC as investment manager of such private investment vehicles. The shares may also be deemed beneficially owned by Jeremy C. Green as the principal of Redmile Group, LLC. Redmile Group, LLC and Mr. Green each disclaim beneficial ownership of these shares, except to the extent of its or his pecuniary interest in such shares, if any. The address for each of the above person and entities is One Letterman Drive, Building D, Suite D3-300, San Francisco, California 94129.

(5) The shares are held of record by Sanofi Foreign Participations B.V., wholly owned subsidiary of Sanofi. Sanofi has the ability to exercise voting and dispositive power over the shares held by Sanofi Foreign Participations B.V. The address for Sanofi Foreign Participations B.V. is Paasheuvelweg 25, 1105BP Amsterdam, the Netherlands.

(6) Represents holdings of Ysios BioFund III FCRE, or Ysios. Ysios Capital Partners SGEIC SA, or Ysios Capital, is the management company of Ysios. Investment decisions with respect to the shares held by Ysios are made by an investment committee at Ysios Capital, of which Joël Jean-Mairet, Ph.D., a member of our board of directors and a General Partner at Ysios Capital, is a member. Dr. Jean-Mairet disclaims beneficial ownership of all shares held by Ysios, except to the extent of his pecuniary interest therein. The address for Ysios is c/o Ysios Capital Partners SGEIC SA, Avenida de la Libertad, 25, 4 A-B, 20004, San Sebastián, Spain.

(7) Consists of 5,000 common shares and 213,855 common shares underlying options exercisable within 60 days of December 31, 2021.

(8) Consists of 3,500 common shares and 135,489 common shares underlying options exercisable within 60 days of December 31, 2021.

(9) Consists of 30,000 common shares and 59,117 common shares underlying options exercisable within 60 days of December 31, 2021.

(10) Consists of 77,350 common shares and 7,813 common shares underlying options exercisable within 60 days of December 31, 2021.

(11) Consists of 7,140 common shares and 64,063 common shares underlying options exercisable within 60 days of December 31, 2021.

(12) Consists of 60,145 common shares and 5,000 common shares underlying options exercisable within 60 days of December 31, 2021.

(13) Consists of 800 common shares and 53,811 common shares underlying options exercisable within 60 days of December 31, 2021.

(14) Consists of 10,000 common shares and 13,087 common shares underlying options exercisable within 60 days of December 31, 2021.

(15) Consists of 10,000 common shares and 5,000 common shares underlying options exercisable within 60 days of December 31, 2021. Dr. Magni, a member of our board of directors, is a partner at Versant Ventures. Dr. Magni disclaims any beneficiary ownership or reportable pecuniary interest in the shares held by Versant except to the extent of his pecuniary interest therein.

(16) Consists of 7,813 common shares underlying options exercisable within 60 days of December 31, 2021.

(17) Consists of 5,000 common shares underlying options exercisable within 60 days of December 31, 2021.

(18) Consists of 5,000 common shares underlying options exercisable within 60 days of December 31, 2021. Pursuant to a Nominee and Indemnity Agreement between Stefan Luzi and Gilde Healthcare, Dr. Luzi holds the legal title of these awards, however Gilde Healthcare holds full economic ownership of these awards.

Accordingly, Dr. Luzi disclaims beneficial ownership of these shares, except to the extent of its or his pecuniary interest in such shares, if any.

B. Related Party Transactions

Under our related party transaction policy, related person transactions (as defined by the policy) must be reviewed by, and are subject to the approval or ratification of, our board of directors or a designated committee thereof consisting solely of independent directors, including the audit committee. Our articles of association require us to indemnify our current and former directors to the fullest extent permitted by law, subject to certain exceptions, and we have entered into indemnification agreements with all of our directors.

Each of our executive officers has entered into an employment agreement with us for an indefinite period of time. The employment agreements generally provide for base salary, sign-on bonuses, discretionary annual bonuses based on a percentage of base salary and eligibility to receive equity awards and to participate in the Company's benefits plans.

Please refer to *Item 6: Directors, Senior Management and Employees* for additional information on our board of directors and senior management. We did not have any material related party transactions during 2021.

C. Interests of Experts and Counsel

Not required for Annual Reports.

Item 8: Financial Information

A. Consolidated Financial Statements and Other Financial Information

Financial Statements

Our financial statements, accompanying notes and Reports of Independent Registered Public Accounting Firm are included in Item 17 of this annual report on Form 20-F, which are incorporated in this Item 8 by reference. As of this annual report, we have changed our reporting currency for our financial statements and all other financial information included in this annual report to USD, having previously reported in EUR. We believe this presentation better conforms to the expectations of our investor base as a U.S. public company.

Dividend Distribution Policy

We have never paid or declared any cash dividends 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 if the 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. Subject to such restrictions, any future determination to pay dividends 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 a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board deems relevant.

B. Significant Changes

None.

Item 9: The Offer and Listing

Our common share is listed on the NASDAQ Global Select Market under the trading symbol "LVTX."

Item 10: Additional Information

Memorandum and articles of association

The information in response to this item is contained under the caption "Description of share capital and articles of association" and "Comparison of Dutch corporate law and our articles of association and U.S. corporate law" in our Form F-1 Registration Statement (registration number: 333-253795) filed with the SEC on March 23, 2021 and is incorporated herein by reference.

Taxation

The following summary contains a description of material Dutch and U.S. federal income tax considerations of the acquisition, ownership and disposition of our common shares. This summary should not be considered a comprehensive description of all the tax considerations that may be relevant to the decision to acquire our common shares.

Material U.S. federal income tax considerations for U.S. Holders

The following is a description of the material U.S. federal income tax considerations to the U.S. Holders described below of owning and disposing of our common shares. It is not a comprehensive description of all tax considerations that may be relevant to a particular person's decision to acquire securities. This discussion applies only to a U.S. Holder that holds our common shares as a capital asset within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended, or the Code, for tax purposes (generally, property held for investment). In addition, it does not describe all of the tax considerations that may be relevant in light of a U.S. Holder's particular circumstances, including state and local tax considerations, estate or gift tax considerations, or the application of the alternative minimum tax considerations, the Medicare contribution tax on net investment income, or the special tax accounting rules under Section 451(b) of the Code, and tax considerations applicable to U.S. Holders subject to special rules, such as:

- banks, insurance companies, and certain other financial institutions;
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding common shares as part of a hedging transaction, "straddle," wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to common shares;
- persons whose "functional currency" for U.S. federal income tax purposes is not USD;
- brokers, dealers or traders in securities, commodities or currencies;
- tax-exempt entities or government organizations;
- S corporations, partnerships, or other entities or arrangements classified as partnerships or pass-throughs for U.S. federal income tax purposes (and investors therein);
- regulated investment companies or real estate investment trusts;
- persons who acquired our common shares pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons that own or are deemed to own (including by attribution) ten percent or more of our shares (by vote or value); and
- persons holding our common shares in connection with a trade or business, permanent establishment, or fixed base outside the United States.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds common shares, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding common shares and partners in such partnerships are encouraged to consult their tax advisors as to the particular U.S. federal income tax consequences of holding and disposing of common shares.

The discussion is based on the Code, administrative pronouncements, judicial decisions, final, temporary and proposed Treasury Regulations, and the income tax treaty between the Netherlands and the United States, or the Treaty, all as of the date hereof, changes to any of which may affect the tax considerations described herein —possibly with retroactive effect.

A “U.S. Holder” is a holder who, for U.S. federal income tax purposes, is a beneficial owner of common shares who is eligible for the benefits of the Treaty and is:

(1) an individual who is a citizen or resident of the United States;

(2) a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein, or the District of Columbia;

(3) an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or

(4) a trust if (a) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (b) the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

U.S. Holders are encouraged to consult their tax advisors concerning the U.S. federal, state, local and non-U.S. tax consequences of owning and disposing of our common shares in their particular circumstances.

Passive foreign investment company

A non-U.S. corporation will be classified as a PFIC for any taxable year in which, after applying certain look-through rules, either:

- at least 75% of its gross income is passive income (such as interest income); or
- at least 50% of its gross assets (determined on the basis of a quarterly average) is attributable to assets that produce passive income or are held for the production of passive income.

For this purpose, cash is generally a passive asset and passive income generally includes dividends, interest, royalties and rents (other than royalties and rents derived in the active conduct of a trade or business and not derived from a related person). For purposes of this test, we will be treated as owning our proportionate share of the assets and earning our proportionate share of the income of any other corporation, the equity of which we own, directly or indirectly, 25% or more (by value).

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 ending December 31, 2020. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis and the applicable law is subject to varying interpretation. In particular, the characterization of our assets as active or passive may depend in part on our current and intended future business plans, which are subject to change. In addition, for our current and future taxable years, the total value of our assets for PFIC testing purposes may be determined in part by reference to the market price of our common shares from time to time, which may fluctuate considerably. Under the income test, our status as a PFIC depends on the composition of our income which will depend on a variety of factors that are subject to uncertainty, including the characterization of certain intercompany payments and payments from tax authorities, transactions we enter into and our corporate structure. There can be no assurance that the IRS would not successfully challenge our position. Accordingly, our U.S. counsel expresses no opinion with respect to our PFIC status for any prior, current or future taxable year.

If we are classified as a PFIC in any year with respect to which a U.S. Holder owns the common shares, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns the common shares, regardless of whether we continue to meet the tests described above unless (1) we cease to be a PFIC and the U.S. Holder has made a “deemed sale” election under the PFIC rules, or (2) the U.S. Holder (A) makes a “QEF Election” (defined below) or (B) is eligible to make and makes a mark-to-market election (as described below), with respect to all taxable years during such U.S. Holder’s holding period in which we are a PFIC. If such a deemed sale election is made, a U.S. Holder will be deemed to have sold the common shares the U.S. Holder holds at their fair market value as of the date of such deemed sale and any gain from such deemed sale would be subject to the rules described below. After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, the U.S. Holder’s common shares with respect to which such election was made will not be treated as shares in a PFIC and the U.S. Holder will not be subject to the rules described below with respect to any “excess distribution” the U.S. Holder receives from us or any gain from an actual sale or other disposition of the

common shares. U.S. Holders should consult their tax advisors as to the possibility and consequences of making a deemed sale election if we cease to be a PFIC and such election becomes available.

For each taxable year we are treated as a PFIC with respect to a U.S. Holder, the U.S. Holder will be subject to special tax rules with respect to any "excess distribution" such U.S. Holder receives and any gain such U.S. Holder recognizes from a sale or other disposition (including a pledge) of common shares, unless (1) such U.S. Holder makes a "qualified electing fund" election, or QEF Election, with respect to all taxable years during such U.S. Holder's holding period in which we are a PFIC, or (2) our common shares constitute "marketable stock" and such U.S. Holder makes a mark-to-market election (as discussed below). Distributions a U.S. Holder receives in a taxable year that are greater than 125% of the average annual distributions a U.S. Holder received during the shorter of the three preceding taxable years or the U.S. Holder's holding period for the common shares will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over a U.S. Holder's holding period for the common shares;
- the amount allocated to the current taxable year, and any taxable year prior to the first taxable year in which we became a PFIC, will be treated as ordinary income; and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years prior to the year of disposition or "excess distribution" cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of the common shares cannot be treated as capital gains, even if a U.S. Holder holds the common shares as capital assets.

If we are a PFIC, a U.S. Holder will generally be subject to similar rules with respect to distributions we receive from, and our dispositions of the stock of, any of our direct or indirect subsidiaries that also are PFICs, as if such distributions were indirectly received by, and/or dispositions were indirectly carried out by, such U.S. Holder. U.S. Holders should consult their tax advisors regarding the application of the PFIC rules to our subsidiaries.

If a U.S. Holder makes an effective QEF Election, the U.S. Holder will be required to include in gross income each year, whether or not we make distributions, as capital gains, such U.S. Holder's pro rata share of our net capital gains and, as ordinary income, such U.S. Holder's pro rata share of our earnings in excess of our net capital gains. However, a U.S. Holder can only make a QEF Election with respect to common shares in a PFIC if such company agrees to furnish such U.S. Holder with certain tax information annually. We do not currently expect to provide such information in the event that we are classified as a PFIC.

U.S. Holders can avoid the interest charge on excess distributions or gain relating to our common shares by making a mark-to-market election with respect to the common shares, provided that the common shares are "marketable stock." Common shares will be marketable stock if they are "regularly traded" on certain U.S. stock exchanges or on a non-U.S. stock exchange that meets certain conditions. For these purposes, the common shares will be considered regularly traded during any calendar year during which they are traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. Any trades that have as their principal purpose meeting this requirement will be disregarded. Each U.S. Holder should consult its tax advisor as to the whether a mark-to-market election is available or advisable with respect to the common shares.

A U.S. Holder that makes a mark-to-market election must include in ordinary income for each year an amount equal to the excess, if any, of the fair market value of our common shares at the close of the taxable year over the U.S. Holder's adjusted tax basis in the common shares. An electing holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder's adjusted basis in the common shares over the fair market value of the common shares at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains for prior years. Gains from an actual sale or other disposition of the common shares will be treated as ordinary income, and any losses incurred on a sale or

other disposition of the shares will be treated as an ordinary loss to the extent of any net mark-to-market gains for prior years. Once made, the election cannot be revoked without the consent of the IRS unless the common shares cease to be marketable stock.

However, a mark-to-market election generally cannot be made for equity interests in any lower-tier PFICs that we own, unless shares of such lower- tier PFIC are themselves "marketable stock." As a result, even if a U.S. Holder validly makes a mark-to-market election with respect to our common shares, the U.S. Holder may continue to be subject to the PFIC rules (described above) with respect to its indirect interest in any of our investments that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. U.S. Holders should consult their tax advisors as to the availability and desirability of a mark-to-market election, as well as the impact of such election on interests in any lower-tier PFICs.

Unless otherwise provided by the U.S. Treasury, each U.S. shareholder of a PFIC is required to file an annual report containing such information as the U.S. Treasury may require. A U.S. Holder's failure to file the annual report will cause the statute of limitations for such U.S. Holder's U.S. federal income tax return to remain open with regard to the items required to be included in such report until three years after the U.S. Holder files the annual report, and, unless such failure is due to reasonable cause and not willful neglect, the statute of limitations for the U.S. Holder's entire U.S. federal income tax return will remain open during such period. U.S. Holders should consult their tax advisors regarding the requirements of filing such information returns under these rules.

WE STRONGLY URGE A U.S. HOLDER TO CONSULT YOUR TAX ADVISOR REGARDING THE IMPACT OF OUR PFIC STATUS ON THE U.S. HOLDER'S INVESTMENT IN THE COMMON SHARES AS WELL AS THE APPLICATION OF THE PFIC RULES TO INVESTMENT IN THE COMMON SHARES.

Taxation of distributions

Subject to the discussion above under "Passive Foreign Investment Company," distributions paid on common shares, other than certain distributions of common shares, will generally be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Because we may not calculate our earnings and profits under U.S. federal income tax principles, we expect that distributions generally will be reported to U.S. Holders as dividends. Non corporate U.S. holders may qualify for the preferential rates of taxation applicable to long term capital gains (i.e., gains from the sale of capital assets held for more than one year) with respect to dividends on ADSs if we are a "qualified foreign corporation." A non-United States corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (a) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of these rules and which includes an exchange of information provision (which includes the Treaty), or (b) with respect to any dividend it pays on ADSs which are readily tradable on an established securities market in the United States. Therefore, subject to the discussion under "Passive Foreign Investment Company," above, if the Treaty is applicable, or if the ADSs are readily tradable on an established securities market in the United States, such dividends will generally be "qualified dividend income" in the hands of non-corporate U.S. holders eligible for the preferential tax rates, provided that certain conditions are met, including conditions relating to holding period and the absence of certain risk reduction transactions. The amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will generally be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend. The amount of any dividend income paid in foreign currency will be the USD amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into USD. If the dividend is converted into USD on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into USD after the date of receipt. Such gain or loss would generally be treated as U.S.-source ordinary income or loss. The amount of any distribution of property other than cash (and other than certain pro rata distributions of common shares or rights to acquire common shares) will be the fair market value of such property on the date of distribution. For foreign tax credit purposes, our dividends will generally be treated as passive category income. The rules relating to the

determination of the U.S. foreign tax credit are complex, and U.S. Holders should consult their tax advisors regarding the availability of a foreign tax credit in their particular circumstances and the possibility of claiming a deduction (in lieu of the foreign tax credit) for any foreign taxes paid or withheld.

Sale or other taxable disposition of common shares

Subject to the discussion above under "Passive Foreign Investment Company," gain or loss realized on the sale or other taxable disposition of common shares will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the common shares for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the common shares disposed of and the amount realized on the disposition, in each case as determined in USD. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. The deductibility of capital losses is subject to limitations.

If the consideration received by a U.S. Holder is not paid in USD, the amount realized will be the USD value of the payment received determined by reference to the spot rate of exchange on the date of the sale or other disposition. However, if the common shares are treated as traded on an "established securities market" and you are either a cash-basis taxpayer or an accrual-basis taxpayer that has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), you will determine the USD value of the amount realized in a non-USD currency by translating the amount received at the spot rate of exchange on the settlement date of the sale. If you are an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, you will recognize foreign currency gain or loss to the extent of any difference between the USD amount realized on the date of sale or disposition and the USD value of the currency received at the spot rate on the settlement date. U.S. Holders should consult their tax advisors regarding the tax consequences if foreign taxes are imposed on a taxable disposition of common shares and their ability to credit such foreign tax against their U.S. federal income tax liability.

Information reporting and backup withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

Information with respect to foreign financial assets

Certain U.S. Holders who are individuals (and, under proposed regulations, certain entities) may be required to report information relating to the common shares, subject to certain exceptions (including an exception for common shares held in accounts maintained by certain U.S. financial institutions). Such U.S. Holders who fail to timely furnish the required information may be subject to a penalty. Additionally, if a U.S. Holder does not file the required information, the statute of limitations with respect to tax returns of the U.S. Holder to which the information relates may not close until three years after such information is filed. U.S. Holders should consult their tax advisors regarding their reporting obligations with respect to their ownership and disposition of the common shares.

Material Dutch tax considerations

Scope of discussion

The following is a general summary of certain material Dutch tax consequences of the acquisition, holding and disposal of the common shares. This summary does not purport to describe all possible tax considerations or consequences that may be relevant to a holder or prospective holder of our common shares and does not purport to deal with the tax consequences applicable to all categories of investors, some of

which (such as trusts or similar arrangements) may be subject to special rules. In view of its general nature, this general summary should be treated with corresponding caution.

This summary is based on the tax laws of the Netherlands, published regulations thereunder and published authoritative case law, all as in effect on the date hereof, and all of which are subject to change, possibly with retroactive effect. Where the summary refers to "the Netherlands" or "Dutch" it refers only to the part of the Kingdom of the Netherlands located in Europe.

This discussion is for general information purposes only and is not Dutch tax advice or a complete description of all Dutch tax consequences relating to the acquisition, holding and disposal of the common shares. Holders or prospective holders of our common shares should consult their own tax advisors regarding the Dutch tax consequences relating to the acquisition, holding and disposal of the common shares in light of their particular circumstances.

Please note that this summary does not describe the Dutch tax consequences for:

(i) a holder of common shares if such holder has a substantial interest (*aanmerkelijk belang*) or deemed substantial interest (*fictief aanmerkelijk belang*) in us under the Dutch Income Tax Act 2001 (*Wet inkomstenbelasting 2001*). Generally, a holder of securities in a company is considered to hold a substantial interest in such company, if such holder alone or, in the case of an individual, together with such holder's partner for Dutch income tax purposes, or any relatives by blood or marriage in the direct line (including foster children), directly or indirectly, holds (i) an interest of 5% or more of the total issued and outstanding capital of that company or of 5% or more of the issued and outstanding capital of a certain class of shares of that company; or (ii) rights to acquire, directly or indirectly, such interest; or (iii) certain profit sharing rights in that company that relate to 5% or more of the company's annual profits or to 5% or more of the company's liquidation proceeds. A deemed substantial interest may arise if a substantial interest (or part thereof) in a company has been disposed of, or is deemed to have been disposed of, on a non-recognition basis;

(ii) a holder of common shares, if the common shares held by such holder qualify or qualified as a participation (*deelneming*) for purposes of the Dutch Corporate Income Tax Act 1969 (*Wet op de vennootschapsbelasting 1969*). Generally, a holder's shareholding of 5% or more in a company's nominal paid-up share capital qualifies as a participation. A holder may also have a participation if (a) such holder does not have a shareholding of 5% or more but a related entity (statutorily defined term) has a participation or (b) the company in which the shares are held is a related entity (statutorily defined term).

(iii) pension funds, investment institutions (*fiscale beleggingsinstellingen*) and tax exempt investment institutions (*vrijgestelde beleggingsinstellingen*) (each as defined in the Dutch Corporate Income Tax Act 1969) and other entities that are, in whole or in part, not subject to or exempt from Dutch corporate income tax as well as entities that are exempt from corporate income tax in their country of residence, such country of residence being another state of the European Union, Norway, Liechtenstein, Iceland or any other state with which the Netherlands has agreed to exchange information in line with international standards; and

(iv) a holder of common shares if such holder is an individual for whom the common shares or any benefit derived from the common shares is a remuneration or deemed to be a remuneration for (employment) activities performed by such holder or certain individuals related to such holder (as defined in the Dutch Income Tax Act 2001).

Dividend withholding tax

Dividends distributed by us generally are subject to Dutch dividend withholding tax at a rate of 15%. Generally, we are responsible for the withholding of such dividend withholding tax at source; the Dutch dividend withholding tax is for the account of the holder of common shares.

The expression "dividends distributed" includes, among other things:

- distributions in cash or in kind, deemed and constructive distributions and repayments of paid-in capital not recognized for Dutch dividend withholding tax purposes;
- liquidation proceeds, proceeds from the redemption of common shares, or proceeds from the repurchase of common shares by us or one of our subsidiaries or other affiliated entities, other than as a temporary

portfolio investment (*tijdelijke belegging*), in each case to the extent such proceeds exceed the average paid-in capital of those common shares as recognized for Dutch dividend withholding tax purposes;

- an amount equal to the par value of common shares issued or an increase of the par value of common shares, to the extent that it does not appear that a contribution, recognized for Dutch dividend withholding tax purposes, has been made or will be made; and
- partial repayment of the paid-in capital, recognized for Dutch dividend withholding tax purposes, if and to the extent that we have net profits (*zuivere winst*), unless (i) the general meeting has resolved in advance to make such repayment and (ii) the par value of the common shares concerned has been reduced by an equal amount by way of an amendment of our articles of association. The term "net profits" includes anticipated profits that have yet to be realized.

Individuals and corporate legal entities who are resident or deemed to be resident of the Netherlands for Dutch income tax purposes, generally are entitled to an exemption of or a credit for any Dutch dividend withholding tax against their Dutch (corporate) income tax liability. The same generally applies to holders of common shares that are neither resident nor deemed to be resident of the Netherlands if the common shares are attributable to a Dutch permanent establishment of such non-resident holder.

A holder of common shares resident of a country other than the Netherlands may, depending on such holder's specific circumstances, be entitled to exemptions from, reduction of, or full or partial refund of, Dutch dividend withholding tax under Dutch national tax legislation, EU law, or treaties for the avoidance of double taxation in effect between the Netherlands and such other country.

Remittance to the Dutch tax authorities

Under certain circumstances, we may not be required to remit all amounts withheld as Dutch dividend withholding tax to the Dutch tax authorities. If we have received a profit distribution from a qualifying foreign subsidiary (as described in the Dutch Dividend Withholding Tax Act 1965; *Wet op de dividendbelasting 1965*) which distribution (i) is exempt from Dutch corporate income tax and (ii) has been subject to a foreign withholding tax of at least 5%. The amount that does not have to be remitted to the Dutch tax authorities can generally not exceed the lesser of:

- 3% of the dividends distributed by us subject to Dutch dividend withholding tax; and
- 3% of the dividends and profit distributions, before deduction of foreign withholding taxes, received by us from qualifying foreign subsidiaries in the calendar year in which we distributed the dividends (up to the date of the distribution by us) and the two preceding calendar years, as far as such dividends and profit distributions have not yet been taken into account for purposes of establishing the above mentioned reduction.

Although this reduction reduces the amount of Dutch dividend withholding tax that we are required to remit to the Dutch tax authorities, it does not reduce the amount of Dutch dividend withholding tax that we are required to withhold on dividends distributed by us.

Dividend stripping

Pursuant to legislation to counteract "dividend stripping", a reduction, exemption, credit or refund of Dutch dividend withholding tax is denied if the recipient of the dividend is not the beneficial owner as described in the Dutch Dividend Withholding Tax Act 1965. This legislation generally targets situations in which a shareholder retains its economic interest in shares but reduces the withholding tax costs on dividends by a transaction with another party. It is not required for these rules to apply that the recipient of the dividends is aware that a dividend stripping transaction took place. The Dutch State Secretary of Finance takes the position that the definition of beneficial ownership introduced by this legislation will also be applied in the context of a double taxation convention.

Conditional withholding tax on dividends (as of 1 January 2024)

As of 1 January 2024, a Dutch conditional withholding tax will be imposed on dividends distributed by us to entities related (*gelieerd*) to us (within the meaning of the Dutch Withholding Tax Act 2021; *Wet bronbelasting 2021*), if such related entity:

(i) is considered to be resident (*gevestigd*) in a jurisdiction that is listed in the yearly updated Dutch Regulation on low-taxing states and non-cooperative jurisdictions for tax purposes (*Regeling laagbelastende staten en niet-coöperatieve rechtsgebieden voor belastingdoeleinden*) (a "Listed Jurisdiction"); or

(ii) has a permanent establishment located in a Listed Jurisdiction to which the Shares are attributable; or

(iii) holds the Shares for the main purpose or one of the main purposes to avoid taxation for another person or entity and there is an artificial arrangement or transaction or a series of artificial arrangements or transactions; or

(iv) is not considered to be the beneficial owner of the Shares in its jurisdiction of residence because such jurisdiction treats another entity as the beneficial owner of the Shares (a hybrid mismatch); or

(v) is not resident in any jurisdiction (also a hybrid mismatch); or

(vi) is a reverse hybrid (within the meaning of Article 2(12) of the Dutch Corporate Income Tax Act 1969), if and to the extent (x) there is a participant in the reverse hybrid which is related (*gelieerd*) to the reverse hybrid, (y) the jurisdiction of residence of such participant treats the reverse hybrid as transparent for tax purposes and (z) such participant would have been subject to the Dutch conditional withholding tax in respect of dividends distributed by the Company without the interposition of the reverse hybrid, all within the meaning of the Dutch Withholding Tax Act 2021.

The Dutch conditional withholding tax on dividends will be imposed at the highest Dutch corporate income tax rate in effect at the time of the distribution (currently 25.8%). The Dutch conditional withholding tax on dividends will be reduced, but not below zero, by any regular Dutch dividend withholding tax withheld in respect of the same dividend distribution. As such, based on the currently applicable rates, the overall effective tax rate of withholding the regular Dutch dividend withholding tax (as described above) and the Dutch conditional withholding tax on dividends will not exceed the highest corporate income tax rate in effect at the time of the distribution (currently 25.8%).

Taxes on income and capital gains

Dutch resident entities

Generally, if the holder of common shares is an entity a resident or deemed to be resident of the Netherlands for Dutch corporate income tax purposes (a “Dutch Resident Entity”), any income derived or deemed to be derived from the common shares or any capital gains realized on the disposal or deemed disposal of the common shares is subject to Dutch corporate income tax at a rate of 15% with respect to taxable profits up to €395,000 and 25.8% with respect to taxable profits in excess of that amount (rates and brackets for 2022).

Dutch resident individuals

If the holder of common shares is an individual resident or deemed to be resident of the Netherlands for Dutch income tax purposes (a “Dutch Resident Individual”), any income derived or deemed to be derived from the common shares or any capital gains realized on the disposal or deemed disposal of the common shares is subject to Dutch income tax at progressive rates (with a maximum of 49.5% in 2022), if:

(i) the common shares are attributable to an enterprise from which the holder of common shares derives a share of the profit, whether as an entrepreneur (*ondernemer*) or as a person who has a co-entitlement to the net worth (*medegerechtigd tot het vermogen*) of such enterprise without being a shareholder (as defined in the Dutch Income Tax Act 2001); or

(ii) the holder of common shares is considered to perform activities with respect to the common shares that go beyond ordinary asset management (*normaal, actief vermogensbeheer*) or otherwise derives benefits from the common shares that are taxable as benefits from miscellaneous activities (*resultaat uit overige werkzaamheden*).

If the above-mentioned conditions (i) and (ii) do not apply to the Dutch Resident Individual, the Dutch Resident Individual's, net investment assets (*rendementsgrondslag*) for the year will be subject to an annual Dutch income tax on a deemed return (with a maximum of 5.53% in 2022) under the regime for savings and investments *(inkomen uit sparen en beleggen*), insofar the individual's net investment assets for the year exceed a statutory threshold (*heffingvrij vermogen*). The net investment assets for the year are the fair market value of the investment assets less the allowable liabilities on January 1 of the relevant calendar year. The common shares are included as investment assets. For the net investment assets on January 1, 2022, the deemed return ranges from 1.82% up to 5.53% (depending on the aggregate amount of the net investment assets of the Dutch Resident Individual on January 1, 2022). The deemed return will be adjusted annually on the basis of historic market yields.

The deemed return on the Dutch Resident Individual's net investment assets for the year is taxed at a flat rate of 31% (rate for 2022). Actual income or capital gains realized in respect of the Shares are as such not subject to Dutch income tax.

On 24 December 2021, the Dutch Supreme Court ruled that the Dutch income tax levy on savings and investments, in 2017 and 2018, violated the European Convention on Human Rights. The tax consequences of the Dutch Supreme Court are not immediately clear. The new Dutch Government intends to start calculating the taxation on savings and investments on actual returns realized from savings and investments (instead of on a deemed return) starting in 2025. The Supreme Court ruling could make the Dutch Government move faster on the issue. Prospective investors should carefully consider the tax consequences of this Supreme Court ruling and consult their own tax advisor about their own tax situation.

Non-residents of the Netherlands

A holder of common shares that is neither a Dutch Resident Entity nor a Dutch Resident Individual will not be subject to Dutch (corporate) tax in respect of income derived from or deemed to be derived from the common shares or in respect of any capital gains realized on the disposal or deemed disposal of the common shares, provided that:

(i) such holder does not have an interest in an enterprise or deemed enterprise (as defined in the Dutch Income Tax Act 2001 and the Dutch Corporate Income Tax Act 1969) which, in whole or in part, is either effectively managed in the Netherlands or carried on through a permanent establishment, a deemed permanent establishment or a permanent representative in the Netherlands and to which enterprise or part of an enterprise the common shares are attributable; and

(ii) in the event the holder is an individual, such holder does not carry out any activities in the Netherlands with respect to the common shares that go beyond ordinary asset management and does not otherwise derive benefits from the common shares that are taxable as benefits from miscellaneous activities in the Netherlands.

Gift and inheritance taxes

Residents of the Netherlands

Gift or inheritance taxes will arise in the Netherlands with respect to a transfer of the common shares by way of a gift by, or on the death of, a holder of common shares who is resident or deemed resident of the Netherlands at the time of the gift or such holder's death.

Non-residents of the Netherlands

No gift or inheritance taxes will arise in the Netherlands with respect to a transfer of the common shares by way of a gift by, or on the death of, a holder of common shares who is neither resident nor deemed to be resident of the Netherlands, unless:

(i) in the case of a gift of a common share by an individual who at the date of the gift was neither resident nor deemed to be resident of the Netherlands, such individual dies within 180 days after the date of the gift, while being resident or deemed to be resident of the Netherlands; or

(ii) in the case of a gift of a common share is made under a condition precedent, the holder of the common shares is resident or is deemed to be resident of the Netherlands at the time the condition is fulfilled; or

(iii) the transfer is otherwise construed as a gift or inheritance made by, or on behalf of, a person who, at the time of the gift or death, is or is deemed to be resident of the Netherlands.

For purposes of Dutch gift and inheritance taxes, amongst others, a person that holds the Dutch nationality will be deemed to be resident of the Netherlands if such person has been a resident of the Netherlands at any time during the ten years preceding the date of the gift or such person's death. Additionally, for purposes of Dutch gift tax, amongst others, a person not holding the Dutch nationality will be deemed to be resident of the Netherlands if such person has been a resident of the Netherlands at any time during the twelve months preceding the date of the gift. Applicable tax treaties may override deemed residency.

Value added tax (VAT)

No Dutch VAT will be payable by a holder of common shares in respect of any payment in consideration for the holding or disposal of the common shares.

Other taxes and duties

No Dutch registration tax, stamp duty or any other similar documentary tax or duty will be payable by, or on behalf of, a holder of common shares in respect of any payment in consideration for the acquisition, holding or disposal of the common shares.

Residency

A holder of common shares will not become, and will not be deemed to be, resident of the Netherlands for Dutch tax purposes by reason only of the acquisition and holding of the common shares.

Material Contracts

Except as otherwise disclosed in this Annual Report (including the exhibits thereto), we are not currently, and have not been in the last two years, party to any material contract, other than contracts entered into in the ordinary course of business.

Item 11: Quantitative and Qualitative Disclosures About Market Risk

We are exposed to a variety of risks in the ordinary course of our business, including, but not limited to, foreign currency risk and interest rate risk. We regularly assess each of these risks to minimize any adverse effects on our business as a result of those factors. For a detailed discussion, see Note 20 of the consolidated financial statements for the years ended December 31, 2021 and 2020 included elsewhere in this annual report.

Item 12: Description of Securities Other than Equity Securities

None.

PART II

Item 13: Defaults, Dividend Arrearages and Delinquencies

None.

Item 14: Material Modifications to the Rights of Security Holders and Use of Proceeds

Use of Proceeds

Our IPO of common share was effected pursuant to a registration statement on Form F-1 (File No 333-253795) that was declared effective by the SEC on March 24, 2021, pursuant to which we registered the offering and sale of 7,125,712 shares of common share, $0.14 par value per share (including 425,712 shares available to the underwriters' for exercise of an option to purchase additional shares) at a public offering price of $15.00 per share for an aggregate public offering price of $106.8 million.

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. None of such payments were direct or indirect payments to any of (i) our directors or officers or their associates, (ii) persons owning 10 percent or more of our common share, or (iii) our affiliates.

There has been no material change in the planned use of proceeds from our IPO from that described in the final prospectus related to the offering, which we filed with the SEC on March 26, 2021. As of December 31, 2021, we have used approximately $28.4 million of the funds received from our IPO for clinical trials and payments to research and development consultants.

Item 15: Controls and Procedures

Disclosure Controls and Procedures

As of December 31, 2021, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act). There are inherent limitations to the effectiveness of any disclosure controls and procedures system, including the possibility of human error and circumventing or overriding them. Accordingly, even if effective, disclosure controls and procedures can provide only reasonable assurance of achieving their control objectives. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

Based on such evaluation, as of December 31, 2021, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective due to material weaknesses in our internal control over financial reporting primarily related to (a) the lack of consistent and documented risk assessment procedures and control activities related to our financial reporting, among which are a sufficient level of management review and approval, manual processes, roles and responsibilities, and adequate application and controls over information technology and (b) our ability to: (i) design and maintain formal accounting policies, procedures and controls over the fair presentation of our financial statements; and (ii) design and maintain controls over the preparation and review of journal entries and financial statements, including maintaining appropriate segregation of duties.

While we took steps during the year ended December 31, 2021 to remediate these material weaknesses and have enhanced our internal control over financial reporting in preparation for compliance with Section 404(a) of the Sarbanes-Oxley Act for the year ending December 31, 2022, such remediation measures have been operational for a limited period of time and have not been tested. As such, we cannot consider these material weaknesses as remediated as of December 31, 2021. We have therefore developed a remediation plan designed to address these material weaknesses and other existing deficiencies. Such plan includes the redesign of critical processes and controls associated with internal control over financial reporting. Based on such plan, we are currently implementing additional processes and measures to ensure operating effectiveness. Specifically, we are implementing proper segregation of duties and management review and approvals across all key business processes, and have hired additional internal and external accounting resources. Although we intend to complete the remediation plan as soon as possible, we cannot guarantee at this time when such remediation steps will be completed, and management may determine the need to

enhance other existing controls and procedures or implement additional controls as the remediation progresses.

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Item 16A: Audit Committee Financial Expert

Our board of directors has determined that Karen Wilson, independent director, is a financial expert serving on our audit committee and is the chair of the audit committee. The qualifications of Karen Wilson as financial expert are incorporated by reference to Item 6 of this annual report on Form 20-F.

Item 16B: Code of Ethics

The Company has adopted a Code of Business Conduct and Ethics (Code of Ethics), approved by the board of directors, which is applicable to all employees, including our principal executive officer, principal financial officer, principal accounting officer and controller. A copy of this Code of Ethics is available on our Company website at https://ir.lavatherapeutics.com/corporate-governance/governance-overview.

Item 16C: Principal Accountant Fees and Services

A. Audit Fees

Audit fees in 2021 and 2020 were $1.1 million and $0.2 million, respectively, and relate to audit services provided by our principal accountants, PricewaterhouseCoopers Accountants N.V., in connection with our annual audits, quarterly reviews, and review of registration statements.

B. Audit-Related Fees

None.

C. Tax Fees

Tax fees were nil and less than $0.1 million in 2021 and 2020, respectively. Tax fees in 2020 related to assistance in preparing tax compliance documents.

D. All Other Fees

None.

E. Audit Committee's Pre-Approval Policies and Procedures

The Audit Committee is responsible for the appointment, replacement, compensation, evaluation and oversight of the work of the independent auditors. As part of this responsibility, the Audit Committee pre-approves all audit and non-audit services performed by the independent auditors in order to assure that they do not impair the auditor's independence from the Company in accordance with the Audit Committee's pre-approval policy.

F. Audit Work Performed by Other Than Principal Accountant if Greater than 50%

Not Applicable.

Item 16D: Exemptions from the Listing Standards for Audit Committees

Not applicable.

Item 16E: Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

Item 16F: Change in Registrant's Certifying Accountant

Not applicable.

Item 16G: Corporate Governance

Our corporate governance practices do not differ in any significant way from those followed by domestic companies under the listing standards of the NASDAQ Global Select Market.

Item 16H: Mine Safety Disclosure

Not applicable.

Item 16I: Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 17: Financial Statements

Index to consolidated financial statements

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 statements of financial position of LAVA Therapeutics N.V. and its subsidiary (the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of loss and other comprehensive loss, of changes in equity, and of cash flows for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

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.

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/ R.M.N. Admiraal RA
PricewaterhouseCoopers Accountants N.V.
Eindhoven, the Netherlands
March 24, 2022

We have served as the Company's auditor since 2018, which includes periods before the Company became subject to SEC reporting requirements.

LAVA Therapeutics N.V.
Consolidated statements of loss and other comprehensive loss
(In thousands, except share and per share amounts)

	Notes	For the Year ended December 31, 2021	2020	2019
Revenue:				
Research and license revenue	4	$ 5,000	$ 3,500	$ —
Total revenue		**5,000**	**3,500**	**—**
Operating expenses:				
Research and development	5	(37,193)	(15,701)	(8,347)
General and administrative	6	(12,160)	(2,719)	(1,236)
Total operating expenses		**(49,353)**	**(18,420)**	**(9,583)**
Operating loss		**(44,353)**	**(14,920)**	**(9,583)**
Interest expense, net	7	(625)	(342)	(86)
Foreign currency exchange loss, net	8	(212)	(201)	(18)
Total non-operating expenses		**(837)**	**(543)**	**(104)**
Loss before income tax		**(45,190)**	**(15,463)**	**(9,687)**
Income tax expense	9	(157)	(43)	—
Loss for the year		**$ (45,347)**	**$ (15,506)**	**$ (9,687)**
Other comprehensive loss:				
Foreign currency translation adjustment		(6,210)	(577)	(379)
Total comprehensive loss		**$ (51,557)**	**$ (16,083)**	**$ (10,066)**
Loss per share:				
Loss per share, basic and diluted	10	$ (2.30)	$ (38.85)	$ (21.65)
Weighted average common shares outstanding, basic and diluted		19,758,169	399,126	447,525

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

LAVA Therapeutics N.V.
Consolidated statements of financial position
(In thousands)

	Notes	As of December 31, 2021	2020	January 1, 2020
Assets				
Non-current assets:				
Property and equipment, net	11	$ 1,445	$ 1,113	$ 733
Right-of-use assets	12	501	382	414
Other non-current assets and security deposits		796	769	30
Total non-current assets		**2,742**	**2,264**	**1,177**
Current assets:				
Receivables and other		363	1,140	69
Prepaid expenses and other current assets		2,568	117	62
Deferred offering costs		—	811	—
VAT receivable		371	336	151
Investments	13	42,334	—	—
Cash and cash equivalents	14	90,869	15,818	7,338
Total current assets		**136,505**	**18,222**	**7,620**
Total assets		**$ 139,247**	**$ 20,486**	**$ 8,797**
Equity and Liabilities				
Equity:				
Share capital		$ 3,653	$ —	$ —
Share premium	15	—	41,088	19,561
Equity-settled employee benefits reserve		5,219	922	365
Foreign currency translation reserve		(4,042)	(1,003)	(378)
Additional paid-in capital	15	192,270	—	—
Accumulated deficit		(78,733)	(33,386)	(13,704)
Total equity		**118,367**	**7,621**	**5,844**
Non-current liabilities:				
Deferred revenue		—	1,655	—
Lease liabilities	12	320	271	257
License liabilities	22	5,028	—	—
Borrowings	16	4,284	3,604	1,272
Total non-current liabilities		**9,632**	**5,530**	**1,529**
Current liabilities:				
Trade payables and other	17	2,553	934	422
Lease liabilities	12	261	207	236
License liabilities	22	5,028	—	—
Deferred revenue		1,527	4,521	—
Accrued expenses and other current liabilities	18	1,879	1,673	766
Total current liabilities		**11,248**	**7,335**	**1,424**
Total liabilities		**20,880**	**12,865**	**2,953**
Total equity and liabilities		**$ 139,247**	**$ 20,486**	**$ 8,797**

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

LAVA Therapeutics N.V.
Consolidated statements of changes in equity
(In thousands, except for share amounts)

	Note	Preference						Common shares	Common Share capital	Equity-settled employee benefits reserves	Foreign currency translation reserve	Additional paid in capital	Accumulated deficit	Total
		Series A shares	Series A Share premium	Series B shares	Series B Share premium	Series C shares	Series C Share premium							
Balance at January 1, 2019		**1,755,845**	**$ 1,221**	**3,899,766**	**$ 18,340**	**—**	**$ —**	**447,525**	**$ —**	**$ 173**	**$ —**	**$ —**	**$ (4,017)**	**$ 15,717**
Loss for period		—	—	—	—	—	—	—	—	—	—	—	(9,687)	(9,687)
Share-based compensation expense		—	—	—	—	—	—	—	—	192	—	—	—	192
Foreign currency translation adjustment		—	—	—	—	—	—	—	—		(378)	—	—	(378)
Balance at December 31, 2019		**1,755,845**	**1,221**	**3,899,766**	**18,340**	**—**	**—**	**447,525**	**—**	**365**	**(378)**	**—**	**(13,704)**	**5,844**
Loss for period		—	—	—	—	—	—	—	—	—	—	—	(15,506)	(15,506)
Issuance of Series C Preferred shares ($5.48 per share), net of issuance costs of $647	19	—	—	—	—	4,133,805	22,026	—	—	—	—	—	—	22,026
Series A Preferred and ordinary shares repurchase		(718,250)	(499)	—	—	—	—	(165,750)	—	—	—	—	(4,176)	(4,675)
Share-based compensation expense		—	—	—	—	—	—	—	—	557	—	—	—	557
Foreign currency translation adjustment		—	—	—	—	—	—	—	—	—	(625)	—	—	(625)
Balance at December 31, 2020		**1,037,595**	**722**	**3,899,766**	**18,340**	**4,133,805**	**22,026**	**281,775**	**—**	**922**	**(1,003)**	**—**	**(33,386)**	**7,621**
Loss for period		—	—	—	—	—	—	—	—	—	—	—	(45,347)	(45,347)
Share split		—	(143)	—	(536)	—	(589)	—	1,308	—	—	(40)	—	—
Issuance of Series C Preferred shares ($6.22 per share), net of offering costs of $92		—	—	—	—	9,945,221	60,373	—	1,425	—	—	—	—	61,798
Repurchase of Series A and ordinary shares		(718,250)	(400)	—	—	—	—	(165,750)	(122)	—	—	(4,760)	—	(5,282)
Conversion of preference shares		(319,345)	(179)	(3,899,766)	(17,804)	(14,079,026)	(81,810)	18,298,137	—	—	—	99,793	—	—
Issuance of common stock in initial public offering ($15.00 per share), net of offering costs of $11.5 million		—	—	—	—	—	—	6,700,000	947	—	—	88,115	—	89,062
Issuance of overallotment option		—	—	—	—	—	—	425,712	61	—	—	5,877	—	5,938
Issuance of VUmc common stock		—	—	—	—	—	—	235,664	34	—	—	3,621	—	3,655
Share-based compensation expense	19	—	—	—	—	—	—	—	—	4,297	—	—	—	4,297
Foreign currency translation adjustment		—	—	—	—	—	—	—	—	—	(3,039)	(336)	—	(3,375)
Balance at December 31, 2021		**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**25,775,538**	**$ 3,653**	**$ 5,219**	**$ (4,042)**	**$ 192,270**	**$ (78,733)**	**$ 118,367**

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)

	Notes	December 31, 2021	2020	2019
Cash flows from operating activities:				
Loss before income tax		$ (45,190)	$ (15,463)	$ (9,687)
Adjusted for:				
Depreciation and amortization of non-current assets		331	213	99
Foreign currency exchange loss, net		562	448	—
Depreciation and amortization of right-of-use assets	12	227	251	160
Share-based compensation expense	19	4,297	557	192
Income tax expense		(157)	(43)	—
Amortization of premium on investments		446	—	—
Changes in working capital:				
Receivables and other		777	(1,072)	37
VAT receivable		(35)	(186)	44
Other assets	12	(2,859)	(795)	82
Trade accounts payable and other	17	1,618	323	(190)
Deferred offering costs		1,623	(323)	—
Deferred revenue		(4,649)	6,176	—
License liabilities		13,713	—	—
Other liabilities		649	607	648
Net cash used in operating activities		**(28,647)**	**(9,307)**	**(8,615)**
Cash flows from investing activities:				
Purchases of property and equipment	11	(764)	(502)	(762)
Purchases of investments		(45,291)	—	(30)
Maturities of investments		2,510	—	—
Net cash used in investing activities		**(43,545)**	**(502)**	**(792)**
Cash flows from financing activities:				
Proceeds from common shares from initial public offering, net	14	94,189	—	—
Proceeds from Series C financing, net		61,798	22,025	—
Payment of Series A preferred and common shares repurchased		(5,167)	(4,849)	—
Proceeds from borrowings	16	680	2,033	1,272
Payment of principal portion of lease liabilities		(340)	(240)	(96)
Net cash provided by financing activities		**151,160**	**18,969**	**1,176**
Net increase (decrease) in cash and cash equivalents		**78,968**	**9,160**	**(8,231)**
Cash and cash equivalents at the beginning of year	**14**	15,818	7,338	16,002
Effects of exchange rate changes on the balance of cash held in foreign currencies		(3,917)	(680)	(433)
Cash and cash equivalents at end of year	**14**	**$ 90,869**	**$ 15,818**	**$ 7,338**
Supplemental schedule of noncash operating and financing activities:				
Issuance of 235,664 common shares to VUmc in lieu of payment for license liabilities		$ 3,655	$ —	$ —
Deferred offering costs in accounts payable and accrued expenses		$ —	$ 489	$ —

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

LAVA Therapeutics N.V.
Notes to consolidated financial statements

Corporate and Company information

1.1 Corporate Information

LAVA Therapeutics N.V., formerly LAVA Therapeutics B.V., was founded in 2016 and is incorporated and domiciled in the Netherlands. The Company's registered office is Yalelaan 60, 3584 CM in Utrecht. The Company is registered at the Chamber of Commerce under number 65335740. In connection with becoming a public company, on March 29, 2021 the Company changed its name from "LAVA Therapeutics, B.V." to "LAVA Therapeutics N.V."

The Company and its subsidiary are a clinical-stage immuno-oncology company dedicated to rapidly developing new cancer treatments that leverage the immune system to save patients' lives. Using our Gammabody platform, the Company is developing a portfolio of novel bispecific antibodies designed to engage and leverage the potency and precision of gamma delta (gd) T cells to elicit 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.

The consolidated financial statements of LAVA Therapeutics N.V. were authorized for issue by the Company's board of directors on March 24, 2022.

1.2 Company information

The consolidated financial statements of the Company include:

			% of equity interest	
Name	Legal seat	Country of incorporation	2021	2020
Lava Therapeutics N.V.	Utrecht	The Netherlands	100 %	100 %
Lava Therapeutics INC.	Delaware	United States of America	100 %	100 %

The Company's 100% subsidiary, LAVA Therapeutics, Inc., which was founded in August 2019, is incorporated in the United States of America and acts as a service provider to the parent, LAVA Therapeutics N.V.

2. Summary of significant accounting policies

The principal accounting policies applied in the preparation of these consolidated financial statements are included below. These policies have been consistently applied to all of the years presented, unless otherwise stated.

(a) Basis of preparation

The consolidated financial statements of the Company have been prepared in accordance with and comply with IFRS as issued by the IASB.

The consolidated financial statements of the Company have been prepared on a historical cost basis.

The preparation of the consolidated financial statements in conformity with IFRS requires the application of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the accounting policies. The areas involving a greater degree of judgment or complexity, or areas in which assumptions and estimates are significant to the consolidated financial statements, are disclosed in note 3.

Going concern

These consolidated financial statements have been prepared by management on the assumption that the Company will be able to continue as a going concern, which presumes that the Company will, for the foreseeable future, be able to realize its assets and discharge its liabilities in the normal course of business.

Through December 31, 2021, the Company funded its operations with proceeds from sales of equity financings, collaboration and licensing agreements, government grants and borrowings under various agreements. Since inception the Company has incurred recurring net losses. The Dutch Research and Development Act (WBSO) provides compensation for a part of research and development wages and other costs through a reduction in payroll taxes. WBSO grant amounts are offset against wages and salaries and included in research and development expenses in the consolidated statements of loss and comprehensive loss.

As of December 31, 2021, the Company had an accumulated deficit of $78.7 million. The Company expects to continue to generate operating losses in the foreseeable future. The Company expects that its cash, cash equivalents and investments of $133.2 million as of December 31, 2021 will be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months following the issuance of these financial statements. Accordingly, the consolidated financial statements have been prepared on a going concern basis.

Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. Disruptions in the financial markets in general may make equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. If we are unable to obtain sufficient funding in a timely manner or on commercially acceptable terms, we may have to delay, reduce the scope of, or eliminate one or more of our operating activities, and consider other cost reduction initiatives, such as downsizing our operations 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 and could reduce the price of our common shares and we may ultimately go into 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.

COVID-19

In March 2020, the COVID-19 virus caused a worldwide pandemic. Although the short- and long-term effects of this pandemic are unknown, the Company's business operations have been impacted by the pandemic. To-date these impacts have not been significant to our operations. These have, or may in the future, impact:

- availability of supplies and equipment for our laboratories;
- availability of staff;
- start dates and recruitment in our clinical trials due to risks of opening and available resources at clinical sites;
- availability of study drug; and
- fundraising and access to the capital markets.

Management closely monitors the situation and, to its best ability, is focusing on mitigating measures and contingency plans to limit and prevent any potential impact on our business operations as much as possible. Our financial condition and results of operations are most affected by our capital resources, continued research and development expenses and general and administrative expenses. Although the COVID-19 pandemic has impacted the timing of onboarding investigational sites and enrolling patients in our ongoing Phase 1/2a clinical trial for LAVA-051 and LAVA-1207, to date we have not experienced any material business disruption as a result of the COVID-19 pandemic.

(b) Basis of consolidation

Subsidiaries are all entities over which the Company has control. Control is achieved when the Company is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect

those returns through its power over the entity. Subsidiaries are consolidated from the date on which control over the subsidiary is transferred to the Company and are deconsolidated from the date that control over the subsidiary ceases.

When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies into line with the Company's accounting policies. All intercompany assets and liabilities, equity, income, expenses, and cash flows relating to transactions between members of the Company are eliminated in full on consolidation. Certain prior year amounts have been reclassified to reflect current year presentation.

c) Foreign currency

Items included in the financial statements of each of the Company's entities are measured using the currency of the primary economic environment in which the entity operates. The Company's consolidated financial statements are presented in USD. The parent company, LAVA Therapeutics B.V., has the functional currency of EUR. The subsidiary company, LAVA Therapeutics, Inc., has the functional currency of USD.

As of December 31, 2021, we have changed our reporting currency for our financial statements to USD, having previously reported in EUR. We believe this presentation better conforms to the expectations of our investor base as a U.S. public company. The change in reporting currency was applied retrospectively effective beginning January 1, 2019. Financial statements for all periods presented have been recast into USD.

All monetary assets and liabilities denominated in foreign currencies are translated into USD using exchange rates in effect as of the date of the balance sheet date. The USD-translated amounts of nonmonetary assets and liabilities as of January 1, 2020 became the historical accounting basis for those assets and liabilities as of January 1, 2020. Revenue and expense transactions are translated at the approximate exchange rate in effect at the time of the transaction, and certain specific equity transactions are translated at the exchange rate in effect at the time of the transaction. All resulting exchange differences were recognized within currency translation adjustment, a separate component of shareholders' equity.

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions are recognized within foreign currency exchange loss, net, in the consolidated statements of loss and comprehensive loss. Foreign exchange gains and losses resulting from the transaction of monetary assets and liabilities denominated in foreign currencies at year end exchange rates are recognized within foreign currency translation adjustment in the consolidated statements of loss and other comprehensive loss.

The results and financial position of all of the Company entities that have functional currency different from the presentation currency are translated into USD as follows:

- Assets and liabilities are translated at the closing rate at the reporting date;
- Revenue, deferred revenue and components of equity are translated using the rate at the date the relevant event occurred; and
- Income and expenses for each statement of loss and other comprehensive loss are translated at average exchange rates.

d) Segment information

Operating segments are identified based on whether the allocation of resources and/ or the assessment of performance of a particular component of Company's activities are regularly reviewed as a separate operating segment by Company's Chief Operating Decision Maker. In accordance with IFRS, the Company's business activities are organized into one reportable segment, which is consistent with the basis of the internal reports that the management regularly reviews in allocating resources and assessing performance.

e) Cash flow statement

The cash flow statement has been prepared using the indirect method. The cash and cash equivalents disclosed in the cash flow statement consisted of cash at banks.

f) Research and development expenses

The Company expenses research and development expenses as incurred and does not capitalize them pursuant to IAS 38, *Intangible Assets*. 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. The Company accounts for a governmental research and development payroll tax subsidy from Wet Bevordering Speur en Ontwikkelingswerk (WBSO) as a reduction from the research and development personnel-related expenses.

g) General and administrative expenses

The Company's general and administrative expenses consist of personnel-related expenses for employees involved in general corporate functions, including accounting, finance, insurance, tax, legal and human relations, costs associated with outside professional fees such as legal counsel and auditors, costs associated with use by these functions of facilities and equipment, such as depreciation expenses, premises maintenance expenses and other general corporate expenses. General and administrative expenses are expensed as incurred.

h) Share-based awards

Share options granted to employees and consultants providing similar services are measured at the grant date fair value of the equity instruments granted. The grant date fair value is determined through the use of an option-pricing model considering the following variables:

a) the exercise price of the option;

b) the expected life of the option;

c) the current value of the underlying shares;

d) the expected volatility of the share price;

e) the dividends expected on the shares; and

f) the risk-free interest rate for the life of the option.

The Company accounts for these awards as equity-settled share-based payment awards. For the Company's share option plans, management's judgment is that the Black-Scholes valuation formula is the most appropriate method for determining the fair value of the options considering the terms and conditions attached to the grants made and to reflect exercise behavior. Prior to the Company's IPO, as a private company there was no published share price information available. Consequently, the Company estimated the fair value of its shares and the expected volatility of that share value for option grants prior to the IPO. These assumptions and estimates are further discussed in note 19 to the financial statements.

The result of the share option valuations and the related compensation expense that is recognized for the respective vesting periods during which services are received is dependent on the model and input parameters used. Even though management considers the fair values reasonable and defensible based on the methodologies applied and the information available, others might derive a different fair value for the options.

i) Employee benefits

The Company provides defined contribution plans to its employees. Contributions to defined contribution plans are expensed when employees provide services. The Company has no further payment obligations

once the contributions have been paid. The Company's post-employment schemes do not include any defined benefit plans.

j) Income taxes

Income tax expense comprises current and deferred tax. It is recognized in profit or loss except to the extent that it relates to a business combination, or items recognized directly in equity or in other comprehensive income. Current tax comprises the expected tax payable or receivable on the taxable income or loss for the year and any adjustment to tax payable or receivable in respect of previous years. It is measured using tax rates enacted or substantively enacted at the reporting date. Current tax also includes any tax arising from dividends. Current tax assets and liabilities are offset only if certain criteria are met.

Deferred tax is recognized in respect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Deferred tax is not recognized for:

- temporary differences on the initial recognition of assets or liabilities in a transaction that is not a business combination and that affects neither accounting nor taxable profit or loss;
- temporary differences related to investments in subsidiaries, associates, and joint arrangements to the extent that the Company is able to control the timing of the reversal of the temporary differences and it is probable that they will not reverse in the foreseeable future; and
- taxable temporary differences arising on the initial recognition of goodwill.

Deferred tax assets are recognized for unused tax losses, unused tax credits and deductible temporary differences to the extent that it is probable that future taxable profits will be available against which they can be used. Deferred tax assets are reviewed at each reporting date and are reduced to the extent that it is no longer probable that the related tax benefit will be realized; such reductions are reversed when the probability of future taxable profits improves.

Unrecognized deferred tax assets are reassessed at each reporting date and recognized to the extent that it has become probable that future taxable profits will be available against which they can be utilized.

Deferred tax is measured at the tax rates that are expected to be applied to temporary differences when they reverse, using tax rates enacted or substantively enacted at the reporting date.

The measurement of deferred tax reflects the tax consequences that would follow from the manner in which the Company expects, at the reporting date, to recover or settle the carrying amount of its assets and liabilities.

k) Cash and cash equivalents

Cash and cash equivalents in the consolidated statements of financial position comprise of cash at banks and on hand and short-term deposits with a maturity of three months or less, which are subject to an insignificant risk of changes in value.

For the purposes of the consolidated statements of cash flows, cash and cash equivalents consist of cash and short-term deposits, as defined above, net of outstanding bank overdrafts.

l) Investments

Our investments in debt securities consist entirely of investments in highly-rated corporate bonds, with maturities ranging from three months to one year. All of these investments are classified as current assets in our consolidated statements of financial position. All investments in debt securities have investment-grade credit quality indicators as published by Moody's and Standard & Poor's (S&P). We have the intent and ability to hold all investments in debt securities until maturity. Accordingly, all investments are recorded at amortized

cost on our consolidated statements of financial position, with the amortization of bond premiums or discounts and earned interest income recorded in our consolidated statements of loss.

m) Property and equipment

Property, plant, and equipment are stated at cost less accumulated depreciation and accumulated impairment losses, if any. The cost of an item of property, plant and equipment is recognized as an asset if it is probable that future economic benefits associated with the item will flow to the entity and the cost of the item can be measured reliably.

Property, plant, and equipment include major expenditures for new assets, improvements and replacement assets that extend the useful lives of assets or increase their revenue-generating capacities. Repair and maintenance costs are expensed as incurred.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets, as follows:

Building improvements	10
Laboratory equipment	5
Office equipment	5
Information and communication equipment (ICT)	5

The estimated useful life for building improvements is the shorter of the estimated useful life and the lease term. Depreciation of property, plant and equipment used for Laboratory equipment and ICT equipment is included within research and development expenses in the consolidated statements of loss and other comprehensive loss. Depreciation of all other property, plant and equipment is allocated between research and development and general and administrative expenses based on headcount.

The carrying amount of an item of property, plant and equipment is derecognized on disposal, or when no future economic benefits are expected from its use or disposal. The gain or loss arising from the derecognition of an item of property, plant, and equipment (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in “Gain / (loss) on disposal of non-current assets, net” in the consolidated statements of loss and other comprehensive loss when the asset is derecognized.

Management reviews the carrying amount of property, plant, and equipment for impairment when there is an indication that the carrying amount may exceed the expected recoverable amount.

n) Impairment of long-lived assets

Assets that are subject to depreciation or amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. An impairment loss is recognized in the consolidated statements of loss and other comprehensive loss consistent with the function of the assets, for the amount by which the asset’s carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset’s fair value less costs of disposal and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are largely independent cash inflows. Prior impairments of non-financial assets (other than goodwill) are reviewed for possible reversal each reporting period.

o) Provisions

Provisions are recognized when the Company has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation, and a reliable estimate can be made of the amount of the obligation. Provisions are reviewed at the end of each reporting period and adjusted to reflect the current best estimate. If it is no longer probable that an outflow of resources embodying economic benefits will be required to settle the obligation, the provision is reversed.

p) Value added tax

Expenses and assets are recognized net of the amount of value added tax (VAT) except when the VAT incurred on a purchase of assets or services is not recoverable from the taxation authority, in which case the VAT is recognized as part of the cost of acquisition of the asset or as part of the expense item.

The net amount of the VAT recoverable from, or payable to, the taxation authority is included as part of receivables or payables in the consolidated statements of financial position.

q) Financial instruments

(i) ***Financial assets***

The Company's financial assets are comprised of cash and cash equivalents, investments, trade and other receivables, security deposits, other current and non-current assets. All financial assets are recognized initially at fair value plus transaction costs that are attributable to the acquisition of the financial asset. Purchases and sales of financial assets are recognized on the settlement date; the date that the Company receives or delivers the asset. The Company classifies its financial assets primarily as cash and cash equivalents and receivables. Receivables are non-derivative financial assets, with fixed or determinable payments that are not quoted in an active market. They are included in current assets.

Financial assets are derecognized when the rights to receive cash flows from the asset have expired, or the Company has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full.

(ii) ***Financial liabilities***

The Company's financial liabilities are comprised of trade and other payables, lease liabilities, and borrowings. All financial liabilities are recognized initially at fair value.

After initial recognition, borrowings are subsequently measured at amortized cost using the effective interest method. The effective interest method amortization is included in finance costs in the consolidated statements of loss and other comprehensive loss.

Payables and borrowings are classified as current liabilities unless the Company has an unconditional right to defer settlement of the liability for at least 12 months after the reporting date.

Financial liabilities are derecognized when the obligation under the liability is discharged, cancelled, or expires.

(iii) ***Fair value measurements***

The Company does not hold any financial assets and financial liabilities other than those measured at amortized cost. Management assessed that the carrying values of the Company's financial assets and financial liabilities measured at amortized cost are a reasonable approximation of their fair values.

r) Leases

The Company is party to lease contracts relating to laboratory and office facilities located in the Netherlands and the U.S.

(i) ***Right-of-use assets***

The Company recognizes right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The recognized right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term. Right-of- use assets are subject to impairment.

(ii) ***Lease liabilities***

At the commencement date of the lease, the Company recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees.

In calculating the present value of lease payments, the Company uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the in-substance fixed lease payments or a change in the assessment to purchase the underlying asset.

3. Significant accounting judgments, estimates and assumptions

The preparation of the Company's consolidated financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets, liabilities, and equity in the consolidated financial statements and the accompanying disclosures. Estimates and judgments are based on historical experience and other factors, including expectations of future events, and are continually evaluated. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

Judgments

In the process of applying the Company's accounting policies, management has made the following judgments, which have the most significant effect on the amounts recognized in the consolidated financial statements:

Clinical trial expenses

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

We determine accrual estimates based on estimates of the services received and efforts expended that take into account discussion with applicable personnel and outside service providers as to the progress or state of completion of trials. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from our estimates. We make estimates of our accrued expenses and prepaid assets as of each balance sheet date in our financial statements based on the facts and circumstances known to us at that time. Our clinical trial accrual and prepaid assets are dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Although we do not expect our estimates to differ materially from amounts we actually incur, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low for any particular period.

Deferred tax assets

Deferred tax assets have not been recognized in respect of tax losses, because the Company has no history of generating taxable profits and at the statement of financial position date, there is no convincing evidence that sufficient taxable profit will be available against which the tax losses can be utilized.

In order to promote innovative technology development activities and investments in new technologies, a corporate income tax incentive has been introduced in Dutch tax law called the Innovation Box. Profits from self-developed qualifying intangible assets are effectively subject to a 7% income tax rate for 2020 and 9% income tax rate for 2021 and future years, instead of the general headline rate of 25% (25.8% as of 2022). Lava Therapeutics N.V. believes it qualifies for the Innovation Box and is in this respect currently in a process for obtaining advance certainty from the Dutch tax authorities.

Estimates and assumptions

The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date, which have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below. The Company based its assumptions and estimates on parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond the control of the Company. Such changes are reflected in the assumptions when they occur.

New standards, interpretations and amendments adopted by the Company

The Company adopted the following standards, interpretations, or amendments as of January 1, 2021, none of which had a significant impact on the Company's financial statements:

- Amendments to IFRS 9, IAS 39 and IFRS 7: Interest Rate Benchmark Reform (Phase 2).

The Company has not early adopted any standards, interpretations or amendments that have been issued, but are not yet effective. The Company intends to adopt these new and amended standards and interpretations, if applicable, when they become effective. There are no standards presently known that are not yet effective and that would be expected to have a material impact on the Company in current or future reporting periods and on foreseeable future transactions.

4. Revenue

Research and license agreement

In May 2020, the Company entered into the Janssen Agreement. As part of the Janssen Agreement, the Company received a non-refundable upfront payment of $8 million. As of December 31, 2021, there was $1.5 million of unearned income related to this payment. The revenue has been recognized for twenty months beginning in May 2020, as this method of recognition matches the pattern in which we provide research services to Janssen. The unearned income is being recognized as revenue on a straight-line basis over the remaining four-month term of the research activities under the Janssen Agreement. The Janssen Agreement includes research, development and commercial milestones, which would initiate additional milestone payments. Each milestone payment was recorded as revenue when achieved, as each was linked to the completion of specific research and development activities, rather than recorded over time like the upfront payment.

The Company is entitled to receive tiered royalties based on commercial sales levels from low to mid-single digit percentages of net sales of licensed products. Royalties are payable on a licensed product-by-licensed product and country-by-country basis beginning with the first commercial sale of such licensed product in such country of sale and expiring ten years after such sale, subject to specified and capped reductions for the market entry of biosimilar products, loss of patent coverage of licensed products, and for payments owed to third parties for additional rights necessary to commercialize licensed products in the territory and expires ten (10) years after such sale. The Company is eligible to receive a research milestone and further payments upon the achievement of certain development and commercial milestones.

The Company's deferred revenue balance relates to amounts received, but not yet earned under the Janssen Agreement. The following table presents changes in the deferred revenue balance:

(in thousands)	
Balance at January 1, 2020	$ —
Deferral of revenue	(8,000)
Recognized during the period	2,500
Foreign currency translation difference	(676)
Balance at December 31, 2020	**(6,175)**
Deferral of revenue	—
Recognized during the period	4,000
Foreign currency translation difference	648
Balance at December 31, 2021	**$ (1,527)**

Development milestones

In December 2020, the Company achieved the first Research Milestone, as defined in the Janssen Agreement, triggering a milestone payment of $1.0 million. In September 2021, the Company achieved the second Research Milestone, triggering a milestone payment of $1.0 million.

Revenue for the year ended December 31, 2021 was $5.0 million, which consisted of $4.0 million related to the upfront payment and $1.0 million related to the development milestone. Revenue for the year ended December 31, 2020 was $3.5 million, which consisted of $2.5 million related to the upfront payment and $1.0 million related to the development milestone.

5. Research and development expenses

Research and development expenses include the following categories:

	For the Year Ended December 31,		
(in thousands)	2021	2020	2019
VUmc license expenses	$ 14,357	$ 203	$ —
Pre-clinical and clinical trial expenses	14,188	11,325	5,118
Personnel-related expenses	4,955	2,276	1,360
Research and development activities expenses	1,843	1,022	1,624
Share-based compensation expense	1,036	232	181
Facilities and other research and development expenses	814	643	64
	$ 37,193	**$ 15,701**	**$ 8,347**

Refer to note 22 for additional information about VUmc license expenses. Government grants, which are a reduction of payroll taxes in the Netherlands, amounted to $1.7 million in 2021, $1.0 million in 2020 and $0.6 million in 2019. These amounts are an offset to wages and salaries that are part of our research and development expenses in the income statement. The increase in the respective periods was primarily due to increased research activities in the Netherlands.

6. General and administrative expenses

General and administrative expenses include the following categories:

(in thousands)	For the Year Ended December 31, 2021	2020	2019
Personnel-related expenses	$ 3,800	$ 1,474	$ 477
Share-based compensation expense	3,261	326	11
Professional and consultant fees	2,593	683	674
Insurance, facilities, fees and other related costs	2,506	236	74
	$ 12,160	**$ 2,719**	**$ 1,236**

7. Interest expense, net

(in thousands)	For the Year Ended December 31, 2021	2020	2019
Interest expense on borrowings and deposits, net	$ 564	$ 253	$ 13
Interest expense related to leases	61	89	73
	$ 625	**$ 342**	**$ 86**

8. Foreign currency exchange loss, net

Foreign currency exchange loss, net was primarily due to the foreign currency cash position held by the Netherlands parent company, LAVA Therapeutics N.V., as well as transactions with partners and vendors denominated in currencies other than EUR. Foreign currency exchange loss for the years ended December 31, 2021, 2020 and 2019 were $0.2 million, $0.2 million and $0.0 million, respectively.

9. Taxation

The Company is subject to income taxes in the Netherlands and the United States.

Netherlands

No tax charge or income was recognized during the reporting periods since the Company is in a loss-making position and has a history of losses. As of December 31, 2021 the Company has Dutch tax loss carryforwards of $8.5 million. The 2021 taxable amounts are not final as the 2021 Dutch corporate income tax return is still in draft. The 2020 Dutch corporate income tax return is final and has been filed.

As a result of the Dutch corporate income tax law, tax loss carryforwards are not subject to a time limitation and remain available for offset indefinitely. Actual offset of these losses is however limited to 50% of the taxable amount that exceeds EUR 1 million (previously losses carry forward were subject to a time limitation of six years whereas losses from 2018 and prior years were subject to a time limitation of nine years – all losses that were still available for offset on 1 January 2022 became available for offset indefinitely).

(in thousands)	Loss per year
2017	$ 883
2018	2,823
2019	1,110
2020	—
2021	3,718
	$ 8,534

In order to promote innovative technology development activities and investments in new technologies, a corporate income tax incentive has been introduced in Dutch tax law called the “Innovation Box.” The effective rate for Innovation Box profits is 9%. Lava Therapeutics N.V. has applied for the Innovation Box and its request is currently under final review with the Dutch Tax Authorities. In the 2019, 2020 and 2021 tax

returns an amount of $8.3 million, $15.5 million and $36 million, respectively, of IP development costs were capitalized for tax purposes. In total, $59.8 million of IP development costs was capitalized. This amount can fiscally be offset against future income derived from this IP.

On the basis of the 2021 annual accounts according to IFRS, there are accounting-to-tax differences of $4.2 million. These differences primarily relate to non-deductible share-based payment expenses. Other differences relate to the IFRS 16 lease amounts and expenses which were treated as non-deductible for Dutch corporate income tax purposes and other non-deductible mixed expenses.

Up to and including 2021, deferred income tax assets and liabilities are only recognized for temporary differences in relation to the IFRS 16 lease assets and liabilities.

Deferred income tax assets can also be recognized for tax losses to the extent that the realization of the related tax benefit through future taxable profits is probable. The Company recognizes deferred tax assets arising from unused tax losses or tax credits only to the extent there is convincing other evidence that sufficient taxable profit will be available against which the unused tax losses or unused tax credits can be utilized by the Company. Management concluded that there is not sufficient probability as per IAS 12, *Income Taxes,* that there will be future taxable profits available in the foreseeable future against which the unused tax losses can be used; therefore, a deferred tax asset has not been recognized.

The statute of limitation in the Netherlands is five years, starting from the day after the end of the tax year and any extensions granted for filing the corporate income tax returns. The tax authorities are allowed to audit years for which a final assessment has already been imposed. Since inception was in 2016, all tax years are currently open for an audit by the Dutch tax authorities.

United States

A tax charge was recognized during the reporting periods due to the U.S. profitable position. The activities of LAVA Therapeutics, Inc. are limited and regard only to the CEO, CFO and CMO for LAVA Therapeutics N.V. and related staff who are domiciled in the U.S. The remuneration of LAVA Therapeutics, Inc. is based on the costs incurred for the services rendered including a profit mark-up.

10. Earnings per share (EPS)

Basic EPS is calculated by dividing the profit/(loss) for the period attributable to common equity holders of the parent by the weighted average number of common shares outstanding during the period.

Diluted EPS is calculated by dividing the profit/(loss) attributable to common equity holders of the parent (after adjusting for the effect of dilution) by the weighted average number of common shares outstanding after adjustments for the effects of all dilutive potential common shares.

At December 31, 2021, 2020 and 2019, outstanding share-based awards were excluded from the diluted weighted average number of common shares calculation because their effect would have been anti-dilutive.

The following table reflects the loss and share data used in the basic and diluted EPS calculations:

	For the Year Ended December 31,		
(in thousands, except for share and per share amounts)	**2021**	**2020**	**2019**
Loss for the year	$ (45,347)	$ (15,506)	$ (9,687)
Weighted average number of common shares	19,758,169	399,126	447,525
Basic and diluted loss per share	$ (2.30)	$ (38.85)	$ (21.65)

11. Property and equipment

Movements in property and equipment were as follows:

(in thousands)	Building improvements	Laboratory equipment	Office equipment	ICT equipment	Total
Cost					
Balance at January 1, 2020	**$ 40**	**$ 687**	**$ 31**	**$ 76**	**$ 834**
Additions	65	378	5	54	502
Foreign currency translation adjustment	7	97	2	9	115
Balance at December 31, 2020	**112**	**1,162**	**38**	**139**	**1,451**
Additions	20	679	—	65	764
Foreign currency translation adjustment	(9)	(117)	(2)	(12)	(140)
Balance at December 31, 2021	**$ 123**	**$ 1,724**	**$ 36**	**$ 192**	**$ 2,075**
Accumulated depreciation					
Balance at January 1, 2020	**$ 1**	**$ 88**	**$ 3**	**$ 9**	**$ 101**
Charge for the year	6	182	7	18	213
Foreign currency translation adjustment	1	20	1	2	24
Balance at December 31, 2020	**8**	**290**	**11**	**29**	**338**
Charge for the year	12	280	8	31	331
Foreign currency translation adjustment	(1)	(32)	(3)	(3)	(39)
Balance at December 31, 2021	**$ 19**	**$ 538**	**$ 16**	**$ 57**	**$ 630**
Carrying amounts					
Property and equipment, net at December 31, 2020	**$ 104**	**$ 872**	**$ 27**	**$ 110**	**$ 1,113**
Property and equipment, net at December 31, 2021	**$ 104**	**$ 1,186**	**$ 20**	**$ 135**	**$ 1,445**

12. Leases

The following table provides information about the Company's right-of-use assets:

(in thousands)	
Balance at January 1, 2020	**$ 414**
Additions	182
Depreciation charges	(251)
Foreign currency exchange difference	37
Balance at December 31, 2020	**382**
Additions	382
Depreciation charges	(227)
Foreign currency exchange difference	(36)
Balance at December 31, 2021	**$ 501**

The following table provides information about the maturities of the Company's lease liabilities at December 31, 2021:

(in thousands)	
2022	$ 327
2023	193
2024	129
2025	43
Total lease commitments	**692**
Less: imputed lease interest	(111)
Total lease liabilities	**$ 581**
Current portion	**$ 261**
Non-current portion	**$ 320**

The average incremental borrowing rate applied to the lease liabilities was 15.78% and 15.6% during the years ended December 31, 2021 and 2020.

Cash outflows related to leases during the years ended December 31, 2021, 2020 and 2019 were $0.3 million, $0.2 million and $0.2 million, respectively.

13. Investments

Our investments in debt securities consist entirely of investments in highly-rated corporate bonds, with maturities ranging from three months to one year. All of these investments are classified as current assets on our consolidated statements of financial position. As of December 31, 2021, the carrying value and fair value of our investments each was $42.3 million.

All investments in debt securities have investment-grade credit quality indicators as published by Moody's and Standard & Poor's (S&P). As of December 31, 2021, our investments in debt securities had credit quality indicators ranging from A3 – AAA as published by Moody's, and A- – AAA as published by S&P. Given the high-quality ratings of these investments in debt securities, we have not recorded an allowance for credit losses as of December 31, 2021.

14. Cash and cash equivalents

	As of December 31,		As of January 1,
(in thousands)	2021	2020	2020
Short-term deposits	$ 76,504	$ 1,228	$ 112
Current bank accounts	14,365	14,590	7,226
	$ 90,869	**$ 15,818**	**$ 7,338**

Short-term deposits are made for varying periods of between one day and three months, depending on the immediate cash requirements of the Company, and earn interest at the respective short-term deposit rates. Information about the credit risk over cash and cash equivalents is presented in Note 21.

15. Share capital, share premium and other capital reserves

The following table provides information about the Company's share capital as of December 31, 2021, 2020 and 2019:

(in thousands, except for share and per share amounts)	Authorized December 31,			Issued and fully paid December 31,			Additional paid-in capital December 31,	Share premium December 31,	
	2021	2020	2019	2021	2020	2019	2021	2020	2019
Common shares of $0.01 each	**—**	**447,525**	**447,525**	**—**	**281,775**	**447,525**	**$ —**	**$ —**	**$ —**
Preference Series A shares of $0.01 each	—	1,755,845	1,755,845	—	1,037,595	1,755,845	—	722	1,221
Preference Series B shares of $0.01 each	—	3,899,766	3,899,766	—	3,899,766	3,899,766	—	18,340	18,340
Preference Series C shares of $0.01 each	—	4,133,805	—	—	4,133,805	—	—	22,026	—
Preference shares of $0.01 each	**—**	**9,789,416**	**5,655,611**	**—**	**9,071,166**	**5,655,611**	**—**	**41,088**	**19,561**
Preference shares of $0.14 each	**45,000,000**	**—**	**—**	**—**	**—**	**—**	**—**	**—**	**—**
Common shares of $0.14 each	**45,000,000**	**—**	**—**	**25,775,538**	**—**	**—**	**192,270**	**—**	**—**
	90,000,000	**10,236,941**	**6,103,136**	**25,775,538**	**9,352,941**	**6,103,136**	**$ 192,270**	**$ 41,088**	**$ 19,561**

Preferred Series Shares

In 2017, the Company issued and sold 1,755,845 Series A Preferred at a price of $0.68 per share for gross proceeds of $1.2 million. The Company incurred minimal issuance costs.

In 2018, the Company issued and sold 3,899,766 Series B Preferred at a price of $4.61 per share for gross proceeds of $17.9 million. The Company incurred minimal issuance costs.

In September 2020, the Company closed an oversubscribed financing of Series C Preferred that resulted in tranche-based commitments of $84.4 million gross and $73.2 million net. In connection with the Series C Preferred financing, the Company agreed to sell the Series C Preferred in three tranches. In connection with the funding of the tranches the Company was obligated to repurchase 1,436,500 shares of Series A preferred of approximately $10.3 million and 331,500 common shares.

On September 15, 2020, the first tranche of gross proceeds of $22.7 million, with $0.6 million of issuance costs and 4,133,805 shares of Series C Preferred, was funded and 718,250 shares amounted to $4.9 million of Series A Preferred were repurchased, resulting in net proceeds of $17.2 million.

On March 17, 2021, the Company effected a 221:1 share split of the Company's issued and outstanding common shares and a proportional adjustment to the existing conversion ratios for the Company's convertible preferred shares. The par value per share and authorized common and convertible preferred shares were adjusted as a result of the share split. All common shares and common share per share amounts within the financial statements and notes thereto have been adjusted for all periods presented to give effect to this share split, including reclassifying an amount equal to the change in par value of common shares to additional paid-in capital.

On March 18, 2021, the remaining milestones required to fund the remaining two tranches of the Series C Preferred financing were waived, and the funding of both tranches prior to the completion of the IPO was authorized. The two remaining tranches funded additional net proceeds of $56.6 million in the aggregate, after repurchasing the 718,250 shares of Series A Preferred and 165,750 common shares from one investor.

Automatic Conversion of Preferred Shares – On March 29, 2021, the Company effected an amendment to its Articles of Association, as amended. This amendment eliminated the minimum price per common share for

an underwritten public offering that would result in the automatic conversion of all outstanding Series A, Series B, and Series C preferred shares of the Company.

Common shares

On March 29, 2021, the Company completed an IPO of common shares pursuant to its registration statement on Form F-1, as amended (file 333-253795) under the symbol “LVTX” in the United States on Nasdaq. Pursuant to the registration statement, the Company issued and sold 6,700,000 shares of $0.14 par value common share at a price of $15.00 per share. Net proceeds from the IPO were approximately $89.0 million after deducting underwriting discounts and commissions of $7.0 million and offering costs of $4.5 million.

On April 19, 2021, underwriters of the Company’s IPO consummated the exercise of their option to purchase 425,712 common shares from the Company at the price of $15.00 per share resulting in additional IPO proceeds to the Company of $5.9 million after deducting underwriting discounts and commissions of $0.4 million.

On June 2, 2021, the Company issued 235,664 common shares to the VUmc representing the $3.7 million payable in accordance with the VUmc agreement.

The following table provides information about the Company’s major shareholders on a non-diluted basis:

	As of December 31,	
	2021	2020
Gilde Healthcare	21.0 %	26.0 %
Versant Venture Capital VI, L.P.	17.8 %	26.0 %
Novo Holdings A/S	12.9 %	9.4 %
Redmile Biopharma Investments	10.8 %	5.7 %
Sanofi Foreign Participations B.V.	7.4 %	5.7 %
Ysios Capital Partners, SGECR,S.A.U.	6.2 %	7.2 %
Other shareholders	23.9 %	20.0 %
	100.0 %	**100.0 %**

16. Borrowings

In 2019, the Company applied for, and received a $5.5 million Innovation Credit (the “Credit”) from Rijksdienst voor Ondernemend Nederland (RVO). The Credit contributes to the development of one of the Company’s main projects, and certain assets of that project are pledged as a guarantee.

Borrowings under the Credit, which bear interest at 10.0%, will be received in quarterly installments through 2023, based on the level of the underlying cost base of the project in each period. The repayment of principal and accrued interest is due on December 31, 2023.

At December 31, 2021 and 2020, the Company had $4.3 million and $3.6 million, respectively in borrowings under the Credit, all of which was classified as long-term, and includes accrued interest.

The Credit contains customary limitations on the Company and its shareholders, including the shareholders of the Company 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 needs to file a progress report after each of the five reporting periods: March 2020, December 2020, December 2021, October 2022, and July 2023. Based on the progress report, RVO will decide to continue to pay future installments if the following conditions are met:

- Activities during reporting period were completed successfully
- Perspective on completion of the project and future commercialization are still good
- The Company has financed its own contribution in the project sufficiently

At December 31, 2021, the Company was in compliance with all of the terms of the Credit.

Interest expense incurred from the Credit during the years ended December 31, 2021, 2020 and 2019 were $0.3 million, $0.2 million and $0.0 million, respectively.

17. Trade payables and other

The Company had accounts payable balances of $2.6 million and $0.9 million as of December 31, 2021 and 2020, respectively. The average credit period on domestic purchases of certain goods is 7-30 days. No interest is charged on the trade payables from the invoice received. Information about the Company's exposure to currency and liquidity risk in relation to its trade and other payables is included in Note 21.

18. Working capital

Prepaid expenses and other current assets

(in thousands)	As of December 31, 2021	As of December 31, 2020	As of January 1, 2020
Prepaid project expenses	$ 1,499	$ —	$ 16
Prepaid other expenses	732	117	46
Prepaid interest on investments	337	—	—
	$ 2,568	**$ 117**	**$ 62**

Accrued expenses and other current liabilities

(in thousands)	As of December 31, 2021	As of December 31, 2020	As of January 1, 2020
Research and development external project costs	$ 983	$ 946	$ 414
Professional fees	425	206	210
Other	310	107	14
Personnel-related expenses	161	114	128
Deferred offering costs	—	300	—
	$ 1,879	**$ 1,673**	**$ 766**

19. Share-based compensation

19.1 Description of equity incentive plans

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

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

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

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

- 25% of the options vest on the first anniversary of the vesting commencement date, and the remaining 75% of the options vest in 36 monthly installments for each full month of continuous

service provided by the option holder thereafter, such that 100% of the options shall become vested on the fourth anniversary of the vesting commencement date.

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

Share-based options

During 2021 and 2020, the board of directors granted 1,801,088 options and 1,463,462 options, respectively, to employees and non-employees.

The following table provides information about share-based awards as of December 31, 2021 and 2020:

	2018 Stock Option Plan			2020 U.S. Stock Option Plan			2021 Long-term Incentive Option Plan		
	Number of options	Weighted average exercise price $	Weighted average remaining contractual term (yrs)	Number of options	Weighted average exercise price $	Weighted average remaining contractual term (yrs)	Number of options	Weighted average exercise price $	Weighted average remaining contractual term (yrs)
Outstanding at January 1, 2020	**226,083**	**0.01**	**(*)**	**—**	**—**		**—**	**—**	**—**
Granted	394,264	0.01		1,069,198	2.76		—	—	
Exercised	—	—		—	—		—	—	
Forfeited	—	—		—	—		—	—	
Outstanding at December 31, 2020	**620,347**	**0.01**	**(*)**	**1,069,198**	**2.76**	**9.50**	**—**	**—**	**—**
Granted	—	—		493,938	12.69		1,307,150	6.03	
Exercised	—	—		—	—		—	—	
Forfeited	—	—		—	—		—	—	
Outstanding at December 31, 2021	**620,347**	**0.01**	**(*)**	**1,563,136**	**5.90**	**8.90**	**1,307,150**	**6.03**	**9.90**
Exercisable at December 31, 2021	216,377			301,676			—		

(*) contract term does not have fixed end date

As of December 31, 2021 outstanding options had exercise prices ranging from $0.01 to $15.00.

19.2 Measurement of fair values

The fair value of the equity-settled employee share options has been measured using the Black-Scholes formula. Service and non-market performance conditions attached to the transactions were not taken into account in measuring fair value.

The assumptions used in the measurement of the fair values and the weighted average fair value of the share options granted during the years ended on December 31, 2021, 2020 and 2019:

	December 31, 2021		December 31, 2020	December 31, 2019
	NL	US	NL	NL
Expected annual volatility	80.1%	80.1%	75.5% - 90.0%	90.0%
Expected life, years	6.08	6.08	3.92	3.92
Fair value of the common share	$ 3.42 - 5.23	$ 3.12 - 8.71	$ 2.10 - 2.76	$ 1.86
Exercise price	$ 5.10 - 7.77	$ 5.10 - 15.00	$ 0	$ 0
Dividend yield	—	—	—	—
Risk-free interest rate	(0.30%) - (0.53%)	0.94% - 1.34%	(0.62%)	(0.44%) - (0.76%)
Weighted average grant date fair value	$ 3.61	$ 5.95	$ 2.71	$ 1.86

In 2021, options were granted with a contractual exercise price in both EUR and USD. In 2020, all options were granted with a contractual exercise price in EUR. Since the Company was a private company until March 2021, company-specific historical and implied volatility information is not available. Expected volatility is therefore estimated based on the observed daily share price returns of publicly traded peer companies over a historic period equal to the period for which expected volatility is estimated. The group of comparable listed companies are publicly traded entities active in the business of developing antibody-based therapeutics, treatments and drugs and are selected taking into consideration the availability of meaningful trading data history and market capitalization. The Company will continue to use this method for calculation of expected volatility data until sufficient historical market data is available for estimating the volatility of our common shares.

Valuation of common shares

As of our IPO in March 2021, the fair value of the common shares is determined by the market value of our shares on the Nasdaq Global Select Market under the symbol “LVTX.”

Prior to our IPO, the fair value of the common shares was determined by the Company’s management board and supervisory board and took into account the most recently available valuation of common shares performed by an independent valuation firm and the assessment of additional objective and subjective factors the Company believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant.

The Company’s management board and supervisory board considered numerous objective and subjective factors to determine their best estimate of the fair value of our common shares as of each grant date, including:

- the progress of our research and development programs;
- achievement of enterprise milestones, including entering into collaboration and licensing agreements, as well as funding milestones;
- contemporaneous third-party valuations of our common shares for our most recent share issuances;
- our need for future financing to fund operations;

- the rights and preferences of our preference shares and our preference shares relative to our common shares;
- the likelihood of achieving a discrete liquidity event, such as a sale of our Company or an initial public offering given prevailing market conditions; and
- external market and economic conditions impacting our industry sector.

In determining the fair values of the common shares as of each grant date, three generally accepted approaches were considered: income approach, market approach and cost approach. In addition, the guidance prescribed by the American Institute of Certified Public Accounts *Audit and Accounting Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation* had been considered.
The "prior sale of company stock" method, a form of the market approach, had been applied to estimate the total enterprise value. The prior sale of company stock method considers any prior arm's length sales of the Company's equity securities. Considerations factored into the analysis included: the type and amount of equity sold, the estimated volatility, the estimated time to liquidity, the risk-free rate, the timing compared to the common shares valuation date and the financial condition and structure of the Company at the time of the sale. As such, the value per share had been benchmarked to the external transactions of Company stock and external financing rounds. For determining the value of the Company's shares, the prior sale of company stock method had been relied on to estimate the total value of the Company's equity. Throughout this period, financing rounds were held, which resulted in the issuance of preferred shares. The preferred shares were transacted with numerous existing and new investors, and therefore the pricing in these financing rounds was considered a strong indication of fair value.

Given that there were multiple classes of equity, the Option Pricing Method (OPM) had been applied in order to allocate equity to the various equity classes. The OPM treats securities as call options on the enterprise's equity value, with exercise prices based on the liquidation preference and conversion features of preferred stock and strike prices of options. An incremental discount for lack of marketability (DLOM) was applied with a range from 10% to 25%, corresponding to the time to exit to reflect the increased risk arising from the inability to readily sell the shares. Under this method, the cost of the put option, which can hedge the price change before the privately held shares can be sold, was considered as the basis to determine the DLOM.
The related share-based compensation expenses for the years ended December 31, 2021, 2020 and 2019 were $4.3 million, $0.6 million and $0.2 million, respectively, as referenced in notes 5 and 6.

20. Related parties

Key management compensation

Key management includes members of the Company's executive committee and the board of directors. The compensation paid or payable to key management for the Board and employee services includes their participation in share-based compensation arrangements. The compensation paid to these individuals are presented below for the years ended December 31, 2021, 2020 and 2019. The disclosure amounts are based on the expense recognized in the consolidated statements of loss and other comprehensive loss.

	For the Year Ended December 31,		
(in thousands)	2021	2020	2019
Key management compensation			
Short term employee benefits	$ 3,099	$ 1,518	$ 1,314
Share-based payments	2,924	372	322
Post-employment benefits	92	74	64
	$ 6,115	**$ 1,964**	**$ 1,700**

Director and shareholder compensation

A member of the Company's board of directors and existing shareholder receive consultancy fees. The compensation paid to this individual is presented below for the years ended December 31, 2021, 2020 and 2019. At December 31, 2021, 2020 and 2019, related party expenses of less than $0.1 million, respectively, were reported in the Company's trade payables and other balances. The disclosure amounts are based on the expense recognized in the consolidated statements of loss and other comprehensive loss.

	For the Year Ended December 31,		
(in thousands)	2021	2020	2019
Director and shareholder compensation			
Board fees	$ 227	$ —	$ —
Consultancy fees	20	55	91
	$ 247	**$ 55**	**$ 91**

21. Financial instruments, risk management and capital management

21.1 Financial assets and financial liabilities

The following table shows the carrying amounts of financial assets and financial liabilities. The Company does not hold any financial assets and financial liabilities other than those measured at amortized cost. Management assessed that the carrying values of the Company's financial assets and financial liabilities measured at amortized cost are a reasonable approximation of their fair values.

21.2 Financial risk management

	As of December 31,		As of January 1,
(in thousands)	2021	2020	2020
Financial assets measured at amortized cost			
Cash and cash equivalents (note 14)	$ 90,869	$ 15,818	$ 7,338
Investments (note 13)	42,334	—	—
Other non-current assets and security deposits	796	769	30
Receivables and other	363	1,140	69
Total financial assets	**$ 134,362**	**$ 17,727**	**$ 7,437**
Financial liabilities measured at amortized cost			
Borrowings (note 16)	$ 4,284	$ 3,604	$ 1,272
Trade payables and other (note 17)	2,553	934	422
Accrued expenses and other current liabilities (note 18)	1,879	1,673	766
Lease liabilities (note 12)	581	478	493
Total financial liabilities	**$ 9,297**	**$ 6,689**	**$ 2,953**

The Company is exposed to a variety of financial risks: market risk and credit risk. The Company's overall risk management program seeks to minimize potential adverse effects of these financial risk factors on the Company's financial performance.

21.2.1 Market risk

Market risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate because of changes in market prices. Market risk, which mostly impacts the Company, comprises two types of risk: interest rate risk and currency risk. Financial instruments affected by market risk include cash, cash equivalents, investments, accounts receivable and trade and other payables. All of these financial instruments generally are short term in nature with maturities and settlement dates between one and nine months. A 1% fluctuation

The Company does not enter into any derivative financial instruments to manage its exposure to foreign currency risk and interest rate risk. Due to the conservative nature of our investment portfolio and other financial instruments, we do not believe an immediate 1.0% increase in interest rates or currency rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect a sudden change in market interest rates to affect materially our operating results or cash flows.

21.2.2 Credit risk

Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument or customer contract, leading to a financial loss. The Company is exposed to credit risk from its operating activities (primarily accounts receivable) and from its cash and cash equivalents held with banks.

Cash and cash equivalents

The Company held cash and cash equivalents at December 31, 2021 and 2020 of $90.9 million and $15.8 million, respectively. For the years ending December 31, 2021 and 2020, the Company held 100% of its cash and cash equivalents with large, well-known institutions.

21.3 Capital management

The Company manages its capital to ensure that the Company will be able to continue as a going concern while the maximizing return to shareholders through the optimization of the debt and equity balance.

The capital structure of the Company consists of net debt (borrowings as detailed in Note 16 offset by cash and cash equivalents) and equity (as detailed in the consolidated statements of financial position).

In order to achieve this overall objective, the Company's capital management, among other things, aims to ensure that it meets financial covenants attached to the borrowings that define capital structure requirements.

No changes were made in the objectives, policies, or processes for managing capital during the year ended December 31, 2021.

22. Commitments and Contingencies

Lease contract

In December 2021, the Company entered into a lease contract for laboratory and office space in Utrecht with a commencement date in November 2022. The lease agreement has an end date on March 31, 2026 and includes cancellation provisions. The total lease commitment under the agreement amounts to $2.3 million.

Legal proceedings

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

Contingent liabilities

In January 2017, we entered into VUmc Agreement, as amended. Under the VUmc Agreement, VUmc 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 VUmc, effectively including research and other services provided in collaboration by VUmc since 2017 to develop, make, and sell licensed products. VUmc 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.

We are obligated to pay VUmc sub to low single-digit tiered royalties on net sales of products covered by claims included in the assigned patent rights. Royalties are payable on a country-by-country basis for a royalty term that expires upon the expiration of the last valid claim in the assigned patent rights in such country that would be infringed by the use, manufacture, or sale of a product in such country in the absence of us having rights to such patent right. In connection with our IPO, we issued to VUmc 235,664 of our common share and paid $0.3 million in cash. On each of the first and second anniversary of our IPO, we are required to pay $5.0 million. Such payment shall be made in cash or common shares, at the election of the Company, valued using the closing price of common shares on the date two trading days prior to the respective anniversary of our IPO. The Company and VUmc have been collaborating since 2017 and VUmc makes available certain employees to the Company who perform research activities for the benefit of the Company. In accordance with IFRS, these obligations are reflected in the accompanying consolidated statements of financial position.

Item 18: Financial Statements

Not applicable.

Item 19: Exhibits

Exhibit number	Description of Document	Incorporation by Reference			
		Form	Exhibit	File Date	File Number
1.1	English translation of Articles of Association of LAVA Therapeutics N.V.	Form F-1/A	3.2	3/18/2021	**333-253795**
4.2	Restated and Amended License and Assignment Agreement, dated as of February 25, 2021, by and among Lava Therapeutics, B.V., and Stichting VUmc.	Form F-1/A	10.1	3/18/2021	**333-253795**
2.1	Description of Securities	Form 20-F	2.1	3/24/2022	
4.3	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/A	10.2	3/18/2021	**333-253795**
4.4#	Form of Indemnification Agreement for executive directors and executive officers.	Form F-1/A	10.3	3/18/2021	**333-253795**
4.5	Form of Indemnification Agreement for non-executive directors.	Form F-1/A	10.4	3/18/2021	**333-253795**
4.6#	2018 Stock Option Plan.	Form F-1/A	10.5	3/18/2021	**333-253795**
4.7#	2020 U.S. Stock Option Plan.	Form F-1/A	10.6	3/18/2021	**333-253795**
4.8#	2021 Employee Share Purchase Plan.	Form F-1/A	10.8	3/18/2021	**333-253795**
8.1	Subsidiaries of the Registrant.	Form 20-F	8.1	3/24/2022	
12.1*	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934				
12.2*	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934				

13.1*	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.			
13.2*	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.			
15.1	Consent of Independent Registered Public Accounting Firm	Form 20-F	15.1	3/24/2022
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

Indicated a management contract or compensatory plan, contract or arrangement

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

LAVA Therapeutics N.V.
(Registrant)

/s/ Fred Powell
Fred Powell
Chief Financial Officer

Date: December 23, 2022

EXHIBIT 12.1

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO EXCHANGE ACT RULE 13A-14(A) OR 15D-14(A) AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Steve Hurly, certify that:

1. I have reviewed this annual report on Form 20-F/A of LAVA Therapeutics N.V.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) [language omitted in accordance with Exchange Act Rule 13a-14(a)] for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [language omitted in accordance with Exchange Act Rule 13a-14(a)];

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) [language omitted in accordance with Exchange Act Rule 13a-14(a)] for the company and have:

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: December 23, 2022

By: /s/ Steve Hurly

Name: Steve Hurly

Title: Director and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 12.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO EXCHANGE ACT RULE 13A-14(A) OR 15D-14(A) AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Fred Powell, certify that:

1. I have reviewed this annual report on Form 20-F/A of LAVA Therapeutics N.V.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) [language omitted in accordance with Exchange Act Rule 13a-14(a)] for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [language omitted in accordance with Exchange Act Rule 13a-14(a)];

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) [language omitted in accordance with Exchange Act Rule 13a-14(a)] for the company and have:

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: December 23, 2022

By: /s/ Fred Powell

Name: Fred Powell

Title: Chief Financial Officer (Principal Financial Officer)

EXHIBIT 13.1

Certification by the Principal Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of LAVA Therapeutics N.V. (the "Company") on Form 20-F/A for the fiscal year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steve Hurly, Director and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: December 23, 2022

By: /s/ Steve Hurly

Name: Steve Hurly

Title: Director and Chief Executive Officer (Principal Executive Officer)

EXHIBIT 13.2

Certification by the Principal Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of LAVA Therapeutics N.V. (the "Company") on Form 20-F/A for the fiscal year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Fred Powell, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: December 23, 2022

By: /s/ Fred Powell

Name: Fred Powell

Title: Chief Financial Officer (Principal Financial Officer)