

As confidentially submitted to the Securities and Exchange Commission on January 22, 2021  
This draft registration statement has not been publicly filed with the United States Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

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

Form F-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

**LAVA Therapeutics B.V.\***

(Exact Name of Registrant as Specified in its Charter)

Not Applicable

(Translation of Registrant's Name into English)

The Netherlands  
(State or other Jurisdiction of  
Incorporation or Organization)

2834  
(Primary Standard Industrial Classification  
Code Number)

Not Applicable  
(I.R.S. Employer Identification  
Number)

Yalelaan 60  
3584 CM Utrecht, the Netherlands  
+31 6 3000 3035  
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Corporation Service Company  
251 Little Falls Drive  
Wilmington, Delaware 19808  
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of all communications, including communications sent to agent for service, should be sent to:

Christian Plaza  
Divakar Gupta  
Joshua A. Kaufman  
Cooley LLP  
One Freedom Square  
Reston, Virginia 20190  
+1 703 456 8000

Paul van der Bijl  
Niek de Kort  
NautaDutilh N.V.  
Beethovenstraat 400  
1082 PR Amsterdam, the Netherlands  
+31 20 71 71 000

Deanna Kirkpatrick  
Yasin Keshvargar  
Davis Polk & Wardwell LLP  
450 Lexington Avenue  
New York, New York 10017  
+1 212 450 4000

Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act.

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 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price(1)(2)	Amount of registration fee(3)
Common shares, nominal value €0.12 per share	\$	\$

(1) Estimated solely for purpose of calculating the amount of registration fee pursuant to Rule 457(o) of the Securities Act of 1933, as amended.

(2) Includes the aggregate offering price of additional common shares that may be acquired by the underwriters.

(3) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

\* We intend to convert the legal form of our company under Dutch law from a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) to a public company with limited liability (*naamloze vennootschap*) and to change our name from LAVA Therapeutics B.V. to LAVA Therapeutics N.V. prior to the consummation of this offering.

[Table of Contents](#)

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated \_\_\_\_\_, 2021

Preliminary prospectus

**shares**



**LAVA Therapeutics B.V.**

*to be converted and renamed*

**LAVA Therapeutics N.V.**

*(incorporated in the Netherlands)*

## **Common shares**

We are offering our common shares. This is our initial public offering and no public market currently exists for our common shares. We expect the initial public offering price to be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per share. We intend to apply to list our common shares on The Nasdaq Global Market, or Nasdaq, under the symbol "LVRX."

**Investing in our common shares involves a high degree of risk. Please read "[Risk Factors](#)" beginning on page 13 of this prospectus.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

We are an "emerging growth company" under the federal securities laws and will be subject to reduced public company reporting requirements for this prospectus and future filings.

	Per share	Total
Public Offering Price	\$ _____	\$ _____
Underwriting Discount(1)	\$ _____	\$ _____
Proceeds to us (Before Expenses)	\$ _____	\$ _____

(1) We refer you to "Underwriting" beginning on page \_\_\_\_\_ for additional information regarding underwriting compensation.

Delivery of the common shares is expected to be made on or about \_\_\_\_\_, 2021. We have granted the underwriters an option for a period of 30 days to purchase additional shares of our common shares. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be \$ \_\_\_\_\_, and the total proceeds to us, before expenses, will be \$ \_\_\_\_\_.

*Joint book-running managers*

**J.P. Morgan**

**Jefferies**

**SVB Leerink**

*Lead manager*

**Wedbush PacGrow**

Prospectus dated \_\_\_\_\_, 2021

## [Table of Contents](#)

We are responsible for the information contained in this prospectus. We have not authorized anyone to provide you with different information, and we take no responsibility for any other information others may give you. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front cover of this prospectus.

# Table of contents

<a href="#">Presentation of financial and other information</a>	ii
<a href="#">Cautionary statement regarding forward-looking statements</a>	ii
<a href="#">Summary</a>	1
<a href="#">Risk factors</a>	13
<a href="#">Market and industry data</a>	81
<a href="#">Trademarks, service marks and tradenames</a>	82
<a href="#">Use of proceeds</a>	83
<a href="#">Dividend policy</a>	84
<a href="#">Corporate reorganization</a>	85
<a href="#">Capitalization</a>	86
<a href="#">Dilution</a>	88
<a href="#">Selected financial data</a>	90
<a href="#">Management's discussion and analysis of financial condition and results of operations</a>	91
<a href="#">Business</a>	102
<a href="#">Management</a>	161
<a href="#">Principal shareholders</a>	168
<a href="#">Related party transactions</a>	170
<a href="#">Description of share capital and articles of association</a>	172
<a href="#">Common shares eligible for future sale</a>	191
<a href="#">Material income tax considerations</a>	193
<a href="#">Material Dutch tax considerations</a>	199
<a href="#">Underwriting</a>	204
<a href="#">Expenses of the offering</a>	215
<a href="#">Legal matters</a>	216
<a href="#">Experts</a>	217
<a href="#">Enforcement of civil liabilities</a>	218
<a href="#">Where you can find more information</a>	219
<a href="#">Index to financial statements</a>	F-1

**For investors outside the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction, other than the United**

**States, where action for that purpose is required. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of our common shares and the distribution of this prospectus outside the United States.**

We are incorporated in the Netherlands and a majority of our outstanding securities are owned by non-U.S. residents. Under the rules of the United States Securities and Exchange Commission, or SEC, we are currently eligible for treatment as a “foreign private issuer.” As a foreign private issuer, we will not be required to file periodic reports and financial statements with the SEC as frequently or as promptly as domestic registrants whose securities are registered under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

## About this prospectus

Prior to the closing of this offering, we will complete a corporate reorganization described in more detail under “Corporate Reorganization”, in the course of which we will be converted into a public company under Dutch law (*naamloze vennootschap*) and our legal name will change to LAVA Therapeutics N.V. Unless otherwise indicated or the context otherwise requires, all references in this prospectus to “LAVA Therapeutics,” the “Company,” “we,” “our,” “ours,” “ourselves,” “us,” or similar terms refer to (i) LAVA Therapeutics B.V. prior to the completion of the corporate reorganization and (ii) LAVA Therapeutics N.V. after the completion of the corporate reorganization. See “Corporate Reorganization.”

## Presentation of financial and other information

This prospectus includes our audited consolidated financial statements as of and for the year ended December 31, 2019 prepared in accordance with the International Financial Reporting Standards, or IFRS, as adopted by the International Accounting Standards Board, or IASB.

This prospectus includes our unaudited condensed consolidated interim financial statements as of and for the six months ended June 30, 2020, which have been prepared in accordance with IAS 34 as issued by the IASB. The interim financial statements are not necessarily indicative of the financial results to be expected for the annual period.

Our business is primarily conducted in the European Union, and we maintain our books and records in euros, and our financial statements are presented in euros. All references in this prospectus to “\$,” “US\$,” “U.S.\$,” “U.S. dollars,” “dollars” and “USD” mean U.S. dollars and all references to “€,” “EUR” and “euros,” mean euros, unless otherwise noted.

Prior to the consummation of this offering, we intend to convert 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 audited financial statements for the year ended and as of December 31, 2019 and the unaudited financial statements for the six months ended and as of June 30, 2020 are the financial statements for LAVA Therapeutics B.V.

## Cautionary statement regarding forward-looking statements

This prospectus contains statements that constitute forward-looking statements. Many of the forward-looking statements contained in this prospectus can be identified by the use of forward-looking words such as “anticipate,” “believe,” “could,” “expect,” “should,” “plan,” “intend,” “estimate” and “potential,” among others.

## [Table of Contents](#)

Forward-looking statements appear in a number of places in this prospectus 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 this prospectus. Forward-looking statements include, but are not limited to, statements about:

- our operations as a clinical-stage 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 ability to take advantage of abbreviated regulatory pathways for any of our product candidates;
- 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 for the manufacture of 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 ability to defend against any claims by third parties that we are infringing, misappropriating or otherwise violating their intellectual property rights;
- our expectations regarding the use of proceeds from this offering;
- 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."

---

[Table of Contents](#)

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.

**Explanatory note**

In addition to our financial statements as of and for the fiscal year ended December 31, 2019, we have included unaudited financial statements as of and for the six months ended June 30, 2020 on a voluntary basis. Pursuant to the applicable provisions of the Fixing America's Surface Transportation Act, we are omitting our financial statements for the fiscal year ended December 31, 2018 and six months ended June 30, 2019 because they will not be required to be included in the prospectus at the time of the contemplated offering. We intend to amend the registration statement to include all financial information required by Regulation S-X at the date of such amendment before distributing a preliminary prospectus to investors. Accordingly, we note that this draft registration statement includes a qualified audit report, solely as it relates to the omission of comparative periods otherwise required by International Financial Reporting Standards, or IFRS, which will be replaced by an unqualified audit report prior to effectiveness of our registration statement upon inclusion of our financial statements as of and for the fiscal year ended December 31, 2020.

## Summary

*This summary highlights information contained elsewhere in this prospectus. This summary may not contain all the information that may be important to you, and we urge you to read this entire prospectus carefully, including the “Risk Factors,” “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections and our audited and condensed unaudited financial statements, including the notes thereto, included in this prospectus, before deciding to invest in our common shares.*

### Overview

We are a clinical-stage biotechnology company focused on transforming cancer treatment by developing a platform of novel bispecific antibodies engineered to selectively induce gamma-delta T cell-mediated immunity against tumor cells. Our approach activates Vg9Vd2 T cells, a specific and relatively abundant gamma-delta effector T cell subset, upon cross-linking to a selected tumor target by our bispecific gamma-delta T cell engagers, or gamma-delta bsTCEs. These cells have the natural ability to distinguish tumor cells from healthy cells by sensing certain intracellular metabolites that are enriched in cancer cells. Activated Vg9Vd2 T cells are engaged for direct tumor cell killing and, in addition, orchestrate an immunological cascade response that includes activation of innate and adaptive immune cells in the tumor microenvironment. Our preclinical data demonstrate that Vg9Vd2 T cell activation by our gamma-delta bsTCEs kills patient-derived tumor cells with high potency and specificity thereby providing a significant opportunity to deliver effective and safe therapeutics to patients. We expect that activation of adaptive immunity by our approach has the potential to provide durable immune responses with the potential of enhancing patient survival. We believe we are the only company developing bispecific gamma-delta T cell engaging antibodies for the treatment of cancer.

Based on the established correlation of Vg9Vd2 T cell prevalence with favorable outcomes and survival in hematologic malignancies and solid tumors, we believe our gamma-delta bsTCEs have the potential to treat patients with a wide variety of cancers, both as monotherapy and as part of combination regimens. Our lead product candidate, LAVA-051, is advancing toward a Phase 1/2a clinical trial for the treatment of CD1d-expressing hematologic cancers including chronic lymphocytic leukemia, or CLL, multiple myeloma, or MM, and acute myeloid leukemia, or AML. We are also developing our gamma-delta bsTCEs in solid tumors, led by LAVA-206x207, which targets prostate-specific membrane antigen, or PSMA, for the treatment of prostate cancer. We plan for LAVA-051 to enter the clinic in \_\_\_\_\_, followed by LAVA-206x207 in \_\_\_\_\_.

The anti-tumor potential of Vg9Vd2 T cells has previously been studied in multiple clinical trials, which were conducted through adoptive transfer or by *in vivo* activation of this cell type. These trials demonstrated that systemic activation of Vg9Vd2 T cells was generally well-tolerated by patients and resulted in objective clinical responses, but the overall results were not consistent or robust enough to support further development. Based on our preclinical data, we believe that an important root cause for underwhelming efficacy of these approaches was the systemic, non-tumor specific activation of Vg9Vd2 T cells and exhaustion of gamma-delta T cells. We believe a targeted approach utilizing a gamma-delta bsTCE could materially improve clinical responses with the bispecific antibody directing the Vg9Vd2 T cells to the tumor cells and specifically activating them *in situ* while maintaining a favorable safety profile.

Classical 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, or CAR-T cells, have provided convincing clinical activity against selected cancers. Nonetheless, the promise of TCEs for broader use as cancer therapy has not yet been fully realized. Stark drawbacks of these classical TCEs

include significant dose limiting toxicities resulting from the excessive release of cytokines, referred to as cytokine release syndrome, or CRS. CD3-based TCEs have additional limitations because of their broad activation of T cells, including both effector T cells and regulatory cells, or Tregs. Activation of Tregs dampens anti-cancer immunity, potentially resulting in decreased or no therapeutic efficacy, particularly in patients with high local amounts of Tregs in the tumor microenvironment. 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 furthermore has also been associated with significant risk of CRS.

### **Our gamma-delta bsTCE platform**

We believe that our gamma-delta bsTCEs represent a new class of targeted immuno-oncology drugs that can overcome the limitations of classical TCE approaches by exploiting the unique characteristics of Vg9Vd2 T cells. Our platform provides off-the-shelf therapeutics leveraging the validated benefits of antibody-based treatments, including standardized development. We designed our platform to be fully modular and compatible with existing approved and development-stage anti-tumor antibodies to facilitate expedited discovery and development of novel compounds.

Our gamma-delta bsTCEs specifically engage proinflammatory effector Vg9Vd2 T cells that retain their inherent tumor specificity thereby leveraging the natural ability of Vg9Vd2 T cells to distinguish tumor cells from healthy cells. The conditional activation of Vg9Vd2 T cells is designed for high precision in order to avoid a broad systemic, non-tumor specific, activation, systemic T cell exhaustion and CRS. We believe that the high tumor selectivity and potency of our gamma-delta bsTCEs, together with the low risk of CRS, may result in a broad therapeutic window and may therefore provide benefit to a wide range of patients. Activated Vg9Vd2 T cells have the ability to 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.

We have generated compelling preclinical data using patient tumor tissues that demonstrate the potency of our gamma-delta bsTCE platform in the preferred killing of tumor cells compared to healthy cells for both hematologic malignancies and solid tumors. Studies in non-human primates support the potential benign safety profile of gamma-delta bsTCE therapeutics through excellent tolerability with low activity against healthy cells and low induction of cytokines. Based on these findings, we believe that our gamma-delta bsTCE platform may be amenable for the development of targeted therapeutics in a wide variety of tumor indications.

Based on strong preclinical data, we believe our gamma-delta bsTCE platform has the potential to generate potent and safe therapeutics that could become new standards of care in treating cancer. We are currently advancing a pipeline of multiple gamma-delta bsTCEs for the development of potential therapeutics in both hematologic malignancies and solid tumors.



**Our pipeline**



Our portfolio is led by LAVA-051, a unique, humanized gamma-delta bsTCE targeting CD1d-expressing hematologic cancers, including CLL, MM, and AML. LAVA-051 is designed to be an effective anti-tumor agent against CD1d-expressing tumor cells and works via a dual mechanism of action, or MoA. LAVA-051 cross-links CD1d-expressing tumor cells and Vg9Vd2 T cells, resulting in conditional Vg9Vd2 T cell activation, the secretion of cytolytic molecules and cytokines and subsequent tumor killing. In addition, the CD1d-binding moiety of the bsTCE is uniquely able to enhance the interaction of CD1d and the T cell receptor of invariant NKT cells, or iNKT cells, which are a population of innate-like lymphocytes that play an important role in orchestrating immune responses in cancer. As published in 2020 in *Nature Cancer*, we demonstrated that this feature led to effective iNKT cell activation and anti-tumor activity. We believe the combined Vg9Vd2 T cell and iNKT cell activating properties and the resulting cascade response contribute to the potential of LAVA-051 to provide rapid cytotoxicity, as well as long-term antitumor immune responses. We are also evaluating opportunities to develop LAVA-051, or derivatives thereof, for the treatment of CD1d-expressing solid tumors.

In November 2020, we filed a Clinical Trial Application, or CTA, with the Competent Regulatory Authority of The Netherlands, or CCMO, to conduct a Phase 1/2a clinical trial with LAVA-051 in patients with relapsed and/or refractory CLL, MM and AML, which we expect to begin enrolling in . In addition, we expect to file an Investigational New Drug, or IND, application with the U.S. Food and Drug Administration, or FDA, in , after which patients from the U.S. will also be included in the ongoing Phase 1 part of the clinical trial.

We are also advancing a second program, LAVA-206x207, a gamma-delta bsTCE targeting PSMA for the potential treatment of prostate cancer. We expect to submit CTA or IND applications for LAVA-206x207 in and initiate a Phase 1/2a trial in metastatic castration-resistant prostate cancer in . In addition to our two named lead programs, we are advancing a portfolio of discovery programs, which we expect will provide the opportunity for additional CTA/IND submissions in .

Our platform capabilities are further validated by a research collaboration and license agreement with Janssen Biotech, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, which we entered into in May 2020. Under the terms of this agreement, we are responsible for discovering and developing novel gamma-delta bsTCEs specific for an undisclosed target for the treatment of cancer. We received an upfront payment from Janssen of \$8.0 million, have achieved the milestone necessary to receive a \$1.0 million research

milestone payment, and are eligible to receive potential additional research, development, regulatory and commercial milestones, as well as tiered royalties on sales, for any licensed product.

## **Our team and investors**

We were founded in 2016 as a spinout from the VU University in Amsterdam, the Netherlands by leaders in the field of therapeutic antibodies and immuno-oncology, with significant insights and development capabilities in the field of gamma-delta T cells and, specifically, gamma-delta bsTCEs. We have attracted a talented group of industry experts and scientists that now comprise a highly experienced team of over 30 employees, including Stephen Hurly, our Chief Executive Officer, who has more than 25 years of leadership experience across life science companies and investment banking; Paul Parren, Ph.D., our Executive Vice President and Head of Research and Development and professor of Molecular Immunology at the Leiden University Medical Center; Benjamin Winograd, M.D., Ph.D., our Chief Medical Officer; Hans van der Vliet, M.D., Ph.D., co-founder and our Chief Scientific Officer and professor of Medical Oncology at the Amsterdam UMC—Cancer Center Amsterdam; and Ton Adang, Ph.D., our Chief Development Officer. Across the leadership team, the team has been involved in the filing of more than 43 INDs and has contributed to the development of 23 approved cancer products.

Since our founding, we have received tranche-based commitments of approximately \$108.0 million in capital from premier investors, including Versant Ventures, Novo Holdings A/S, Sanofi Ventures, Redmile Group, LLC, Gilde Healthcare, MRL Ventures Fund, Ysios Capital and BB Pureos Bioventures, of which \$44.4 million has been funded to date.

## **Our strategy**

Our goal is to deliver gamma-delta bsTCE therapeutics that change the standard of care and improve outcomes for patients with hematologic malignancies and solid tumors. We are focused on discovering, developing and ultimately commercializing proprietary, off-the-shelf, targeted gamma-delta bsTCEs that leverage the power of gamma-delta T cells with high potency and precision to orchestrate anti-tumor immune responses. Key components to our strategy are to:

- Establish ourselves as the leader in the gamma-delta T cell space.
- Advance our lead product candidate, LAVA-051, in hematologic tumors through clinical development and explore additional indications in solid tumors.
- Advance our product candidate, LAVA-206x207, in prostate cancer through clinical development and explore additional indications in solid tumors.
- Leverage our platform to continue 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.

## **Corporate information**

We were incorporated under the laws of the Netherlands on February 15, 2016, as a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*), and prior to the consummation of this offering, we intend to convert into a Dutch public company with limited liability (*naamloze vennootschap*). See “Corporate Reorganization”. Our principal executive offices are located at Yalelaan 60, 3584 CM Utrecht, the Netherlands. Our telephone number at this address is +31 6 3000 3035.

Our website address is [www.lavatherapeutics.com](http://www.lavatherapeutics.com). The information contained on, or that can be accessed through, our website is not a part of, and shall not be incorporated by reference into, this prospectus. We have included our website address as an inactive textual reference only.

## **Risks associated with our business**

Our business and our ability to execute our strategy are subject to many risks. Before making a decision to invest in our common stock, you should carefully consider all of the risks and uncertainties described in the section titled “Risk Factors” immediately following this prospectus summary section and all of the other information in this prospectus. These risks include, but are not limited to the following:

- We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.
- We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- Even if this offering is successful, we will require substantial additional funding to finance our operations. 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.
- Our product candidates and related technologies are novel approaches to cancer treatment that present significant challenges, and our ability to generate product revenue is dependent on the success of one or more of our product candidates, which will require additional clinical testing before we can seek regulatory approval and begin commercial sales.
- We are dependent on the successful clinical development, regulatory approval and commercialization of our product candidates, including gamma-delta T cell engagers, or bsTCEs. We cannot give any assurance that any of our 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 and our ability to generate product revenue will be adversely affected.
- Our product candidates are in early stages of development, and therefore they will require extensive additional preclinical and clinical testing. Success in preclinical studies or early-stage clinical trials may not be indicative of results in future clinical trials and we cannot assure you that any ongoing, planned or future clinical trials will lead to results sufficient for the necessary regulatory approvals.
- The clinical and commercial utility of our gamma-delta bsTCE platform is uncertain and may never be realized. Additionally, certain aspects of the function and production of gamma-delta T cells are poorly understood or currently unknown, and may only become known through further preclinical and clinical testing.
- If we encounter difficulties in enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- The COVID-19 pandemic could continue to adversely impact our business, including our clinical trials, supply chain and business development activities.
- Clinical product candidate development involves a lengthy and expensive process and involves uncertain outcomes. We may incur additional costs and encounter substantial delays or difficulties in our clinical trials.

- If we are required by the FDA to obtain approval of a companion diagnostic test in connection with approval of any of our product candidates, and we do not obtain, or face delays in obtaining, FDA approval of a diagnostic device, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.
- 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, or 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 rely on third parties for the manufacturing process of our product candidates, and failure by those parties to adequately perform their obligations could harm our business.
- We have entered into a research collaboration and license agreement with Janssen Biotech, Inc. for the development and commercialization of potential product candidates, which may pose a number of risks to our business.
- Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If we breach the license and assignment agreement with Stichting VUmc, or the VUmc Agreement, any of the other agreements under which we acquire or license intellectual property rights from third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose the ability to continue the development and commercialization of our product candidates.
- 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.
- We are a Dutch public company. The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions and may not protect investors in a similar fashion afforded by incorporation in a U.S. jurisdiction.

### **Implications of being an emerging growth company**

As a company with less than \$1.07 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- the ability to present only two years of audited financial statements in addition to any required interim financial statements and correspondingly reduced disclosure in management’s discussion and analysis of financial condition and results of operations in this prospectus;
- exemption from the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, in the assessment of our internal controls over financial reporting, which would otherwise be applicable beginning with the second annual report following consummation of the offering; and
- to the extent that we no longer qualify as a foreign private issuer, (i) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (ii) exemptions from the

requirements of holding a non-binding advisory vote on executive compensation, including golden parachute compensation.

We may take advantage of these exemptions until such time that we are no longer an emerging growth company. We will cease to be an emerging growth company upon the earliest to occur of (i) the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; (ii) the date we qualify as a “large accelerated filer” with at least \$700 million of equity securities held by non-affiliates; (iii) the issuance, in any three year period, by our company of more than \$1.0 billion in non-convertible debt securities held by non-affiliates; and (iv) the last day of the fiscal year ending after the fifth anniversary of our initial public offering of our common shares.

We may choose to take advantage of some but not all of these reduced burdens. For example, we have presented only two years of audited financial statements and only two years of related “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure in this prospectus, and intend to take advantage of the exemption from auditor attestation on the effectiveness of our internal control over financial reporting. Accordingly, the information that we provide shareholders and holders of our common shares may be different than you might obtain from other public companies.

In addition, Section 107 of the JOBS Act provides that an emerging growth company can use the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Given that we currently report and expect to continue to report under IFRS as issued by the IASB, we will not be able to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required by the IASB.

### **Implications of being a foreign private issuer**

We are also considered a “foreign private issuer” under U.S. securities laws. In our capacity as a foreign private issuer, we are exempt from certain rules under the Exchange Act that impose certain disclosure obligations and procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, members of our board of directors, or Board, and our principal shareholders are exempt from the reporting and “short-swing” profit recovery provisions of Section 16 of the Exchange Act and the rules under the Exchange Act with respect to their purchases and sales of our securities. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. In addition, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information.

We may take advantage of these exemptions until such time as we are no longer a foreign private issuer. We will remain a foreign private issuer until the end of the fiscal year following the last date of our second fiscal quarter when more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (i) the majority of our members of the Board or executive officers are U.S. citizens or residents; (ii) more than 50% of our assets are located in the United States; or (iii) our business is administered principally in the United States.

Accordingly, the information contained herein may be different from the information you receive from other public companies.

## **Enforcement of civil liabilities**

We are organized and existing under the laws of the Netherlands, and, as such, under Dutch private international law rules the rights of our shareholders and the civil liability of our directors and executive officers are governed in certain respects by the laws of the Netherlands. The ability of our shareholders in certain countries other than the Netherlands to bring an action against us, our directors and executive officers may be limited under applicable law. In addition, 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 prospectus, 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.

## The offering

<b>Issuer</b>	LAVA Therapeutics N.V.
<b>Common shares offered by us</b>	shares
<b>Common shares to be outstanding after this offering</b>	shares ( shares if the underwriters exercise their option to purchase additional shares from us in full)
<b>Underwriters' option to purchase additional shares</b>	shares
<b>Use of proceeds</b>	<p>We estimate that the net proceeds to us from this offering will be approximately \$ million (or approximately \$ million if the underwriters exercise in full their option to purchase up to additional common shares), based on an assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>We currently expect to use the net proceeds from the offering, together with a portion of our cash, cash equivalents, short-term investments, and non-current financial assets (in aggregate) to advance our portfolio of gamma-delta bsTCE product candidates into multiple proof-of-concept clinical trials for the treatment of hematologic malignancies and solid tumors, and the remainder for working capital and other general corporate purposes.</p> <p>See "Use of Proceeds."</p>
<b>Risk factors</b>	<p>You should read the section titled "Risk Factors" for a discussion of factors to consider carefully, together with all the other information included in this prospectus, before deciding to invest in our common shares.</p>
<b>Dividend policy</b>	<p>We have never paid or declared any cash dividends in the past, and we do not anticipate paying any cash dividends in the foreseeable future. We intend to retain all available funds and any future earnings to fund the further development and expansion of our business. As of the completion of our corporate reorganization, under Dutch law, we may only pay dividends and other distributions from our reserves to the extent our shareholders' equity (<i>eigen vermogen</i>) exceeds the sum of our paid-in and called-up share capital plus the reserves we must maintain under Dutch law or our articles of association and (if it concerns a distribution of profits) after adoption of our statutory annual accounts by our general meeting from which it appears that such dividend distribution is allowed. Subject to those restrictions, any future determination to pay dividends or other distributions from our reserves will be at the discretion of</p>

our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors we deem relevant. See “Dividend Policy.”

**Proposed Nasdaq symbol** “LVRX”

The number of our common shares to be outstanding immediately after this offering is based on shares outstanding as of June 30, 2020; after giving effect to the conversion of all of our outstanding preferred shares, into an aggregate of common shares immediately prior to the consummation of this offering and excludes:

- common shares issuable upon the exercise of share options outstanding as of at a weighted average exercise price of \$ per share; and
- common shares reserved for future issuance under our employee share option programs as described in “Management—Equity Incentive Plans.”

Unless otherwise indicated, all information contained in this prospectus assumes or gives effect to:

- no exercise of the outstanding options described above after June 30, 2020;
- the completion, prior to the consummation of this offering, of our corporate reorganization, as further described under the section titled “Corporate Reorganization”, which includes the transition from our current two-tier governance system with a separate management and supervisory boards into a one-tier governance system with a board of directors consisting of executive and non-executive directors;
- no exercise by the underwriters of their option to purchase additional common shares in this offering; and
- an initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus.



## Summary financial data

You should read the following summary financial data together with our financial statements and the related notes thereto included elsewhere in this prospectus and the “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of this prospectus. We have derived the statement of comprehensive loss data as of and for the year ended December 31, 2019 from our audited financial statements and the statement of financial position data and the statement of comprehensive loss data as of and for the six months ended June 30, 2020 from our unaudited financial statements included elsewhere in this prospectus. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

We maintain our books and records in euros, and prepare our financial statements in accordance with International Financial Reporting Standards, or IFRS, as adopted by the International Accounting Standards Board, or IASB.

(in thousands)	For the six months ended June 30, 2020 (unaudited)	For the year ended December 31, 2019 (amounts in thousands except share and per share data)
<b>Statement of Comprehensive Loss Data:</b>		
<b>Revenue</b>		
Research and license revenue	€ 592	€ —
<b>Total revenue</b>	<b>592</b>	<b>—</b>
<b>Operating expenses:</b>		
Research and development	(6,010)	(7,470)
General and administrative	(1,353)	(1,111)
<b>Total operating expenses</b>	<b>(7,363)</b>	<b>(8,581)</b>
<b>Operating loss</b>	<b>(6,771)</b>	<b>(8,581)</b>
Interest expense, net	(108)	(78)
Foreign currency exchange loss, net	(268)	(16)
<b>Total non-operating expense</b>	<b>(376)</b>	<b>(94)</b>
<b>Loss before income taxes</b>	<b>(7,147)</b>	<b>(8,675)</b>
Income tax benefit / (expense)	—	—
<b>Loss for the period</b>	<b>€ (7,147)</b>	<b>€ (8,675)</b>
<b>Total comprehensive loss for the period</b>	<b>€ (7,147)</b>	<b>€ (8,675)</b>
<b>Loss per share, basic and diluted</b>	<b>€ (3,529.4)</b>	<b>€ (4,284.1)</b>
Weighted average common shares outstanding, basic and diluted	2,025	2,025
Pro forma net loss per share, basic and diluted (unaudited)(1)		
Pro forma weighted average common shares outstanding, basic and diluted (unaudited)(1)		

(1) Pro forma to reflect the conversion of all of our outstanding preferred shares into an aggregate of common shares immediately prior to the consummation of this offering. Pro forma basic net loss per share and diluted net loss per share are the same because outstanding options would be anti-dilutive due to our net loss in this period.

	As of June 30, 2020 (unaudited)		
	Actual	Pro forma(1)	Pro forma as adjusted(2)
(euros in thousands)			
<b>Statement of Financial Position Data:</b>			
Cash and cash equivalents	€ 8,341	€	€
Total assets	9,788		
Total liabilities	11,474		
Accumulated deficit	(19,326)		
Total equity (deficit)	(1,686)		

(1) The pro forma balance sheet data gives effect to the conversion of all classes of preferred shares into common shares.

(2) The pro forma as adjusted balance sheet data give further effect to the sale by us of common shares in this offering at the initial public offering price of \$ per share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, total assets and total equity by \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions. Each increase or decrease of 1.0 million in the number of shares we are offering would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, total assets and total equity by \$ million, assuming no change in the assumed initial public offering price per share and after deducting the estimated underwriting discounts and commissions. This pro forma as adjusted information is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing.

## 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 prospectus, including our financial statements and the related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before deciding whether to invest in our common shares. 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.*

### Risks related to our financial position and capital needs

***We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.***

We have incurred significant operating losses since inception. Our net loss was \$                    million and \$                    million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of \$                    million. Although we have received milestone payments to date, 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 research and preclinical and clinical development of our product candidates, organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting clinical trials. Prior to the initiation of our Phase 1 clinical trial of LAVA-051, we have never conducted clinical trials, and we have not previously obtained regulatory approval for, or commercialized, any product candidates. 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-206x207;
- initiate, conduct and complete any ongoing, anticipated or future preclinical studies and clinical trials for our current and future product candidates;
- seek regulatory and marketing approvals for LAVA-051, LAVA-206x207 and any of our other product candidates that successfully complete clinical trials;
- maintain, protect and expand our intellectual property portfolio;
- 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;
- seek to identify, discover, develop and commercialize additional product candidates;
- hire and retain additional clinical, regulatory and scientific personnel;
- add 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;

## [Table of Contents](#)

- scale our business up to commercial manufacturing, if and when applicable, or upon approval from the Food and Drug Administration, or FDA, or the European Medicines Agency, or EMA; 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. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our current and future product candidates, obtaining regulatory approval, establishing and validating commercial-scale current good manufacturing practices, or cGMP, facilities, marketing and selling any products for which we obtain regulatory approval (including through third parties), as well as discovering or acquiring and developing additional product candidates. We are only in the preliminary stages of some of these activities. We may never succeed in these activities 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, expand our business or continue our operations. A decline in the value of our common shares could also cause you to lose all or part of your investment.

***We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

We are an early clinical-stage biotechnology company with a limited operating history upon which you can evaluate our business and prospects. Our operations to date have been limited to financing and staffing our company, developing our technology, identifying and developing LAVA-051 and LAVA-206x207 and our other product candidates, undertaking preclinical studies, business planning and raising capital. We are preparing to start enrollment in a clinical trial for LAVA-051. However, all of our other research programs are still in the preclinical or research stage of development, and the risk of failure in the biopharmaceutical industry for programs or products candidates at such stage of development is even higher than those in the clinical stage of development. We have not yet demonstrated an ability to successfully conduct or complete any clinical trials, including large-scale, pivotal clinical trials, obtain marketing approval, manufacture a clinical or commercial scale product or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. Typically, it takes about six to 10 years to develop a new drug from the time it enters clinical trials to when it is approved for treating patients, but in many cases it may take longer. 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 genetic medicine 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, if any of our product candidates are approved, capable of supporting commercial activities. We may not be successful in such a transition.

## [Table of Contents](#)

***Even if this offering is successful, we will require substantial additional funding to finance our operations. 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.***

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for, our product candidates and advance our other programs. Other unanticipated costs may also arise. 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. Based on our research and development plans, we believe that the net proceeds from this offering, together with our existing cash, will be sufficient to fund our operations until . 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 our ongoing preclinical studies and clinical trials of our product candidates, after accounting for any COVID-19-related delays or other effects on our development programs;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of other product candidates that we may pursue;
- 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;
- 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 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.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval in order to generate revenue from product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether terminate our research and development programs or future commercialization efforts.

## Risks related to the development of our product candidates

***Our product candidates and related technologies are novel approaches to cancer treatment that present significant challenges, and our ability to generate product revenue is dependent on the success of one or more of our product candidates, which will require additional clinical testing before we can seek regulatory approval and begin commercial sales.***

Our product candidates and related technologies represent novel approaches to cancer treatment generally, and developing and commercializing our product candidates subjects us to a number of challenges. T cell engagers developed by other companies have been observed to cause safety issues, which have resulted in a delay or abandonment of those clinical programs. The commercially available T cell engagers developed by other companies have only been approved for niche indications. Our product candidates could be perceived as having similar complications which could similarly affect their clinical development, and could also be perceived to have additional complications, owing to their unique MoA.

We currently generate no revenues from sales of any products, we have never obtained marketing approval for a product candidate and we may never be able to develop a marketable product. Our ability to generate product revenue is highly dependent on our ability to obtain regulatory approval of and successfully commercialize one or more of our lead product candidates, which will require additional clinical and non-clinical development, regulatory review and approval in each jurisdiction in which we intend to market them, substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts before we can generate any revenue from product sales. We cannot be certain that any of our product candidates will be successful in clinical studies and they may not receive regulatory approval even if they are successful in clinical studies.

The success of our product candidates, including our lead product candidates, will depend on several factors, including the following:

- successful and timely completion of our planned clinical trials;
- initiation and successful patient enrollment and completion of additional clinical trials on a timely basis;
- 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 future collaborators, if any;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishment of supply arrangements with third-party raw materials and drug product suppliers and manufacturers;
- establishment of scaled production arrangements with third-party manufacturers to obtain finished products that are appropriately packaged for sale;
- obtaining and maintaining patent protection, regulatory exclusivity and other intellectual property-related protection, in the United States, Europe and other target markets;
- enforcing and defending our intellectual property and proprietary rights, including our licensed intellectual property;
- successful launch of commercial sales following any marketing approval;

## [Table of Contents](#)

- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property and proprietary rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator.

In addition, because our lead product candidates are our most advanced product candidates, and because our other product candidates are based on similar technology, if our lead product candidates encounter safety or efficacy problems, developmental delays, regulatory issues, or other problems, our development plans and business could be significantly harmed. Further, competitors who are developing products with similar technology may experience problems with their products that could identify problems that would potentially harm our business.

***We are dependent on the successful clinical development, regulatory approval and commercialization of our product candidates, including gamma-delta T cell engagers, or bsTCEs. We cannot give any assurance that any of our 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 and our ability to generate product revenue will be adversely affected.***

Our business is dependent on our ability to successfully complete development of, obtain regulatory approval for, and, if approved, successfully commercialize 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 our product candidate 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 expect that a substantial portion of our efforts and expenses over the next several years will be devoted to the development of our lead product candidates, LAVA-051 and LAVA-206x207, including initiating enrollment in clinical trials for LAVA-051. Our gamma-delta bsTCEs product candidates, including LAVA-051 and LAVA-206x207, are in early stages of development and may never be commercialized.

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 one or more of our product candidates to additional regulatory authorities. We have not applied or obtained regulatory approval for any product candidate in the United States or abroad, and 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.

All of our product candidates will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before they can be successfully commercialized. Prior to obtaining approval to commercialize any product candidate in the United States, Europe or elsewhere, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, EMA or comparable regulatory authorities that such product candidate is safe and effective for its intended use(s). Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe that the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA, EMA and other regulatory authorities. The FDA, EMA or other regulatory authorities may also require us to conduct additional preclinical studies or clinical trials for our product

## [Table of Contents](#)

candidates either pre- or post-approval, or it may object to elements of our clinical development program, requiring their alteration.

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 our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

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 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, or BLA, with the FDA, marketing authorization application, or MAA, with the EMA or other submission or to obtain regulatory approval;
- 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.

Even if we eventually complete clinical testing and receive approval of a BLA, or non-U.S. marketing application for our product candidates, the FDA, EMA or the comparable regulatory authorities may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-market clinical trials. The FDA, EMA or the comparable regulatory authorities also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA, EMA or comparable regulatory authorities may not approve or authorize 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 and would adversely impact our business and prospects.

Moreover, because all of our product candidates are based on the same core gamma-delta bsTCE technology, 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. Our failure to timely complete clinical trials, obtain regulatory approval or, if approved, commercialize our product candidates could adversely affect our business, financial condition and results of operations.



## [Table of Contents](#)

***Our product candidates are in early stages of development, and therefore they will require extensive additional preclinical and clinical testing. Success in preclinical studies or early-stage clinical trials may not be indicative of results in future clinical trials and we cannot assure you that any ongoing, planned or future clinical trials will lead to results sufficient for the necessary regulatory approvals.***

In November 2020, we filed a Clinical Trial Application, or CTA, with the Competent Regulatory Authority of the Netherlands (*Centrale Commissie Mensgebonden Onderzoek*), or CCMO, to conduct a Phase 1/2a clinical trial with LAVA-051 in patients with relapsed and/or refractory chronic lymphocytic leukemia, multiple myeloma and acute myeloid leukemia, which we expect to begin enrolling in . In addition, we expect to file an Investigational New Drug, or IND, application with the FDA in . We expect to submit a CTA and/or IND application for LAVA-206x207 in , and to initiate a Phase 1/2a trial for LAVA-206x207 in PSMA-expressing castration resistant prostate cancer in .

Because our product candidates are in early stages of development, they will require extensive preclinical and clinical testing. LAVA-051 is our only product candidate currently entering into clinical trials. Success in preclinical testing and early-stage clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical studies and early clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical studies and earlier clinical trials does not ensure that later efficacy trials will be successful, nor does it predict final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or even if they successfully advance through earlier clinical trials.

For example, although we plan to begin enrolling patients in a Phase 1/2a clinical trial in Europe for LAVA-051, the EMA has not yet made any determination regarding safety and efficacy of such product candidate in the targeted indication. Further, our novel approaches to oncology are unproven and as such, the cost and time needed to develop our product candidates is difficult to predict and our efforts may not be successful. If we do not observe favorable results in clinical trials of our product candidates, we may decide to delay or abandon clinical development of such product candidate. Any such delay or abandonment could harm our business, financial condition, results of operations and prospects.

In addition, the design of a clinical trial can determine whether its results will 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. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks, including failure in late-stage clinical trials even after achieving promising results in preclinical testing and earlier clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval.

Further, we cannot predict with any certainty if or when we might submit a BLA or MAA for regulatory approval for any of our product candidates or whether any such BLA or MAA will be accepted for review by the FDA or EMA, or whether any BLA or MAA will be approved upon review. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for their proposed uses. This failure could cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing

## [Table of Contents](#)

of any BLAs or MAAs with the FDA or EMA and, ultimately, our ability to commercialize our product candidates and generate product revenues.

***The clinical and commercial utility of our gamma-delta bsTCE platform is uncertain and may never be realized. Additionally, certain aspects of the activation and function of gamma-delta T cells are poorly understood or currently unknown, and may only become known through further preclinical and clinical testing.***

To date, gamma-delta T cells and products that induce gamma-delta T cell activation have only been evaluated in 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. Clinical trials thus far have shown the efficacy of gamma-delta T cells, and other clinical trials have produced encouraging results regarding bi-specifics. However, no clinical trials have been conducted regarding our gamma-delta bsTCE platform. Even after the completion of our Phase 1/2a clinical trial for LAVA-051, our gamma-delta bsTCE 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.

We may not ultimately be able to provide the FDA and EMA with substantial clinical evidence to support a claim of safety, efficacy, purity and potency sufficient to enable the FDA and EMA to approve gamma-delta T cell bsTCE product candidates for any indication. This may be because early clinical trials do not meet their endpoints, because later clinical trials fail to reproduce favorable data obtained in earlier clinical trials, because the results of such trials are not statistically significant, because the FDA or EMA disagrees with how we interpret the data from these clinical trials, or because the FDA or EMA does not accept these therapeutic effects as valid endpoints in pivotal clinical trials necessary for market approval. We will also need to demonstrate that our gamma-delta bsTCE product candidates are safe. We do not have data on possible harmful long-term effects of gamma-delta bsTCE 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 gamma-delta bsTCE product candidates is uncertain and is subject to significant risk.

Moreover, actual or perceived safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved by applicable regulatory authorities, of physicians to subscribe to the novel treatment mechanics. The FDA, EMA or other applicable regulatory authorities may impose specific post-market requirements, such as establishment of a Risk Evaluation and Mitigation Strategy, or REMS, and request additional information informing benefits or risks of our products may emerge at any time prior to or after regulatory approval.

Physicians, hospitals and third-party payors are often slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

***Clinical product candidate development involves a lengthy and expensive process and involves uncertain outcomes. We may incur additional costs and encounter substantial delays or difficulties in our clinical trials.***

We may not commercialize, market, promote or sell any product candidate without obtaining marketing approval from the FDA, EMA or other comparable regulatory authority, and we may never receive such approvals. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is

## [Table of Contents](#)

expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome.

A failure of one or more clinical trials can occur at any stage of testing. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Additionally, our upcoming Phase 1/2a trial for LAVA-051 involves studying a relatively small patient population, which makes it difficult to predict whether the favorable results observed in such clinical trial 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 (among other unforeseen events included in this “—Risks related to the development of our product candidates” subsection):

- delays in reaching a consensus with regulatory authorities on the design, location or implementation of our clinical trials;
- delays or setbacks in patient 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 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 may slow potential enrollment, reduce the number of eligible patients for clinical trials, or 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.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us 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.

In addition, the clinical trial requirements of the FDA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for product candidates such as ours can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates. Regulatory agencies

## [Table of Contents](#)

administering existing or future regulations or legislation may not allow production and marketing of products utilizing gene regulation technology in a timely manner or under technically or commercially feasible conditions. Regulatory action or private litigation could result in expenses, delays or other impediments to our research programs or the commercialization of resulting products.

Further, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may be delayed in obtaining marketing approval, or not obtain marketing approval at all, obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, and/or have regulatory authorities withdraw or suspend their approval or impose restrictions on distribution in the form of a modified risk evaluation and mitigation strategy, or REMS, among other results. 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.

Additionally, the FDA, EMA or an independent institutional review board, or IRB, may also suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice, or GCP, regulations, that we are exposing participants to unacceptable health risks, or if the FDA, EMA or other applicable regulatory authority finds deficiencies in our investigational new drug applications, or INDs, or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for 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.

***If we are required by the FDA to obtain approval of a companion diagnostic test in connection with approval of any of our product candidates, and we do not obtain, or face delays in obtaining, FDA approval of a diagnostic device, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.***

If safe and effective use of any of our product candidates depends on a diagnostic, known as a companion diagnostic, that is not otherwise commercially available, then the FDA generally will require approval or clearance of that companion diagnostic, at the same time that the FDA approves our product candidates if at all. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. If a satisfactory companion diagnostic is not commercially available, we may be required to create or obtain one that would be subject to regulatory approval requirements. The process of obtaining or creating such diagnostic is time consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable regulatory authorities, and, to date, the FDA has required premarket approval of all companion diagnostics for cancer therapies. 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 genetic alteration that the companion diagnostic was developed to detect.

If the FDA, EMA or a comparable regulatory authority requires approval of a companion diagnostic for any of our product candidates, whether before or after it obtains marketing approval, we, and/or 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.

We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our product candidate, if approved, on a timely or profitable basis, if at all.

***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 certain of our product candidates, including LAVA-051, 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 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 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 clinical trials 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. Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our 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 otherwise 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;

## Table of Contents

- 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 gamma-delta bsTCEs 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 patient 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 evolving 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 clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. 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. In addition, we may rely on clinical research organizations, or CROs, and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to ensure their actual performance.

***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.***

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.

## [Table of Contents](#)

Undesirable side effects caused by our product candidates, implanted devices, 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 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 drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims.

To date, we have not tested our product candidates on patients. As we continue developing our lead product candidates and initiate clinical trials of our additional product candidates, serious adverse events, or SAEs, undesirable or potentially fatal side effects, cytokine release syndrome, 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. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. 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. For example, the FDA could require us to adopt 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 adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone or with collaborators.

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 candidate, if approved by applicable regulatory authorities.

### ***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. Companies have also taken precautions, such as requiring employees to work remotely, imposing travel restrictions and temporarily closing businesses. 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 on employee resources. The effects of government actions and our own policies and those of third parties to reduce the spread of COVID-19 have not significantly



## [Table of Contents](#)

impacted our activities to date, but they may in the future and may negatively impact productivity and slow down or delay our future clinical trials, preclinical studies and research and development activities, may cause disruptions to our supply chain, to the administrative functions of clinical trial sites and/or to the operations of our other partners, and as a result 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 may be affected, directly or indirectly, by the COVID-19 pandemic. As COVID-19 continues to spread, 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 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 Institutional Review Board 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 or materials to conduct our laboratory experiments and/or clinical trials, including PPE;
- 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 fundraising efforts to support our business;
- delays in the development of product candidates;
- delays or disruptions in manufacturing our product candidates;
- interruption of key 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 acquire 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



## [Table of Contents](#)

- 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. In addition, the trading prices for other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. 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 become 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 future clinical trials. Interim, "top-line" or preliminary data from clinical trials that we may complete 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 you or 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 may seek orphan drug designation for some or all of our current or future product candidates, and may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for supplemental market exclusivity.***

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. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. After the FDA grants orphan drug designation, the identity of the biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

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 may seek orphan drug designation for LAVA-051 and some or all of our other current or future product candidates in additional orphan indications in which there is a medically plausible basis for the use of these 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. For example, the FDA has expressed concerns regarding the regulatory considerations for orphan drug designation as applied to tissue agnostic therapies, and the FDA may interpret the Federal Food, Drug and Cosmetic Act, and regulations promulgated thereunder, in a way that limits or blocks our ability to obtain orphan drug designation or orphan drug exclusivity, if our product candidates are approved, for our targeted indications.

***We may not be able identify or discover other product candidates and may fail to capitalize on programs or product candidates that may present a commercial opportunity or for which there is a likelihood of success.***

Our efforts to identify and develop additional product candidates will require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. We may also broaden the reach of our platform by selectively in-licensing technologies or product candidates. Our efforts may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development, approved products or commercial revenues for many reasons, including the following:

- the methodology used may not be successful in identifying potential product candidates;

## [Table of Contents](#)

- competitors may develop alternatives that render any product candidates we develop obsolete;
- any product candidates we develop may be covered by third parties' patents or other exclusive rights;
- a product candidate may demonstrate harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by physicians, patients, the medical community or third-party payors.

We have limited financial and management resources and, as a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater market potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products, including attractive or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in circumstances under which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. In addition, we may not be successful in replicating our approach to product candidate development for other disease indications. If we are unsuccessful in identifying and developing additional product candidates or are unable to do so, our business may be harmed.

***We face significant competition, and many of our competitors have substantially greater experience and resources than we have.***

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 have greater financial and other resources, larger research and development staffs, and more experienced capabilities in researching, developing and testing products than we do. Many of these companies also have more experience in conducting clinical trials, obtaining FDA and other regulatory approvals, and manufacturing, marketing and distributing therapeutic products. Smaller or early clinical-stage 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. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and 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, which could give such products significant regulatory and market timing advantages over any of our product candidates. In addition, large pharmaceutical companies or other companies with greater resources or experience than us may choose to forgo therapy opportunities that would have otherwise been complementary to our product development and collaboration plans. 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**

***We rely on third parties for the manufacturing process of our product candidates, and failure by those parties to adequately perform their obligations could harm our business.***

We do not currently own any facility that may be used as our clinical or commercial-scale manufacturing and processing facility and expect that we will rely on outside vendors for at least a portion of the manufacturing process of our product candidates that we develop. The facilities used by our contract manufacturers must be approved by the FDA, EMA and other regulatory agencies pursuant to inspections that will be conducted after we submit an application for approval to the FDA, EMA or other regulatory agencies. To the extent that we engage third parties for manufacturing services, we will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with confidentiality agreements and the cGMP requirements for manufacture of our product candidates. Stability data is collected after subjecting our batches to various conditions, such as refrigeration, room temperature, and high temperatures, and it is possible that impurities, particulates, leachables, microbiology, and/or degradation of the active pharmaceutical ingredients could occur or other issues could be detected. If the stability data is not acceptable, we may need to change our manufacturing process, which could result in a delay and could materially harm our business.

Growth in the costs and expenses of components or raw materials may also adversely influence our business, financial condition and results of operations. 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.

We have not yet caused any product candidates to be manufactured or processed on a commercial scale and may not be able to do so. We will make changes as we work to optimize the manufacturing process, and we cannot be sure that even minor changes in the process will result in products that are capable or safe and effective. If such contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or other regulatory authorities, we will not be able to secure and/or maintain regulatory approval for our product candidates. In addition, we have no control over the ability of third parties to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or other applicable regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

We also intend to rely on third-party manufacturers to supply us with additional quantities of our product candidates to be used, if approved, for commercialization. We do not yet have a commercial supply agreement for commercial quantities of product. If we are not able to meet market demand for any approved product, it

## [Table of Contents](#)

would negatively impact our ability to generate revenue, harm our reputation, and could have an adverse effect on our business and financial condition.

Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including:

- 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;
- our third-party manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our third-party manufacturers may fail to comply with cGMP requirements and other inspections by the FDA, EMA or other comparable regulatory authorities;
- our inability to negotiate manufacturing agreements with third parties under commercially reasonable terms, if at all;
- breach, termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on single sources for reagents and components;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single-source supplier;
- our third-party manufacturers may not devote sufficient resources to our product candidates;
- we may not own, and may not have exclusive rights to, the intellectual property and proprietary rights in any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
- carrier disruptions or increased costs that are beyond our control; and
- delays or disruptions as a result of the COVID-19 pandemic.

In addition, if we enter into a strategic collaboration with a third party for the commercialization of our current or any future product candidates, we will not be able to control the amount of time or resources that they devote to such efforts. If any strategic collaborator does not commit adequate resources to the marketing and distribution of our current or any future product candidates, it could limit our potential revenues.

Any adverse developments affecting manufacturing operations for our product candidates may result in lot failures, inventory shortages, shipment delays, product withdrawals or 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.

## [Table of Contents](#)

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, or may impact our ability to successfully commercialize our current or any future product candidates once approved. Some of these events could be the basis for FDA, EMA or other regulatory action, including injunction, request for recall, seizure, or total or partial suspension of production.

***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, or 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 BDS. Although we believe that we have a substantial reserve of BDS to support 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 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.

Moreover, to meet anticipated demand, our single-source supplier may need to increase manufacturing capacity, which could involve significant challenges. This may require us and our supplier to invest substantial additional funds and hire and retain the technical personnel who have the necessary experience. Neither we nor our supplier may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all.

***We and our third-party manufacturers may encounter difficulties in the production of our product candidates. If we encounter any such difficulties, our ability to supply our product candidates for clinical trials or, if approved, for commercial sale could be delayed or halted entirely.***

The manufacture of biopharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. The process of manufacturing our product candidates is extremely susceptible to product loss due to contamination,

## [Table of Contents](#)

equipment failure or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates 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.

All of our bsTCEs are manufactured from a vial of a master 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. 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, 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.

***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 the clinical development of our product candidates**

***We intend to partner 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 intend to rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future preclinical studies. We expect to control only certain aspects of the activities of our third-party service



## [Table of Contents](#)

providers, including investigators and CROs. Nevertheless, we will be responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities.

We are, and our future CROs will be, required to comply with the good laboratory practices, or GLPs, and GCPs, which are regulations and guidelines enforced by the FDA and comparable regulatory authorities in the form of International Council for Harmonization 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 GLP preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations. If we or our future 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. Accordingly, if 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 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. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the 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;
- fail to comply with contractual obligations, including with respect to confidentiality;
- experience regulatory compliance issues; or
- 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 future 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, fail to meet expected deadlines, or fail to comply with regulatory and/or 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. While we will have agreements governing their activities, our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and preclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our business. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property and proprietary or confidential



## [Table of Contents](#)

information by CROs, which may compromise our trade secret protection and allow our potential competitors to access and exploit our proprietary technology.

Additionally, the FDA, EMA or other regulatory authorities may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by investigator-initiated trials or our interpretation of preclinical, manufacturing or clinical data from these investigator-initiated trials. If so, regulatory authorities may require us to obtain and submit additional preclinical, manufacturing or clinical data before we may initiate further clinical trials and/or obtain any regulatory approvals.

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 FDA, EMA or other 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.

***Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.***

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. 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 result in 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, any of which could have a negative impact on our business, financial condition, results of operations and prospects.

***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.***

The ability of the FDA to review and approve new products or regulatory submissions can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events, such as the ongoing COVID-19 pandemic, that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to cleared or approved biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, in March 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment 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 their 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.

## **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 breach the license and assignment agreement with Stichting VUmc, or the VUmc Agreement, or any of the other agreements under which we acquire or license intellectual property rights from third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose the ability to continue the development and commercialization of our product candidates.***

The licensing of intellectual property is of critical importance to our business and to our current and future product candidates. We have entered into license agreements and assignments 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-015, LAVA-206x207 or any future product candidates we may develop. These license agreements impose financial and other obligations on us that are relevant to our business and financial operations, and if we fail to comply with our

## [Table of Contents](#)

obligations under these agreements, including obligations to make various milestone and royalty payments and other obligations, we could lose our rights, or face further liability, under such license agreements. 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.

In particular, an important aspect of our platform technology and product candidates derives from rights under the VUmc Agreement. Under the VUmc Agreement, we received a contingent assignment of certain patent rights relevant to LAVA-051 and LAVA-206x207 product candidates. 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, then VUmc may terminate the agreement, and we could be obligated to transfer back to VUmc the assigned patent rights. If the VUmc Agreement is terminated, and we lose our intellectual property rights thereunder, this may result in a complete termination of our product development and any commercialization efforts for LAVA-051 or LAVA-206x207. 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 the section titled “Business—License Agreements.”

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

## [Table of Contents](#)

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 large part, on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our product candidates and our technology. 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-206x207. 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, 2020, we own, co-own or exclusively license two issued U.S. patents, two pending U.S. patent applications, four pending European regional-phase patent applications, four pending PCT patent applications, four issued patents in other territories and 17 pending patent applications in other territories, which are important to the development of our business. For more information relating to our patent portfolio, see the section titled “Business—Intellectual Property.” We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. 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. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. 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 issue 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

## [Table of Contents](#)

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.

In addition, in some circumstances, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering technology that we license from third parties. Therefore, these patents and applications may not be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our

## [Table of Contents](#)

licensors fail to prosecute, maintain, enforce or defend such patents, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize our product candidates that are subject to such license rights could be adversely affected.

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. When new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive, irrevocable, worldwide license authorizing the U.S. government to use the inventions for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed 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. This possibility includes the risk 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. There is also a risk 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.***

The United States Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, 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 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 employ reputable law firms 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. If we, our service providers or our licensors fail to maintain the patents and patent applications covering our products or technologies, our patent protection could be reduced or eliminated and we may not be able to stop a

competitor from marketing products that are the same as or similar to our product candidates, which would have an adverse effect on our competitive position, business, financial condition, results of operations and prospects. 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.

In addition, if we fail to apply for or otherwise fail to obtain applicable patent term extensions or adjustments as a result of such noncompliance, we will have a more limited time during which we can enforce our granted patent rights. In addition, if we are responsible for patent prosecution and maintenance of patent rights in-licensed to us, any of the foregoing could expose us to liability to the applicable patent owner.

***Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.***

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but there can be no assurance that any such extensions will be obtained, and the life of a patent, and the protecting it affords, is limited. Given the amount of time required for the development, testing and regulatory review of product candidates such as LAVA-051 and LAVA-206x207, patents protecting such candidates might expire before or shortly after such candidates are commercialized. At the time of expiration of the relevant patents, the underlying technology covered by such patents can be used by any third party, including competitors. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We expect to seek extensions of patent terms in the United States and, if available, in other countries where we have or may obtain patent rights. 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, for example, Supplementary Protection Certificates in Europe. In particular, a maximum of five and a half years of supplementary protection can be achieved in Europe for an active ingredient or combinations of active ingredients of a medicinal product protected by a basic patent, if a valid marketing authorization exists (which must be the first authorization to place the product on the market as a medicinal product) and if the product has not already been the subject of supplementary protection. 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



## [Table of Contents](#)

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 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. Moreover, 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



## [Table of Contents](#)

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.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may also pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These 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 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.

Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims can be expensive and time-consuming and would divert management's attention from our core business. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs or in-license needed technology. Many of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex intellectual property litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

***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.

## [Table of Contents](#)

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, 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. Although 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 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. The initiation of a claim against a third party might also cause the third party to bring counterclaims against us, such as claims asserting that our patent rights are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, post-grant review or oppositions, or in similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. 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

## [Table of Contents](#)

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. Such a loss of patent protection could harm our business.

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.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares.

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. For example, assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, 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 includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing 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 trade secrets, which increases the possibility that a competitor will discover them or that our 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 trade secrets with them. We may also

## [Table of Contents](#)

conduct joint research and development programs that may require us to share 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 trade secrets. Despite the contractual provisions employed when working with third parties, the need to share 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, that 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 trade secrets. Despite our efforts to protect our 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 trade secrets, our business and competitive position would be harmed.***

In addition to seeking patent protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary or confidential information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into nondisclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees, advisors and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary or confidential information, including our trade secrets. Further, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or other proprietary information. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is

## [Table of Contents](#)

unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, 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 expect to rely on trademarks as one means to distinguish our product candidates that are approved for marketing from the products of our competitors. 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. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully 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 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 are highly dependent on the services of our senior management team and if we are not able to retain our current management team or recruit and retain additional management, clinical and scientific personnel, our business will be harmed.***

We are highly dependent on senior management team. Each of them may currently terminate their employment with us at any time and will continue to be able to do so after the completion of this offering. The loss of the services of these persons could impede the achievement of our research, development and commercialization objectives.



## [Table of Contents](#)

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

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

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

As of December 31, 2020, we had 28 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. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or 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 have entered into a research collaboration and license agreement with Janssen Biotech, Inc. for the development and commercialization of potential product candidates, which may pose a number of risks to our business.***

We have entered into a research collaboration and license agreement with Janssen Biotech, Inc., or Janssen, for the potential discovery and development of multi-specific antibody products that are directed to a specified target in all fields of use. Our existing collaboration arrangement may pose a number of risks, including that Janssen:

- may not have sufficient resources or decide not to devote the necessary resources to our collaboration arrangement due to internal constraints such as budget limitations, lack of human resources, or a change in strategic focus;



## [Table of Contents](#)

- may believe our intellectual property is not valid or is unenforceable, or that the product candidate(s) subject to the collaboration 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
- may delay the development or commercialization of our product candidates in favor of developing or commercializing another party's product candidate.

For more information on the Janssen Agreement, see the section titled "Business—License Agreements."

***We may explore strategic collaborations that may never materialize or we may be required to relinquish important rights to and control over the development and commercialization of our product candidates to any future collaborators.***

Our business strategy includes broadening our platform by exploring strategic partnerships that maximize the potential of our gamma-delta bsTCE programs. As a result, for some of our product candidates, we may in the future determine to collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization of one or more therapeutic products. At the current time however, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations can be complicated and time consuming to negotiate and document.

We may not be able to negotiate strategic collaborations on acceptable terms, if at all. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators 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. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our technology platforms and our business may be materially and adversely affected.

If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. We are unable to predict when, if ever, we will enter into any strategic partnerships 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;

## [Table of Contents](#)

- 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.

Strategic partners may also delay clinical trials, experience financial difficulties, provide insufficient funding, terminate a clinical trial or abandon a product candidate, which could negatively impact our development efforts. Additionally, strategic partners may 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.

If our therapeutic collaborations do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. All of the risks relating to product development, regulatory approval and commercialization described in this prospectus 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, it may find it more difficult to attract new collaborators.

***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. Security breaches of our systems (or our vendors', collaborators', contractors', or consultants' systems) could create operational disruptions, compromise the security of personal information, trigger contractual and legal obligations, harm our reputation, subject us to significant liability, and/or adversely affect our business, including the ability to conduct or continue clinical trials, and financial results.***

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. Historically, we have not conducted any information security audits or evaluations on our internal computer systems and 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, that is stored in or otherwise processed by such systems. Due to the COVID-19 pandemic, 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

## [Table of Contents](#)

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, if, for example, third parties attempt to fraudulently induce our employees or third-party service providers to disclose information or usernames and/or passwords, or otherwise compromise the security of our platform, networks, systems and/or physical facilities. 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. Furthermore, if the confidentiality, integrity or availability of personal information stored or otherwise processed by us was disrupted, we could incur significant liability, or our platform, systems or networks may be perceived as less desirable, which could negatively affect our business and damage our reputation. 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, as well as other harms to our business and our competitive position. Remediation of a security breach may involve significant time, resources, and expenses. 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.

We are required to comply with laws, rules and regulations that require us to maintain the security of personal information that we collect, store, use, disclose and otherwise process, and may have contractual and other legal obligations to notify relevant stakeholders of security breaches. 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.

A security breach may also cause us to breach our contractual obligations. Our agreements with certain counterparties may require us to use industry-standard or reasonable measures to safeguard personal information. A security breach, or our failure to otherwise comply with such contractual obligations, could lead to claims by our contractual counterparties or other relevant stakeholders. In addition, our inability to flow down such contractual obligations to our vendors, collaborators, other contractors, or consultants may also cause us to breach our contracts. As a result, we could be subject to legal action or our contractual counterparties could end their relationships with us. There can be no assurance that the limitations of liability or any indemnification provisions in our contracts would be enforceable or adequate, or would otherwise protect us from liabilities or damages.

## [Table of Contents](#)

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. We may be subject to indemnity demands, regulatory proceedings, audits, penalties, fines or litigation based on misuse of our platform with respect to such sensitive information and defending against such litigation and otherwise addressing such matters may be expensive, cause distraction and result in us incurring liability, all of which may affect our business, results of operations and financial condition. For example, under EU data protection laws, we may be required to notify European Data Protection Authorities and the affected individuals, within strict time periods, about any personal information breaches, and may be subject to significant fines if such breaches are found to have resulted from inadequate security measures. 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 our contractual counterparties or other relevant stakeholders, which may adversely affect our business. These proceedings could force us to spend money in defense or settlement, divert management's time and attention, increase our costs of doing business, or adversely affect our reputation. We could be required to fundamentally change our business activities and practices or modify our products and/or platform capabilities in response to such litigation, which could have an adverse effect on our business.

While we maintain general liability insurance coverage and coverage for errors or omissions, we cannot assure you that such coverage will be adequate or otherwise protect us from all liabilities or damages, or all types of liability, with respect to claims associated with security incidents, breaches or other compromises of personal information or that such coverage will continue to be available on acceptable terms or at all. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim. 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, or 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.***

We have not yet determined our PFIC status. 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, including the proceeds from this offering. 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.”

***If a United States person is treated as owning at least 10% of the value or voting power of our common shares, it may be subject to adverse U.S. federal income tax consequences.***

If a U.S. Holder (as defined in the section entitled “Material U.S. Federal Income Tax Considerations for U.S. Holders” hereof) is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our common shares, such U.S. Holder may be treated as a “United States shareholder” with respect to each “controlled foreign corporation” in our group (if any). Because our group includes at least one U.S. subsidiary, if we were to form or acquire any non-U.S. subsidiaries in the future, they may be treated as controlled foreign corporations of any U.S. Holder owning (directly, indirectly or constructively) at least 10% of the value or voting power of our common shares. A United States shareholder of a controlled foreign corporation may be required to report annually and include in its U.S. taxable income its *pro rata* share of certain “Subpart F income,” “global intangible low-taxed income” and investments of earnings in “United States property” by a controlled foreign corporation, regardless of whether the controlled foreign corporation makes any distributions of profits or income to such United States shareholder. An individual that is a United States shareholder with respect to a controlled foreign corporation generally will not be allowed certain tax deductions or foreign tax credits in respect of its income that would be allowed to a United States shareholder that is a U.S. corporation. We cannot provide any assurances that we will assist investors in determining whether any non-U.S. subsidiaries that we may form or acquire in the future would be treated as a controlled foreign corporation or whether such investor would be treated as a United States shareholder with respect to any of such controlled foreign corporations. Further, we cannot provide any assurances that we will furnish to any U.S. shareholder information that may be necessary to comply with the reporting and tax paying obligations discussed above. The Internal Revenue Service, or IRS, has provided limited guidance on situations in which investors may rely on publicly available information to comply with their reporting and taxpaying obligations with respect to foreign-controlled controlled foreign corporations. Failure to comply with these reporting obligations may subject you to significant monetary penalties and may prevent the statute of limitations with respect to your U.S. federal income tax return for the year for which reporting was due from starting. U.S. Holders should consult their tax advisers regarding the potential application of these rules to their investment in our common shares.

***Tax authorities may disagree with our positions and conclusions regarding certain tax positions, resulting in unanticipated costs, taxes or non-realization of expected benefits.***

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, the IRS or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable nexus, often referred to as a “permanent establishment” under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material unanticipated income taxes, interest and penalties are payable by us, and we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

***Future changes to tax laws could materially adversely affect our company and reduce net returns to our shareholders.***

The tax treatment of the company is subject to changes in tax laws, regulations and treaties, or the interpretation thereof, tax policy initiatives and reforms under consideration and the practices of tax authorities in jurisdictions in which we operate, as well as tax policy initiatives and reforms related to the Organization for Economic Co-Operation and Development's, or OECD, Base Erosion and Profit Shifting, or BEPS Project, the work of the OECD/G20 Inclusive Framework on Pillar One and Pillar Two, the European Commission's state aid investigations and other initiatives.

Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid. We are unable to predict what tax reform may be proposed or enacted in the future, possibly with retroactive effect, or what effect such changes would have on our business, but such changes, to the extent they are enacted in future tax legislation, regulations, policies or practices, could affect our financial position and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders, and increase the complexity, burden and cost of tax compliance.

***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 and reduce the demand for our product.***

Our business exposes us to product liability risks, which are inherent in the testing, manufacturing, marketing and sale of biopharmaceutical products. For example, we may be sued if any product we develop allegedly causes or is perceived to cause injury or is found to be otherwise unsuitable during product testing, 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.

Gamma-delta bsTCEs may cause unforeseen harmful side effects, such as CRS and on-target/off-tumor side effects.

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.

## **Risks related to commercialization and regulatory compliance**

***The FDA 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.***

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We are not permitted to market any biological drug product in the United States until we receive approval of a BLA from the FDA. We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign authorities. A BLA must include extensive preclinical and clinical data and sufficient supporting information to establish the product candidate's safety and effectiveness for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing and controls for the product.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of allogeneic T cell therapies for cancer. We may also request regulatory approval of future product candidates by target, regardless of cancer type or origin, which the FDA may have difficulty accepting if our clinical trials only involved cancers of certain origins. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials, as the FDA often adheres to the Advisory Committee's recommendations. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

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;



## Table of Contents

- negotiating the terms of any collaboration agreements we may choose to initiate or conclude;
- 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 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;
- difficulty in having patients complete a trial 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 of defending intellectual property disputes, including patent infringement actions brought by third parties;
- the effect of competing technological and market developments;
- 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;
- the cost of establishing sales, marketing and distribution capabilities for any product candidate for which we may receive regulatory approval in regions where we choose to commercialize our products on our own; 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. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted or by the FDA or other regulatory authorities due to



## [Table of Contents](#)

a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or based on a recommendation by the Data Safety Monitoring Committee. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

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.

***Even if we obtain regulatory approvals for our product candidates, they will remain subject to ongoing regulatory oversight.***

Even if we obtain regulatory approvals for our product candidates, such approvals will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record keeping and submission of safety and other post-market information. Any regulatory approvals that we receive for our product candidates may also be subject to a REMS, to limitations on 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.

In addition, product candidate manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or foreign marketing application. 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.

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.

## [Table of Contents](#)

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and harm our business, financial condition, results of operations and prospects.

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 any 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.

***Because we are subject to environmental, health and safety laws and regulations, we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities which may adversely affect our business and financial condition.***

Our operations, including our research, development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of, and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions. Although we believe our procedures for using, handling, storing and disposing of these

## [Table of Contents](#)

materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from hazardous and biological materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, our production and development efforts may be interrupted or delayed and our financial condition and results of operations may be materially adversely affected.

***We expect that 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, or 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.

***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.

## [Table of Contents](#)

Much like the Anti-Kickback Statute 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.

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be successful in commercializing them, if and when they are approved.***

To successfully commercialize any product candidate that may result from our development programs, we will need to build out our sales and marketing capabilities, either on our own or with others. The establishment and development of our own commercial team or the establishment of a contract sales force to market any product candidate we may develop will be expensive and time-consuming and could delay any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We may seek to enter into collaborations with other entities to utilize their established marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If any current or future collaborators do not commit sufficient resources to commercialize our product candidates, or we are unable to develop the necessary capabilities on our own, we may be unable to generate sufficient revenue to sustain our business. We compete with many companies that currently have extensive, experienced and well-funded marketing and sales operations to recruit, hire, train and retain marketing and sales personnel. We will likely also face competition if we seek third parties to assist us with the sales and marketing efforts of our product candidates. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

## [Table of Contents](#)

***Our relationships with customers, physicians, and third-party payors are 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 and Product Approval.”

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.

Litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have an adverse effect on our ability to compete in the marketplace.

***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. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a payor's list of covered products, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. 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.

Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Currently, in the allogeneic transplant setting, reimbursement is often made based on a capitated payment system, and obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Therefore, our product candidates may not be reimbursed separately but their cost may instead be bundled as part of a capitated payment received by the provider for the procedure only. We cannot be sure that the clinical results of our trials will be sufficient or meaningful to convince hospitals and/or clinicians to utilize our product or to get third-party payors to change reimbursement to separate outside of the current bundle. A decision by a third-party payor not to cover or separately reimburse for our product candidates or procedures using our product candidates, could reduce physician utilization of our products once approved. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. Additionally, any companion diagnostic test that we develop will be required to obtain coverage and reimbursement separate and apart from the coverage and reimbursement we seek for our product candidates, if approved. If coverage and adequate reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize any product candidates that we develop.

***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 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 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, in March 2010, 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, was passed, which substantially changed the way healthcare is financed by both governmental and private payors in the United States. Since its enactment, however, there have been judicial and Congressional challenges to the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or the Tax Act includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax.

## [Table of Contents](#)

On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case, although it remains unclear when or how the Supreme Court will rule. It is also unclear how other efforts to challenge, repeal or replace the ACA will impact the ACA or our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include 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 December 31, 2020, 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.

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. While some of the proposed measures may require additional authorization to become effective, the U.S. Congress and the Trump administration have indicated that they will continue to seek new legislative and/or administrative measures to control drug 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. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction, particularly in light of the recent presidential election. 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.”



***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, these include rules and regulations promulgated under the authority of the Federal Trade Commission, the Electronic Communications Privacy Act, the Computer Fraud and Abuse Act, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, the Gramm-Leach-Bliley Act, the California Consumer Privacy Act of 2018, or the CCPA, and other state and federal laws relating to data privacy and security. The CCPA requires covered businesses to provide new disclosures to California residents, provide them new ways to opt-out of the sale of personal information, and provides a private right of action and statutory damages for data breaches. Although there are limited exemptions under the CCPA (for example, business-to-business communications), and an exception for protected health information that is subject to HIPAA, the CCPA could impact our business depending on how the CCPA will be interpreted and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal information. As we expand our operations, the CCPA may increase our compliance costs and potential liability. Other states in the United States are beginning to propose laws similar to the CCPA. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business, results of operations and financial condition. In addition, California voters recently approved the California Privacy Rights Act of 2020, or CPRA, which goes into effect on January 1, 2023. It is expected that the CPRA would, among other things, give California residents the ability to limit the use of their personal information, further restrict the use of cross-contextual advertising, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action, provide for increased penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the new law.

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. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly. Additionally, the costs of compliance with, and other burdens imposed by, the laws, regulations, and policies that are applicable to the businesses of our customers may limit the use of, and reduce the overall demand for, our platform. Privacy concerns, whether valid or not, may inhibit market adoption of our platform particularly in certain countries.

Internationally, virtually every jurisdiction in which we operate has established or is in the process of establishing data security and privacy legal frameworks with which we, and vendors, processing personal information on our behalf must comply. For example, the European Union adopted the General Data Protection Regulation, or the GDPR, which went into effect in May 2018 and applies throughout the European Economic



## [Table of Contents](#)

Area, or EEA or Europe, and contains strict requirements for processing the personal information of individuals residing in Europe. The GDPR has increased, and will continue to increase, our compliance burdens, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain, and process personal information about them. In particular, under the GDPR, fines of up to 20 million Euros or up to 4% of the annual global turnover of the preceding financial year of the noncompliant company, whichever is greater, could be imposed for violations of certain of the GDPR's requirements. Such penalties are in addition to any civil litigation claims, e.g. by data subjects. The GDPR requirements apply to any processing of personal data wholly or partly by automated means by us or on our behalf, irrespective of the location of the processing or the nationality of the individuals whose personal data we process, and therefore include not only to third-party transactions, but also to transfers of information between us and our subsidiaries, including employee information. In addition, Europe and other foreign jurisdictions have enacted laws, regulations, standards and common practices that relate to the privacy of clinical trial data, including as a condition to approve clinical trials. These requirements are evolving and uncertain and they may result in delays to our ability to launch clinical trials or limit the jurisdictions in which we may conduct clinical trials.

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. The Court of Justice of the European Union, or "CJEU," recently raised questions about whether the European Commission's Standard Contractual Clauses, one of the primary mechanisms used by U.S. companies to import personal information from Europe, complies with the GDPR. While the CJEU upheld the validity of Standard Contractual Clauses, the CJEU ruled that the underlying data transfers must be assessed on a case-by-case basis by the data controller to determine whether the personal information will be adequately protected. Further, the European Commission recently proposed updates to the Standard Contractual Clauses. At present, there are few if any viable alternatives to the Standard Contractual Clauses and, therefore, 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.

Further, the United Kingdom's decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is still unclear whether the transfer of personal information from the EU to the United Kingdom will in the future remain lawful under the GDPR. The United Kingdom-EU post-Brexit trade deal provides that transfers of personal information to the United Kingdom will not be treated as restricted transfers to a non-EU country for a period of up to six months from January 1, 2021. However, unless the EU Commission adopts an "adequacy decision" with respect to the United Kingdom before the end of that transition period, from that date the United Kingdom will be a "third country" under the GDPR and transfers of personal information from the EU to the United Kingdom will require an "adequacy mechanism," such as the Standard Contractual Clauses. Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business. For example, Brazil enacted the General Data Protection Law, New Zealand enacted the New Zealand Privacy Act, China released its draft Personal Information Protection Law, and Canada introduced the Digital Charter Implementation Act.

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. Non-compliance could result in proceedings against us by governmental entities, customers, data subjects or others, and we may face significant fines and penalties. We may also experience difficulty retaining or obtaining new European or multi-national business partners due to the legal requirements, compliance cost, potential risk exposure, and uncertainty for these entities, and we may experience significantly increased liability with respect to these entities pursuant to the terms set forth in our engagements with them. In addition to government regulation, privacy advocates and industry groups may propose new and different self-regulatory standards that may apply to us. Because the interpretation and application of privacy and data protection laws are still uncertain, it is possible that these laws and other actual or alleged legal obligations, such as contractual or self-regulatory obligations, may be interpreted and applied in a manner that is inconsistent with our existing data management practices or the features of our platform. If so, in addition to the possibility of fines, lawsuits and other claims, we could be required to fundamentally change our business activities and practices, which could have an adverse effect on our business. 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.

## **Risks related to this offering and ownership of our common shares**

***No public market for our common shares currently exists, and a public market may not develop or be liquid enough for you to sell your shares quickly or at market price.***

Prior to this offering, there has not been a public market for our common shares. If an active trading market for our common shares does not develop following this offering, you may not be able to sell your shares quickly or at the market price. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares of our common shares and may impair our ability to acquire other companies or technologies by using our common shares as consideration. The initial public offering price of our common shares will be determined by negotiations between us and representatives of the underwriters and may not be indicative of the market prices of our common shares that will prevail in the trading market.

***The market price of our common shares may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common shares in this offering and may subject us to securities litigation suits.***

The market price of our common shares is likely to be 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 not be able to sell your common shares at or above the initial public offering price. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this prospectus, the market price for our common shares may be influenced by, among others, the following:

- the commencement, enrollment or results of our clinical trials of our product candidates or those of our competitors;
- the success of competitive products or therapies or announcements by potential competitors of their product development efforts;

## Table of Contents

- 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 organized and existing under the laws of the Netherlands, and, as such, under Dutch private international law rules the rights of our shareholders and the civil liability of our directors and executive officers are governed in certain respects by the laws of the Netherlands. The ability of our shareholders in certain countries other than the Netherlands to bring an action against us, directors and executive officers may be limited under applicable law. In addition, 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 prospectus, 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. Prior to the closing of this offering, our board of directors will be authorized for a period of five years from the completion of our corporate reorganization to issue shares or grant rights to subscribe for shares up to our authorized share capital from time to time and to limit or exclude pre-emption rights in connection therewith. This could cause existing shareholders to experience substantial dilution of their interest in us.

***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.***

Based upon shares of our shares outstanding as of December 31, 2020, and upon the completion of this offering and without giving effect to any purchases in this offering, our executive officers, directors and shareholders who owned more than 5% of our outstanding common shares before this offering will, in the aggregate, beneficially own shares representing approximately % of our outstanding common shares (or % if the underwriters exercise in full their option to purchase additional shares to cover over-allotments, if any). If our executive officers, directors and shareholders who owned more than 5% of our outstanding common shares acted together, they may be able to significantly influence all matters requiring shareholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. The concentration of voting power and transfer restrictions could delay or prevent an acquisition of our company on terms that other shareholders may desire or result in the management of our company in ways with which other shareholders disagree.

***If research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our share price and trading volume could decline.***

The trading market for our common shares will be influenced by the research and reports that industry or financial analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by industry or financial analysts. Equity research analysts may elect not to provide research coverage of our common shares after the completion of this offering, and such lack of research coverage may adversely affect the market price of our common shares. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our shares could decline if one or more equity research analysts downgrade our shares or issue other unfavorable commentary or research about us. If one or more equity research analysts cease coverage of us or fail to publish reports on us regularly, demand for our shares could decrease, which in turn could cause the trading price or trading volume of our common shares to decline.

***Raising additional capital may cause dilution to our shareholders, including investors in this offering, 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 your rights as a shareholder. 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.

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.

***Because we do not anticipate paying any cash dividends on our shares in the foreseeable future, capital appreciation, if any, will be your sole source of gain.***

You should not rely on an investment in our common shares to provide dividend income. We have never declared or paid cash dividends on our shares. We currently intend to retain all of our future earnings, if any, to finance the expansion and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, and taking into account the requirements as described in the section titled “Dividend Policy”, of our common shares will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common shares in this offering.

***Dividends distributed on our common shares to certain related parties in low-taxed jurisdictions might in the future become subject to an additional Dutch withholding tax on dividends.***

We have not paid a dividend on our common shares in the past and we do not intend to pay any dividends to holders of our common shares. See “Risk Factors—Because we do not anticipate paying any cash dividends on

our shares in the foreseeable future, capital appreciation, if any, will be your sole source of gain.” However, if we ever do pay dividends, then under current Dutch tax law, dividends paid on the common shares are subject to Dutch dividend withholding tax at a rate of 15% under the Dutch Dividend Withholding Tax Act (*Wet op de dividendbelasting 1965*), unless a domestic or treaty exemption applies. See the section titled “Material Dutch Tax Considerations.”

In a letter to the Dutch parliament dated May 29, 2020, the Dutch State Secretary for Finance announced that the government intends to introduce an additional withholding tax on dividends paid (i) to related entities in jurisdictions that have a corporate income tax rate below 9%, (ii) to related entities in jurisdictions that are included on the EU’s blacklist of non-cooperative jurisdictions or (iii) in certain abusive situations, effective January 1, 2024. On September 25, 2020, the Dutch government launched an internet consultation to provide interested parties the opportunity to respond to the draft legislative proposal to introduce the conditional withholding tax on dividends. Pursuant to the proposal published for consultation purposes, the conditional withholding tax on dividend payments will be implemented in the form of an amendment to the recently passed conditional withholding tax on interest and royalty payments pursuant to the Dutch Withholding Tax Act 2021 (*Wet bronbelasting 2021*), which act became effective January 1, 2021. The proposal published for consultation purposes stipulates that the rate will be equal to the highest Dutch corporate income tax rate (currently 25% (2021)) at the time of the dividend payment. At the same time, the current Dutch dividend withholding tax regime is anticipated to remain in place. However, if the dividend withholding tax and the conditional withholding tax on dividends cumulate, the proposal published for consultation purposes stipulates that the conditional withholding tax will be reduced by the dividend withholding tax levied. As a result, if the shareholder being a related entity (A) is established or has a permanent establishment in a jurisdiction that has a corporate tax rate below 9% or in a jurisdiction included on the EU’s blacklist of non-cooperative jurisdictions, (B) is a hybrid entity or a reverse hybrid entity or (C) is interposed to avoid tax otherwise due by another entity, the tax rate on dividends may rise from 15% to the highest corporate tax rate (currently 25% (2021)). For these purposes, an entity is considered a related entity if (i) such entity has a Qualifying Interest (as defined below) in us or (ii) a third party has a Qualifying Interest in both such entity and us. The term “Qualifying Interest” means a directly or indirectly held interest – either individually or jointly as part of a collaborating group (*samenwerkende groep*) – that enables the holder of such interest to exercise a decisive influence on the decisions that can determine the activities of the entity in which the interest is held. An interest of more than 50% is in any event considered a Qualifying Interest. The internet consultation closed on October 23, 2020. After the internet consultation, the Dutch government aims to prepare the final legislative proposal in early 2021.

***One or more taxing authorities could challenge our Dutch tax residency, and if such challenge were to be successful, we could be subject to increased and/or different taxes than we expect, including potentially to a proposed Dutch dividend withholding tax in respect of a deemed distribution of our entire market value less paid-up capital in the event we would relocate to another jurisdiction than the Netherlands.***

As a company incorporated under the laws of the Netherlands, we are deemed to be a resident for Dutch corporate income tax and Dutch dividend withholding tax purposes (regardless our place of effective management) and thus throughout our existence subject to Dutch corporate income tax as a resident taxpayer and our shareholders are generally subject to Dutch dividend withholding tax. Depending on the way we conduct ourselves, however, tax authorities of other jurisdictions may claim that we are also a tax resident in their jurisdiction, for example, if our place of effective management is in that jurisdiction. Based on our current management structure and the current tax laws of the Netherlands and the United States as well as applicable income tax treaties and current interpretations thereof, we should qualify solely as a tax resident of the Netherlands. The applicable tax laws or interpretations thereof may change. Furthermore, whether we have our place of effective management in the Netherlands and are as such solely tax resident in the Netherlands is

## [Table of Contents](#)

largely a question of fact and degree based on all the circumstances, rather than a question of law, which facts and degree may also change. Changes to applicable laws or interpretations thereof, changes to applicable facts and circumstances (for example, a change of directors or the place where board meetings take place), or changes to applicable income tax treaties may result in us becoming (also) a tax resident of another jurisdiction. As a consequence, our overall effective income tax rate and income tax expense could materially increase, which could have a material adverse effect on our business, results of operations, financial condition and prospects, which could cause our share price and trading volume to decline. In addition, as a consequence, dividends distributed by us, if any, may become subject to dividend withholding tax in more than one jurisdiction. The double taxation of income and the double withholding tax on dividends may be reduced or avoided entirely under the applicable double tax treaties. The United States currently do not claim tax residency from companies incorporated outside the United States, like us. However, in the event the United States tax laws would change and we would be considered a tax resident of both the United States and the Netherlands under the domestic laws by reason of our domicile, residence, place of effective management, place of incorporation or other criterion of a similar nature, the double tax treaty between the United States and the Netherlands provides that the competent authorities of the United States and the Netherlands shall endeavor to settle the tax residency by mutual agreement, having regard to the relevant factors mentioned above. In the absence of such agreement, we shall, subject to certain limited exceptions, not be entitled to claim any benefits under the double tax treaty between the United States and the Netherlands. In addition, we may become subject to limited income tax liability in other countries with regard to the income generated in the respective other country, for example, due to the existence of a permanent establishment or a permanent representative in such other country.

In addition, a proposal of law is currently pending before the Dutch parliament, the Emergency act conditional exit tax dividend tax (*Spedwet conditionele eindafrekening dividendbelasting*), or DWT Exit Tax, to counter the loss of Dutch dividend withholding tax claims, which may occur when companies/head offices are relocated from the Netherlands to certain other jurisdictions by way of a cross-border merger, demerger or migration or, in the case of a share-for-share exchange. The aim of the proposal is to discourage multinational companies with head offices in the Netherlands to relocate to a jurisdiction where there is no dividend withholding tax, or where the applicable dividend withholding tax does not apply to earnings attributable to the Dutch period. The proposed bill was announced on July 10, 2020 shortly after Unilever announced the planned relocation of its

head office in the Netherlands to the United Kingdom and Royal Dutch Shell confirmed it was considering to do the same. Under the proposed DWT Exit Tax, we will be deemed to have distributed an amount equal to our entire market value less paid-up capital immediately before the occurrence of certain events, including if we cease to be a Dutch tax resident and become a tax resident of a jurisdiction that does not impose a withholding tax on dividends which is comparable to the Dutch dividend withholding tax or that does impose such a tax, but does not impose such tax on market value created during the period during which we were a tax resident of the Netherlands. This deemed distribution will be subject to a 15% tax. An automatic interest free unconditional indefinite extension for payment of the tax will be granted. However, the extension will expire, inter alia, if and to the extent we would make distributions after the move of our tax residence. In that event, the proposed DWT Exit Tax rules prescribes that we have a right to recover the amount of deferred tax that has been become due from our shareholders through compensation with the shareholder's dividend receivable, irrespective whether that shareholder held the shares in us at the time we became a tax resident of the other jurisdiction. If we do not recover this amount from our shareholders, we will have to pay such part of the deferred tax ourselves. The Dutch parliament has started to debate the DWT Exit Tax in December 2020. It is not certain whether the DWT Exit Tax will be enacted, whether in its present form or with amendments. If enacted in the form in which it is presently pending before the Dutch parliament, however, the DWT Exit Tax will have retroactive effect to 18 September 2020.



## [Table of Contents](#)

***We have broad discretion in the use of our cash resources, including the net proceeds from this offering, and may use them ineffectively, in ways with which you do not agree or in ways that do not increase the value of your investment.***

Our management will have broad discretion in the application of our cash, including the net proceeds from this offering, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common shares. The failure by our management to apply these funds effectively could result in additional operating losses that could have a negative impact on our business, cause the price of our common shares to decline and delay the development of our product candidates. Pending their use, we may invest our cash, including the net proceeds from this offering, in a manner that does not produce income or that loses value. See the section titled “Use of Proceeds” herein for additional information.

***A significant portion of our total outstanding shares are restricted or will be restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common shares to drop significantly, even if our business is performing well.***

Sales of a substantial number of shares of our common shares in the public market could occur at any time, subject to certain restrictions described below. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common shares. After this offering, we will have outstanding common shares based on the number of shares outstanding as of December 31, 2020, and assuming no exercise by the underwriters’ over-allotment option. This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Substantially all of the remaining shares are currently restricted as a result of securities laws or lock-up agreements but will be able to be sold after the offering, as further described in the sections titled “Shares Eligible for Future Sale” and “Underwriting” herein. Moreover, upon the completion of this offering, holders of an aggregate of approximately our common shares will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders. We further intend to register all common shares that we may issue in the future or have issued to date under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements.

***We will 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 will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and rules subsequently implemented by the Securities and Exchange Commission, or the SEC, The Nasdaq Stock Market LLC, the Dutch Civil Code and the Dutch Corporate Governance Code, or DCGC impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will 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.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or 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 will be 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, 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.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common shares.***

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses that were not previously identified. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could harm our business and have a negative effect on the trading price of our shares.

We will be required to disclose changes made in our internal controls and procedures and our management will be required to assess the effectiveness of these controls annually. Our assessment of internal controls and procedures may not detect material weaknesses in our internal control over financial reporting. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation, which could have a negative effect on the trading price of our shares.

## [Table of Contents](#)

***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.***

After the closing of this offering, we will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Prior to the closing of this offering, we have been a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner. To date, we have never conducted a review of our internal control for the purpose of reporting pursuant to Section 404(a) of the Sarbanes-Oxley Act.

In the course of preparing our financial statements for the six months ended June 30, 2020 and the year ended December 31, 2019, we identified control deficiencies that we concluded represented material weaknesses in our internal control over financial reporting. The material weaknesses that we identified relate 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
- the lack of maintaining a sufficient complement of personnel commensurate with our accounting and reporting requirements, and able to: (i) design and maintain formal accounting policies, procedures and controls over the fair presentation of our financial statements; (ii) analyze, record and disclose complex accounting matters timely and accurately, including share-based compensation arrangements and other non-routine transactions; and (iii) design and maintain controls over the preparation and review of journal entries and financial statements, including maintaining appropriate segregation of duties.

Although several oversight and control activities are performed, not all activities are formalized and documented properly. In addition, where control activities are dependent on information used in a control, we do not perform or document controls to determine the completeness and accuracy of such information. We also did not have controls in place to monitor control activities and identify control deficiencies. Currently, we have only three designated finance employees. To address these material weaknesses, we will need to add personnel and continue to develop and implement new financial processes. We intend to take steps to remediate the material weaknesses described above through hiring additional qualified accounting and financial reporting personnel, and further evolving our accounting processes and policies. We will not be able to fully remediate these material weaknesses until these steps have been completed and have been operating effectively for a sufficient period of time.

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, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely

## [Table of Contents](#)

and accurate financial statements which could result in material misstatements in our financial statements and potentially require us to restate our financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our shares could decline, 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. If we are unable to successfully maintain internal control over financial reporting, or identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected. In addition, 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, investors may lose confidence in the accuracy and completeness of our financial reports, we may face restricted access to the capital markets, and our share price may be materially adversely affected. Moreover, we could become subject to investigations by regulatory authorities, which could require additional financial and management resources.

### ***Our internal control over financial reporting may not prevent or detect all errors or acts of fraud.***

Upon the completion of this offering, we will become subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

### ***We are a Dutch public company. The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions and may not protect investors in a similar fashion afforded by incorporation in a U.S. jurisdiction.***

Upon completion of this offering, we will be a public company (*naamloze vennootschap*) under Dutch law. Our corporate affairs are governed by our articles of association, the rules of our board of directors, our other internal rules and policies and by Dutch law. There can be no assurance that Dutch law will not change in the future or that it will serve to protect shareholders in a similar fashion afforded under corporate law principles in the United States, which could adversely affect the rights of our shareholders.

The rights of shareholders and the responsibilities of our directors may be different from the rights and obligations of shareholders and directors in companies governed by the laws of U.S. jurisdictions. In the performance of their duties, our directors are required by Dutch law to consider the interests of our company, its shareholders, its employees and other stakeholders, in all cases with due regard to the principles of reasonableness and fairness. It is possible that some of these stakeholders will have interests that are different from, or in addition to, your interests as a shareholder.

For more information on relevant provisions of Dutch corporation law and of our articles of association, see sections titled “Description of Share Capital and Articles of Association” and “Comparison of (i) Dutch Corporate Law and our Articles of Association and (ii) U.S. Corporate Law.”

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

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

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

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

- a provision that our directors are appointed on the basis of a binding nomination prepared by our board of directors which can only be overruled by a two-thirds majority of votes cast representing more than half of our issued share capital;

## Table of Contents

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

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

***We are subject to the Dutch Corporate Governance Code, but we are not obligated to and do not comply with all the best practice provisions of the Dutch Corporate Governance Code. This may affect your rights as a shareholder.***

Upon the closing of this offering, we will be subject to the Dutch Corporate Governance Code, or the DCGC. The DCGC contains principles and best practice provisions on corporate governance that regulate relations between the board of directors and the general meeting and matters in respect of financial reporting, auditors, disclosure, compliance and enforcement standards. The DCGC is based on a “comply or explain” principle. Accordingly, companies must disclose in their statutory annual reports whether they comply with the provisions of the DCGC. If a company subject to the DCGC does not comply with those provisions, that company would be required to give the reasons for such non-compliance. We do not comply with all best practice provisions of the DCGC. See section titled “Description of Share Capital and Articles of Association.” This may affect your rights as a shareholder and you may not have the same level of protection as a shareholder in a Dutch company that fully complies with the DCGC.

***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.***

As a foreign private issuer, 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 a foreign private issuer, 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.

---

[Table of Contents](#)

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. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. We may also be required to 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.

## Market and industry data

We have obtained the industry, market and competitive position data in this prospectus from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. Industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we are not aware of any misstatements regarding the market or industry data presented herein, our estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the heading “Risk Factors,” “Cautionary Statement Regarding Forward-Looking Information” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this prospectus.

## **Trademarks, service marks and tradenames**

We have proprietary rights to trademarks used in this prospectus, including LAVA Therapeutics, which are important to our business, many of which are registered under applicable intellectual property laws.

Solely for convenience, the trademarks, service marks, logos and trade names referred to in this prospectus are without the ® and ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks and trade names. This prospectus contains additional trademarks, service marks and trade names of others, which are the property of their respective owners. All trademarks, service marks and trade names appearing in this prospectus are, to our knowledge, the property of their respective owners. We do not intend our use or display of other companies' trademarks, service marks, copyrights or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.



## Use of proceeds

We estimate that we will receive net proceeds from this offering of approximately \$ \_\_\_\_\_ million, assuming an offering price of \$ \_\_\_\_\_ per common share, after deducting estimated underwriting discounts and estimated offering expenses payable by us, and assuming no exercise of the underwriters' option to purchase additional common shares. If the underwriters exercise their option in full, we estimate that we will receive net proceeds from this offering of approximately \$ \_\_\_\_\_ million after deducting estimated underwriting discounts and estimated offering expenses payable by us. These estimates are based on the U.S. dollar/EUR exchange rate of \_\_\_\_\_ as of \_\_\_\_\_, 2021.

Each \$1.00 increase or decrease in the assumed initial offering price of \$ \_\_\_\_\_ per common share would increase or decrease our net proceeds from this offering by \$ \_\_\_\_\_ million, assuming the number of common shares, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and estimated offering expenses payable by us. We may also increase or decrease the number of common shares we are offering. An increase or decrease of 1,000,000 common shares offered by us would increase or decrease the net proceeds to us by \$ \_\_\_\_\_ million, assuming that the assumed initial offering price remains the same and after deducting estimated underwriting discounts and estimated offering expenses payable by us. The actual net proceeds payable to us will adjust based on the actual number of common shares sold by us, the actual initial offering price and other terms of this offering determined at pricing.

The principal purposes of this offering are to increase our financial flexibility in order to advance our proprietary and partnered pipeline and build out our commercial capabilities. We currently expect to use the net proceeds from the offering, together with a portion of our cash, cash equivalents, short-term investments, and non-current financial assets (in aggregate) as follows:

- approximately \$ \_\_\_\_\_ million to advance our portfolio of gamma-delta bsTCE product candidates into multiple proof-of-concept clinical trials for the treatment of hematologic malignancies and solid tumors; and
- the remainder for working capital and other general corporate purposes.

We may also use a portion of the net proceeds to in-license, acquire or invest in complementary technologies, products, businesses or assets, either alone or in collaboration with a partner. However, we have no current plans, commitments or obligations to do so.

Our expected use of the net proceeds from the global offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above.

Our management will have broad discretion over the use of the net proceeds from the global offering. The amounts and timing of our expenditures will depend upon numerous factors, including the results of our research and development efforts, the timing, cost and success of preclinical studies and ongoing clinical trials or clinical trials we may commence in the future, the timing of regulatory submissions, our ability to obtain additional financing, the amount of cash obtained through our existing collaborations and future collaborations, if any, and any unforeseen cash needs.

Pending any use described above, we intend to invest the net proceeds of the global offering in short- and intermediate-term interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the European Union and U.S. government.

## Dividend policy

We have never paid or declared any cash dividends in the past, and we do not anticipate paying any cash dividends in the foreseeable future. We intend to retain all available funds and any future earnings to fund the further development and expansion of our business. As of the completion of our corporate reorganization, under Dutch law, we may only pay dividends and other distributions from our reserves to the extent our shareholders' equity (*eigen vermogen*) exceeds the sum of our paid-in and called-up share capital plus the reserves we must maintain under Dutch law or our articles of association and (if it concerns a distribution of profits) after adoption of our statutory annual accounts by our general meeting from which it appears that such dividend distribution is allowed. Subject to those restrictions, any future determination to pay dividends or other distributions from our reserves will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors we deem relevant.

Under our articles of association as they will read upon the closing of this offering, if any preferred shares are or have been outstanding, a dividend is first paid out of our profits, if available for distribution, to the holders or former holders, as applicable, of those preferred shares to the extent they are entitled to such distribution under our articles of association, which we refer to as our preferred dividend. Thereafter, our board of directors may decide that all or part of the remaining profits shown in our adopted statutory annual accounts will be added to our reserves. After reservation of any such profits, any remaining profits will be at the disposal of the general meeting at the proposal of our board of directors for distribution on our common shares, subject to applicable restrictions of Dutch law as set out in the previous paragraph. Our board of directors is permitted, subject to certain requirements and applicable restrictions of Dutch law, to declare interim dividends without the approval of our general meeting. Dividends and other distributions shall be made payable no later than a date determined by us. Claims to dividends and other distributions not made within five years from the date that such dividends or distributions became payable will lapse and any such amounts will be considered to have been forfeited to us (*verjaring*).

# Corporate reorganization

## Introduction

We are a Dutch private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) incorporated on February 15, 2016. Prior to the closing of this offering, we will complete a corporate reorganization in the course of which we will be converted into a public company under Dutch law (*naamloze vennootschap*) and our legal name will change to LAVA Therapeutics N.V. Therefore, investors in this offering will only acquire, and this prospectus only describes the offering of, common shares of LAVA Therapeutics N.V. We refer to the reorganization described above as our “corporate reorganization.”

The corporate reorganization will take place as described below. As of completion of the corporate reorganization, our shareholders will hold an aggregate of \_\_\_\_\_ common shares in LAVA Therapeutics N.V. (inclusive of \_\_\_\_\_ common shares underlying outstanding options under our equity incentive plans that are deemed to be outstanding).

## Conversion of all classes of preferred shares in the capital of LAVA Therapeutics B.V. into common shares

As part of the corporate reorganization, all issued cumulative preference A shares, or the Series A Preferred, cumulative preference B shares, or the Series B Preferred and cumulative preference C shares, or the Series C Preferred in the capital of LAVA Therapeutics B.V. are converted into common shares in the capital of LAVA Therapeutics B.V. on a one for one basis. In accordance with the articles of association of LAVA Therapeutics B.V., such conversion will be effectuated by means of a resolution of the general meeting of LAVA Therapeutics B.V. including the favorable vote of (i) at least seventy per cent (70%) of the votes cast on the Series A Preferred and the Series B Preferred and (ii) two-thirds (2/3) of the votes cast on the Series C Preferred.

Upon completion of this share conversion (and prior to the consummation of this offering), the current shareholders of LAVA Therapeutics B.V. will hold an aggregate of \_\_\_\_\_ common shares of LAVA Therapeutics B.V.

## Conversion of LAVA Therapeutics B.V. into LAVA Therapeutics N.V.

As part of the corporate reorganization, the legal form of LAVA Therapeutics B.V. will be converted from a Dutch private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) into a Dutch public company (*naamloze vennootschap*) and the articles of association of LAVA Therapeutics B.V. will be amended. This will take place by means of the execution of a notarial deed of conversion and amendment, which will take place prior to the listing of our common shares on Nasdaq. This deed will be executed following the delivery of a Dutch auditor's statement confirming that, on a day within five months prior to the conversion, our shareholders' equity (*eigen vermogen*) at least equaled the paid-in part of our issued share capital as set forth in the deed. The conversion will result in a name change from LAVA Therapeutics B.V. to LAVA Therapeutics N.V. Our articles of association as they will read upon the closing of this offering are further described in the section “Description of Share Capital and Articles of Association” and are filed as an English translation of the official Dutch version as an exhibit to the registration statement of which this prospectus forms a part.

## Capitalization

The following table sets forth our cash and cash equivalents and our capitalization as of June 30, 2020:

- on an actual basis;
- on a pro forma basis to give effect to (i) the issuance of \_\_\_\_\_ preferred shares in \_\_\_\_\_, 2021 and (ii) the conversion of all outstanding preferred shares into an aggregate of \_\_\_\_\_ common shares, which will occur upon the consummation of this offering; and
- on a pro forma as adjusted basis to additionally reflect the issuance and sale of \_\_\_\_\_ common shares in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover of this prospectus, after deducting the estimated underwriting discount and commissions and estimated offering expenses payable by us.

Our capitalization following the consummation of this offering will depend on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our financial statements and the related notes thereto included elsewhere in this prospectus and the sections of this prospectus titled “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	As of June 30, 2020		
	Actual	Pro forma	Pro forma as adjusted(1)
	(in thousands, except share and per share data)		
	(unaudited)		
Cash and cash equivalents	€ 8,341	€	€
Total debt, including current portion	€ 1,996	€	
<b>Shareholders' equity:</b>			
Common shares, 2,025 shares issued and outstanding, actual; shares issued and outstanding, pro forma; shares issued and outstanding, pro forma as adjusted			
Series A Preferred shares, 7,945 shares issued and outstanding, actual; shares issued and outstanding, pro forma; shares issued and outstanding, pro forma as adjusted			
Series B Preferred shares, 17,646 shares issued and outstanding, actual; shares issued and outstanding, pro forma; shares issued and outstanding, pro forma as adjusted			
Series C Preferred shares, _____ shares issued and outstanding, actual; shares issued and outstanding, pro forma; shares issued and outstanding, pro forma as adjusted			
Share Premium	17,066		
Reserves	574		
Accumulated Losses	(19,326)		
Total shareholders' equity	(1,686)		
Total capitalization	€ 310	€	€

## Table of Contents

- (1) The pro forma as adjusted information set forth above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, share premium, total shareholders' equity and total capitalization by \$ \_\_\_\_\_ million, assuming that the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. A 1,000,000 share increase or decrease in the number of common shares offered by us, as set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, share premium, total shareholders' equity and total capitalization by \$ \_\_\_\_\_ million, assuming the assumed initial public offering price of \$ \_\_\_\_\_ per common share, the midpoint of the price range set forth on the cover page of this prospectus remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of common shares that will be outstanding after this offering is based on a total of 2,025 common shares outstanding as of June 30, 2020, and excludes:

- \_\_\_\_\_ common shares issuable upon the exercise of options to purchase common shares under our existing Stock Option Plan that were outstanding as of June 30, 2020, with a weighted-average exercise price of \$ \_\_\_\_\_ per share; and
- \_\_\_\_\_ common shares reserved for future grant or issuance following the consummation of this offering under our long-term incentive plan which will replace our existing Stock Option Plan.

## Dilution

If you invest in our common shares, your interest will be diluted to the extent of the difference between the initial public offering price per share and the net tangible book value per share after this offering.

At June 30, 2020, we had a historical net tangible book value of \$ (1.9) million, corresponding to a net tangible book value of \$(933.83) per share. Net tangible book value per share represents the amount of our total assets less our total liabilities, excluding other intangible assets, divided by the total number of our common shares and preferred shares outstanding at June 30, 2020.

Our pro forma net tangible book value as of June 30, 2020 was \$                    million, corresponding to a pro forma net tangible book value of \$                    per share. Pro forma net tangible book value per share represents our pro forma net tangible book value divided by the total number of our common shares issued and outstanding at June 30, 2020, after giving effect to our corporate reorganization and the conversion of all of our preferred shares into common shares immediately prior to the consummation of this offering.

After giving effect to the sale by us of                    common shares in this offering at the assumed initial public offering price of \$                    per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value at June 30, 2020 would have been approximately \$                    million, representing \$                    per common share. This represents an immediate increase in pro forma net tangible book value of \$                    per common share to existing shareholders and an immediate dilution in net tangible book value of \$                    per common share to new investors purchasing common shares in this offering at the assumed initial public offering. Dilution per common share to new investors is determined by subtracting pro forma as adjusted net tangible book value per common share after this offering from the assumed initial public offering price per common share paid by new investors.

The following table illustrates this dilution to new investors purchasing common shares in the offering.

Assumed initial public offering price per common share	\$
Historical net tangible book value per common share at June 30, 2020	
Increase in net tangible book value per common share attributable to the pro forma adjustments described above	
Pro forma net tangible book value per common share at June 30, 2020 (after giving effect to our corporate reorganization and conversion of our preferred shares)	
Increase in net tangible book value per common share attributable to this offering	
Pro forma as adjusted net tangible book value per common share at June 30, 2020 (after giving effect to the corporate reorganization, conversion of our preferred shares and the offering)	
Dilution per common share to new investors	
Percentage of dilution in net tangible book value per common share for new investors	%

If the underwriters exercise their option to purchase additional common shares in full, our pro forma as adjusted net tangible book value per common share after this offering would be \$                    per common share, representing an immediate increase in pro forma as adjusted net tangible book value per common share of \$                    per common share to existing shareholders and immediate dilution of \$                    per common share in pro forma as adjusted net tangible book value per common share to new investors purchasing common shares in this offering, based on an assumed initial public offering price of \$                    per common share, which is the midpoint of the price range set forth on the cover page of this prospectus.

## Table of Contents

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, respectively, would increase (decrease) the pro forma as adjusted net tangible book value after this offering by \$ \_\_\_\_\_ per common share and the dilution per common share to new investors in the offering by \$ \_\_\_\_\_ per common share, assuming that the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same.

The following table sets forth, on a pro forma basis as of June 30, 2020, giving effect to the conversion of all our outstanding preferred shares into an aggregate of \_\_\_\_\_ common shares immediately prior to the consummation of this offering, the differences between the number of common shares purchased from us, the total consideration paid to us and the average price per share paid by existing shareholders and by new investors purchasing common shares in this offering. The calculation below is based on an assumed initial public offering price of \$ \_\_\_\_\_ per common share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares purchased		Total consideration		Average price per share
	Number	Percent	Amount	Percent	
Existing shareholders		%	\$	%	\$
New investors		%		%	
Total		100%		100%	

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, respectively, would increase (decrease) the total consideration paid by new investors by \$ \_\_\_\_\_ million and increase (decrease) the percentage of total consideration paid by new investors by approximately \_\_\_\_\_%, assuming that the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same.

If the underwriters exercise their option to purchase additional common shares in full, the following will occur:

- the percentage of our common shares held by existing shareholders will decrease to approximately \_\_\_\_\_% of the total number of our common shares outstanding after this offering; and
- the percentage of our common shares held by new investors will increase to approximately \_\_\_\_\_% of the total number of our common shares outstanding after this offering.

The number of our common shares shown as outstanding in the tables above excludes:

- common shares issuable upon the exercise of share options outstanding as of June 30, 2020 at a weighted average exercise price of \$ \_\_\_\_\_ per share; and
- common shares reserved for future issuance following the consummation of this offering under our long-term incentive plan as described in “Management—Equity Incentive Plans.”

To the extent these outstanding share options or any newly issued share options are exercised, or we issue additional common shares in the future, there will be further dilution to the new investors purchasing common shares in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our shareholders.

## Selected financial data

You should read the following summary financial data together with our financial statements and the related notes thereto included elsewhere in this prospectus and the “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of this prospectus. We have derived the statement of comprehensive loss data and the statement of financial position data as of and for the year ended December 31, 2019 from our audited financial statements and the statement of comprehensive loss data and the statement of financial position data as of and for the six months ended June 30, 2020 from our unaudited financial statements included elsewhere in this prospectus. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

We maintain our books and records in euros, and prepare our financial statements in accordance with International Financial Reporting Standards, or IFRS, as adopted by the International Accounting Standards Board, or IASB.

<b>(amounts in thousands of Euros except share and per share data)</b>	<b>For the six months ended June 30, 2020</b>	<b>For the year ended December 31, 2019</b>
	<b>(unaudited)</b>	
<b>Statement of Comprehensive Loss Data:</b>		
<b>Revenue</b>		
Research and license revenue	€ 592	€ —
<b>Total revenue</b>	<b>592</b>	<b>—</b>
<b>Operating expenses:</b>		
Research and development	(6,010)	(7,470)
General and administrative	(1,353)	(1,111)
<b>Total operating expenses</b>	<b>(7,363)</b>	<b>(8,581)</b>
<b>Operating loss</b>	<b>(6,771)</b>	<b>(8,581)</b>
Interest expense, net	(108)	(78)
Foreign currency exchange loss, net	(268)	(16)
<b>Total non-operating expense</b>	<b>(376)</b>	<b>(94)</b>
<b>Loss before income taxes</b>	<b>(7,147)</b>	<b>(8,675)</b>
Income tax benefit / (expense)	—	—
<b>Loss for the period</b>	<b>€ (7,147)</b>	<b>€ (8,675)</b>
<b>Total comprehensive loss for the period</b>	<b>€ (7,147)</b>	<b>€ (8,675)</b>
<b>Loss per share, basic and diluted</b>		
Weighted average common shares outstanding, basic and diluted	2,025	2,025

<b>(in thousands of Euros)</b>	<b>June 30, 2020</b>	<b>December 31, 2019</b>
	<b>(unaudited)</b>	
<b>Statement of Financial Position Data:</b>		
Cash and cash equivalents	€ 8,341	€ 6,544
<b>Total assets</b>	<b>9,788</b>	<b>7,844</b>
Total liabilities	11,474	2,633
Accumulated deficit	(19,326)	(12,179)
<b>Total equity (deficit)</b>	<b>(1,686)</b>	<b>5,211</b>



# Management's discussion and analysis of financial condition and results of operations

*You should read the following discussion and analysis of our financial condition and results of operations together with the section titled "Selected Financial Data" our financial statements and the related notes thereto appearing elsewhere in this prospectus. The following discussion is based on our financial information prepared in accordance with the International Financial Reporting Standards, or IFRS, as issued by the IASB, which may differ in material respects from generally accepted accounting principles in other jurisdictions, including U.S. GAAP. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis, as well as the section titled "Special Note Regarding Forward-Looking Statements."*

## Overview

We are a clinical-stage biotechnology company focused on transforming cancer treatment by developing a platform of novel bispecific antibodies designed to selectively induce gamma-delta T cell-mediated immunity against tumor cells. Our approach activates Vg9Vd2 T cells, a specific and relatively abundant gamma-delta effector T cell subset, upon cross-linking to a selected tumor target by our bispecific gamma-delta T cell engagers, or gamma-delta bsTCEs. These cells have the natural ability to distinguish tumor cells from healthy cells by sensing certain intracellular metabolites that are enriched in cancer cells. Activated Vg9Vd2 T cells are engaged for direct tumor cell killing and, in addition, orchestrate an immunological cascade response that includes activation of innate and adaptive immune cells in the tumor microenvironment. Our preclinical data demonstrate that Vg9Vd2 T cell activation by our gamma-delta bsTCEs kills patient-derived tumor cells with high potency and specificity thereby providing a significant opportunity to deliver effective and safe therapeutics to patients. We expect that activation of adaptive immunity by our approach has the potential to provide durable immune responses with the potential of enhancing patient survival. We believe we are the only company developing bispecific gamma-delta T cell engaging antibodies for the treatment of cancer.

We were incorporated in February 2016 in the Netherlands. In 2019, we established our wholly-owned U.S. subsidiary, which began business in January 2020. We are an early clinical-stage company and have not generated any revenue from the sale of products. Since inception, we have incurred operating losses, including €7.1 million for the six months ended June 30, 2020 and €8.7 million for the year ended December 31, 2019. As of June 30, 2020, we had an accumulated deficit of €19.3 million.

To date, we have financed our operations primarily through preferred stock financings, convertible loans and research and development support from government loans and research and license collaborations. Since inception, we have raised approximately €36.2 million in equity financings. We have focused substantially all of our resources on conducting research and development activities, undertaking preclinical studies, organizing and staffing our company, business planning and raising capital.

We will need additional funding to support our continuing operations and pursue our growth strategy. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we continue the development of our product candidates and continue our research activities. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company.

## [Table of Contents](#)

We believe that the anticipated net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements into . We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See “—Liquidity and Capital Resources” below.

### ***Series C preferred financing***

In September 2020, we closed a financing of cumulative preference C shares, or the Series C Preferred, that resulted in tranche-based commitments of €71.0 million gross and €62.2 million net, to fund the advancement of our pipeline and platform. In connection with the Series C Preferred financing, we agreed to sell the Series C Preferred in three tranches. On September 15, 2020, the first tranche of gross €19.1 million and 18,705 preferential shares, was funded and €4.1 million or 3,250 shares of cumulative preference A shares or the Series A Preferred were repurchased along with 750 common shares from one investor, resulting in net proceeds of €15.0 million. Funding of the remaining two tranches is subject to satisfaction of certain milestones. If funded, the two remaining tranches would yield net proceeds of €47.2 million in the aggregate, after repurchasing the 3,250 shares of Series A Preferred and 750 common shares from one investor.

### **Factors affecting our financial condition and results of operations**

Our financial condition and results of operations are affected by continued research and development expenses and the ongoing activities related to the preclinical studies related to our potential product candidates. We are also monitoring the potential impact of the COVID-19 pandemic on our business, operations, financial statements and outlook. 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 a research and license agreement with Janssen Biotech, Inc., which we refer to as the Janssen Agreement. As part of the Janssen Agreement, we received a non-refundable upfront payment of €7.4 million. As of June 30, 2020, there was €6.8 million of unearned income related to this payment. The unearned income is being recognized as revenue on a straight-line basis over the remaining 22 month term of the research activities under the agreement. As of June 30, 2020, the revenue was €0.6 million which represents two months beginning in May 2020. The Janssen Agreement includes research, development and sales milestones, which would initiate additional milestone payments. 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 “Business – License Agreements – Janssen Agreement” and Note 4 to the consolidated financial statements for the six months ended June 30, 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;
- 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, tax, legal and human relations, costs associated with outside professional fees 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 benefit**

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

No tax charge or income was recognized during the reporting periods since we are in a loss-making position and have a history of losses. As of December 31, 2019, we had Dutch tax loss carryforwards of €11.8 million. The 2019 taxable amount, which is expected to result in a tax loss, is not final as the 2019 Dutch corporate income tax return is still in draft. It is expected to be filed prior to the filing deadline of May 1, 2021.

On the basis of the 2019 annual accounts according to IFRS, there are accounting-to-tax differences of €0.3 million. These differences relate to the IFRS 16 lease amounts and expenses which were treated as non-deductible for Dutch corporate income tax purposes of €0.1 million and non-deductible share-based payments and other non-deductible mixed expenses of €0.2 million. For further information on tax loss carryforwards under Dutch corporate income tax law, please refer to Note 8 of the consolidated financial statements.

## Results of operations

The following table sets forth the significant components of our results of operations:

<b>(in thousands of Euros)</b>	<b>For the six months ended June 30, 2020</b>	<b>For the year ended December 31, 2019</b>
	<b>(Unaudited)</b>	
<b>Revenue</b>		
Research and license revenue	€ 592	€ —
<b>Total revenue</b>	<b>592</b>	<b>—</b>
<b>Operating expenses:</b>		
Research and development	(6,010)	(7,470)
General and administrative	(1,353)	(1,111)
<b>Total operating expenses</b>	<b>(7,363)</b>	<b>(8,581)</b>
<b>Operating loss</b>	<b>(6,771)</b>	<b>(78)</b>
Interest expense, net	(108)	(94)
Foreign currency exchange loss, net	(268)	(16)
<b>Total non-operating expense</b>	<b>(376)</b>	<b>(94)</b>
<b>Loss before income taxes</b>	<b>(7,147)</b>	<b>(8,675)</b>
Income tax benefit / (expense)	—	—
<b>Loss for the period</b>	<b>€ (7,147)</b>	<b>€ (8,675)</b>
<b>Total comprehensive loss for the period</b>	<b>€ (7,147)</b>	<b>€ (8,675)</b>

### **Research and license revenue**

Revenue for the six months ended June 30, 2020 was €0.6 million, which was due to the Janssen Agreement. As part of the Janssen Agreement, we received a non-refundable upfront payment of €7.4 million. The revenue has been recognized for two months beginning in May 2020. As of June 30, 2020, there was €6.8 million of unearned income related to this payment. The remaining balance will be recognized on a straight-line basis over the remaining 22 months of the specific milestone of the agreement. We may also receive research, development and commercial milestones and tiered royalty payments under the Janssen Agreement.

We recorded no revenue for the year ended December 31, 2019.

### **Operating expenses**

#### **Research and development expenses**

Our research and development expenses for the six months ended June 30, 2020 were €6.0 million, of which €4.1 million related to pre-clinical studies costs and clinical trial of our lead products, consisting primarily of contract manufacturing costs, €0.9 million of external research and development activities expenses, consisting of direct external expenses, scientific advisory consulting expenses and laboratory supplies, €0.8 million of personnel-related expenses including share-based compensation expense and €0.2 million of facilities and other research and development costs.

## [Table of Contents](#)

For the year ended December 31, 2019, our research and development expenses were €7.5 million, of which €4.6 million related to pre-clinical studies costs and expenses for preparation for our clinical trials. The pre-clinical study and clinical trial expenses mainly consisted of contract manufacturing costs, costs for pre-clinical studies related to our lead products, €1.4 million of research and development activities expenses, consisting primarily of external direct costs, scientific advisory consulting fees and laboratory supplies and €1.5 million of personnel-related expenses, including share-based compensation expense.

### **General and administrative expenses**

Our general and administrative expenses for the six months ended June 30, 2020 were €1.4 million, of which personnel-related expenses were €0.8 million, including share-based compensation expense, professional and consultant fees were €0.4 million, and facilities and miscellaneous expenses were €0.2 million.

General and administrative expenses for the year ended December 31, 2019 were €1.1 million of which personnel-related expenses were €0.4 million, including share-based compensation expense, professional and consultant fees of €0.6 million, and facilities and miscellaneous expenses of €0.1 million.

### **Interest expense, net**

Interest expense, net was primarily due to the accrued interest expense on borrowings under our Innovation Credit from Rijksoverheid, or the Innovation Credit, and interest expense related to our leases. Our interest expense for the six months ended June 30, 2020 (unaudited) and the year ended December 31, 2019 were €108 thousand and €78 thousand, respectively.

### **Foreign currency exchange loss, net**

Foreign currency exchange loss, net was primarily due to the foreign exchange cash activity between the Netherlands parent and our U.S. subsidiary as well as transactions with vendors whose functional currency is not the euro. Our foreign currency exchange loss for the six months ended June 30, 2020 and the year ended December 31, 2019 were €268 thousand and €16 thousand, respectively.

## **Liquidity and capital resources**

### **Overview**

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. As of June 30, 2020, we had cash and cash equivalents of approximately €8.3 million. Our cash and cash equivalents consist primarily of cash in bank accounts and deposits. Historically, we have financed our operations primarily through preferred stock financings, convertible loans and research and development support from government loans and research and license collaborations. Since inception, we have raised approximately €36.2 million of net proceeds in equity financings. Our primary requirements for liquidity and capital are general corporate purposes, capital expenditures and operating expenses related to research and development activities, including conducting preclinical studies and preparation for clinical trials.

In September 2020, we closed a financing of the Series C Preferred, which resulted in tranche-based commitments of €71.0 million gross and €62.2 million net, to fund the advancement of our pipeline and platform. In connection with the Series C Preferred financing, we agreed to sell the Series C Preferred in three tranches. On September 15, 2020, the first tranche of gross €19.1 million and 18,705 preferential shares, was

## [Table of Contents](#)

funded and €4.1 million or 3,250 shares of cumulative preference A shares, or the Series A Preferred, were repurchased along with 750 common shares from one investor, resulting in net proceeds of €15.0 million. Funding of the remaining two tranches is subject to satisfaction of certain milestones. If funded, the two remaining tranches would yield net proceeds of €47.2 million in the aggregate, after repurchasing the 3,250 shares of Series A Preferred and 750 common shares from one investor.

### **Funding Requirements**

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, regulatory approval and successful commercialization of our product candidates, or we enter into collaboration agreements with third parties for our product candidates, we may generate revenue from those product candidates. We do not know when, or if, we will generate any revenue from our product candidates, and we do not expect to generate significant revenue unless and until we obtain regulatory approval of, and commercialize, our product candidates. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue our research and development activities, initiate clinical trials and seek marketing approval for our product candidates. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. In addition, if we obtain approval for any of our product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution.

We believe that, based on our current operating plan, our existing cash and cash equivalents, together with the proceeds of this offering, will be sufficient to meet our anticipated cash needs to finance capital expenditures and operating expenses into . We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate assumes, among other things, that we do not obtain any additional funding through grants or through collaboration agreements. Although we believe that, following the completion of this offering, we will have sufficient cash and cash equivalents to cover our capital expenditures, operating expenses and working capital needs in the ordinary course of business, we may, from time to time, explore additional financing sources.

### **Cash Flows**

The following sets forth a summary of the primary sources and uses of cash:

<b>(in thousands of Euros)</b>	<b>For the six months ended June 30, 2020</b>	<b>For the year ended December 31, 2019</b>
	<b>(unaudited)</b>	
Net cash provided by (used in) operating activities	€ 1,347	€ (7,801)
Net cash used in investing activities	(144)	(750)
Net cash provided by financing activities	862	1,134
Net increase (decrease) in cash, cash equivalents, and restricted cash	€ 2,065	€ (7,417)

#### **Net cash provided by (used in) operating activities**

During the six months ended June 30, 2020, net cash provided by operating activities of €1.3 million, which consisted of a net loss of €7.1 million, adjusted for non-cash charges of €0.7 million and cash provided by changes in our assets and liabilities. The change in assets and liabilities of €7.8 million, was primarily due to €6.8 million in deferred revenue related to the Janssen agreement and the change in trade accounts payable of €0.8 million and other liabilities of €0.3 million.

## [Table of Contents](#)

During the year ended December 31, 2019, net cash used in operating activities was €7.8 million, which consisted of a net loss of €8.7 million, adjusted for the non-cash charges of €0.4 million and cash provided by changes in assets and liabilities of €0.5 million. The change in our operating assets and liabilities was primarily due to an increase of €0.6 million in other liabilities.

### **Net cash used in investing activities**

During the six months ended June 30, 2020, cash used in investing activities was €0.1 million, which resulted from capital expenditures in additional laboratory equipment purchases.

During the year ended December 31, 2019, cash used in investing activities was €0.8 million, which resulted from capital expenditures in additional laboratory equipment purchases.

### **Net cash provided by financing activities**

During the six months ended June 30, 2020, cash provided by financing activities was €0.9 million, which related to the quarterly payments received from the Innovation Credit based on the level of the underlying cost base of the project in each period.

During the year ended December 31, 2019, cash provided by financing activities was €1.1 million, which related to the initial funding from the Innovation Credit.

### **Contractual obligations and commitments**

The table below summarizes the maturity profile of our financial liabilities based on contractual undiscounted payments as of six months ended June 30, 2020:

<b>(in thousands of Euros)</b>	<b>On demand</b>	<b>Within 1 year</b>	<b>1 to 3 years</b>	<b>3 to 5 years</b>	<b>&gt; 5 years</b>	<b>Total</b>
Trade payables and other	—	1,317	—	—	—	1,317
Borrowings	—	—	1,996	—	—	1,996
Lease liabilities	—	135	212	—	—	347
Accrued expenses and other current liabilities	—	1,009	—	—	—	1,009
<b>Total</b>	<b>—</b>	<b>2,461</b>	<b>2,208</b>	<b>—</b>	<b>—</b>	<b>4,669</b>

In 2017, we entered into the VUmc Agreement (as amended in 2018 and 2020). Pursuant to the terms of the VUmc Agreement, in July 2017 VUmc conditionally assigned to us its rights and title to all of the patent rights licensed under the VUmc Agreement. Under the VUmc Agreement, we are obligated to pay royalties on net sales of products covered by claims included in the assigned patent rights. We are also obligated to pay VUmc a tiered percentage of our value upon the listing of the majority of our shares on a stock exchange or other change of control, or an Exit, as defined in the VUmc Agreement, less certain deductions. The Exit payment is capped at a specified amount in the high-teens of millions of Euros and is subject to an offset in the amount of the royalties that we have paid or that have accrued under the VUmc Agreement as of the date of the Exit. For additional information, see “Business – License Agreements – VUmc Agreement” and Note 20 to the consolidated financial statement. The prerequisites of the obligations have not been met and as a result are not reflected in our consolidated financial statements for the six months ended June 30, 2020 and the year ended December 31, 2019.

We had no contingent liabilities or material commitments for capital expenditures as of June 30, 2020.

## [Table of Contents](#)

In addition to the above obligations, we enter into a variety of agreements and financial commitments in the normal course of business, including contracts with CROs and other third parties for preclinical studies and clinical trials, research and development supplies and other testing and manufacturing services. We have obligations to repurchase 3,250 shares of Series A Preferred and 750 common shares of approximately €4.6 million at the closing of the second tranche of the Series C Preferred financing. These contracts generally do not contain minimum purchase commitments and provide for termination on notice, and therefore are cancellable contracts. These payments are not included in the table above as the amount and timing of such payments are not known as of June 30, 2020.

### **Borrowings**

#### *Government note*

In 2019, we applied for, and received a €5.0 million Innovation Credit. The Innovation Credit contributes to the development of one of our main projects, and certain assets of that project are pledged as a guarantee. Borrowings under the Innovation Credit, which bear interest at 10%, will be received in quarterly installments through 2023, based on the level of the underlying cost base in each period. The repayment of the Innovation Credit, including interest, is due on December 31, 2023.

The Innovation Credit contains customary limitations, including prohibiting our shareholders from withdrawing assets (including cash) by means of dividend, as well prohibiting us from making any payment of interest under or repayment of any loan so long as the Innovation Credit has not been repaid in full.

At June 30, 2020, we were in compliance with the terms of the Innovation Credit.

### **Capital expenditures**

Our capital expenditures mainly included payments for laboratory equipment, furniture, computer equipment and other hardware, and leasehold improvements.

### **Off-Balance sheet arrangements**

We have not entered into any off-balance sheet arrangements except for the obligation to repurchase Series A Preferred and common shares of €4.1 million upon the closing of the second tranche of our Series C Preferred financing, and our obligation to make certain payments under the VUmc Agreement upon the closing of this offering, as described in Note 20 of the consolidated financial statements.

### **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 19 of the consolidated financial statements for the six months ended June 30, 2020 and the year ended December 31, 2019 included elsewhere in this prospectus.

### **Critical accounting policies and significant judgments, estimates and assumptions**

We prepare our financial statements in accordance with IFRS as adopted 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



## [Table of Contents](#)

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 prospectus.

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.

### **Deferred tax assets**

We are subject to income taxes in the Netherlands. Significant judgment is required in determining the use of net operating loss carry-forwards 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.

No tax charge or income was recognized during the reporting periods since we are in a loss-making position and have a history of losses. We have tax loss carry-forwards of €11.8 million as of December 31, 2019. As a result of Dutch income tax law, tax loss carry-forwards are subject to a time limitation of six years. However, tax losses incurred up to and including the 2018 tax year, can be set off against any profit in the nine following years. As of 2022, any unexpired losses may be carried forward indefinitely and may be offset against taxable income up to €1.0 million and against 50% of taxable income in excess thereof. We do not assume that the public trading of our common shares as such will negatively affect the tax loss carry-forward position of the Company.

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 the relevant fiscal unity has 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 the fiscal unity. 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." The effective rate for Innovation Box profits is 9%. We believe the company qualifies for the Innovation Box and in this respect are currently in the process for obtaining advance certainty from the Dutch tax authorities.

### **Recent accounting pronouncements**

For further information on recent accounting pronouncements, please refer to Note 3 of the consolidated financial statements.

## Implications of being an emerging growth company

As a company with less than \$1.07 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies.

## Internal control over financial reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with IFRS. As a result of becoming a public company, we will be required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended, to furnish a report by our management on, among other things, the effectiveness of our internal control over financial reporting for the first fiscal year beginning after the effective date of the registration statement of which this prospectus is a part or the date we are no longer an “emerging growth company” as defined in the JOBS Act, if we take advantage (as we expect to do) of the exemptions contained in the JOBS Act. This assessment will need to include disclosures of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company’s annual or interim financial statements will not be detected or prevented on a timely basis.

In connection with the preparation of our financial statements as of and for the year ended December 31, 2019, and as of and for the six months ended June 30, 2020, we identified material weaknesses in the design of 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 failure to maintain a sufficient complement of personnel commensurate with our accounting and reporting requirements as we continue to grow as a company, and ability to: (i) design and maintain formal accounting policies, procedures and controls over the fair presentation of our financial statements; (ii) analyze, record and disclose complex accounting matters timely and accurately, including share-based compensation arrangements and other non-routine transactions; and (iii) design and maintain controls over the preparation and review of journal entries and financial statements, including maintaining appropriate segregation of duties.

Although several oversight and control activities are performed, not all activities are formalized and documented properly. In addition, where control activities are dependent on information used in a control, we do not perform or document controls to determine the completeness and accuracy of such information. We also did not have controls in place to monitor control activities and identify control deficiencies.

To address these material weaknesses, we will need to add personnel and continue to develop and implement new financial processes. We intend to take steps to remediate the material weaknesses described above through hiring additional qualified accounting and financial reporting personnel, and further evolving our

accounting processes and policies. We will not be able to fully remediate these material weaknesses until these steps have been completed and have been operating effectively for a sufficient period of time. We cannot assure you that we will be able to successfully remediate these material weaknesses or that other material weakness will not be discovered in the future.

## **JOBS ACT**

We are an emerging growth company, as defined in the JOBS Act. We intend to rely on certain of the exemptions and reduced requirements provided by the JOBS Act. As an emerging growth company, we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, and (ii) comply with certain requirements that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis).

We would cease to be an emerging growth company upon the earliest to occur of (i) the last day of the fiscal year in which we have more than \$1.07 billion in annual gross revenues; (ii) the date we qualify as a "large accelerated filer," with at least \$700.0 million of equity securities held by non-affiliates; (iii) the issuance, in any three-year period, by our Company of more than \$1.0 billion in nonconvertible debt securities held by non-affiliates; and (iv) the last day of the fiscal year ending after the fifth anniversary of the global offering. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold equity securities.

# Business

## Overview

We are a clinical-stage biotechnology company focused on transforming cancer treatment by developing a platform of novel bispecific antibodies designed to selectively induce gamma-delta T cell-mediated immunity against tumor cells. Our approach activates Vg9Vd2 T cells, a specific and relatively abundant gamma-delta effector T cell subset, upon cross-linking to a selected tumor target by our bispecific gamma-delta T cell engagers, or gamma-delta bsTCEs. These cells have the natural ability to distinguish tumor cells from healthy cells by sensing certain intracellular metabolites that are enriched in cancer cells. Activated Vg9Vd2 T cells are engaged for direct tumor cell killing and, in addition, orchestrate an immunological cascade response that includes activation of innate and adaptive immune cells in the tumor microenvironment. Our preclinical data demonstrate that Vg9Vd2 T cell activation by our gamma-delta bsTCEs kills patient-derived tumor cells with high potency and specificity thereby providing a significant opportunity to deliver effective and safe therapeutics to patients. We expect that activation of adaptive immunity by our approach has the potential to provide durable immune responses with the potential of enhancing patient survival. We believe we are the only company developing bispecific gamma-delta T cell engaging antibodies for the treatment of cancer.

Based on the established correlation of Vg9Vd2 T cell prevalence with favorable outcomes and survival in hematologic malignancies and solid tumors, we believe our gamma-delta bsTCEs have the potential to treat patients with a wide variety of cancers, both as monotherapy and as part of combination regimens. Our lead product candidate, LAVA-051, is advancing toward a Phase 1/2a clinical trial for the treatment of CD1d-expressing hematologic cancers including chronic lymphocytic leukemia, or CLL, multiple myeloma, or MM, and acute myeloid leukemia, or AML. We are also developing our gamma-delta bsTCEs in solid tumors, led by LAVA-206x207, which targets prostate-specific membrane antigen, or PSMA, for the treatment of prostate cancer. We plan for LAVA-051 to enter the clinic in , followed by LAVA-206x207 in

The anti-tumor potential of Vg9Vd2 T cells has previously been studied in multiple clinical trials, which were conducted through adoptive transfer or by *in vivo* activation of this cell type. These trials demonstrated that systemic activation of Vg9Vd2 T cells was generally well-tolerated by patients and resulted in objective clinical responses, but the overall results were not consistent or robust enough to support further development. Based on our preclinical data, we believe that an important root cause for underwhelming efficacy of these approaches was the systemic, non-tumor specific activation of Vg9Vd2 T cells and exhaustion of gamma-delta T cells. We believe a targeted approach utilizing a gamma-delta bsTCE could materially improve clinical responses with the bispecific antibody directing the Vg9Vd2 T cells to the tumor cells and specifically activating them *in situ* while maintaining a favorable safety profile.

Classical T cell engager, or 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, or CAR-T cells, have provided convincing clinical activity against selected cancers. Nonetheless, the promise of TCEs for broader use as cancer therapy has not yet been fully realized. Stark drawbacks of these classical TCEs include significant dose limiting toxicities resulting from the excessive release of cytokines, referred to as cytokine release syndrome, or CRS. CD3-based TCEs have additional limitations because of their broad activation of T cells, including both effector T cells and regulatory cells, or Tregs. Activation of Tregs dampens anti-cancer immunity, potentially resulting in decreased or no therapeutic efficacy, particularly in patients with high amounts of Tregs in the tumor microenvironment. 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 furthermore has also been associated with significant risk for CRS.

**Table of Contents**

We believe that our gamma-delta bsTCEs represent a new class of targeted immuno-oncology drugs that can overcome limitations of classical TCE approaches by exploiting the unique characteristics of Vg9Vd2 T cells. Our platform provides off-the-shelf therapeutics leveraging the validated benefits of antibody-based treatments, including standardized development. We designed our platform to be fully modular and compatible with existing approved and development-stage anti-tumor antibodies to facilitate expedited discovery and development of novel compounds.

Our gamma-delta bsTCEs specifically engage proinflammatory effector Vg9Vd2 T cells that retain their inherent tumor specificity thereby leveraging the natural ability of Vg9Vd2 T cells to distinguish tumor cells from healthy cells. The conditional activation of Vg9Vd2 T cells is designed for high precision in order to avoid a broad systemic (non-tumor specific) activation, systemic T cell exhaustion and CRS. We believe that the high tumor selectivity and potency of our gamma-delta bsTCEs, together with the low risk of CRS, may result in a broad therapeutic window and may therefore provide benefit to a wide range of patients. Activated Vg9Vd2 T cells have the ability to 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.

We have generated compelling preclinical data using patient tumor tissues that demonstrate the potency of our gamma-delta bsTCE platform in the preferred killing of tumor cells compared to healthy cells for both hematologic malignancies and solid tumors. Studies in non-human primates support the potential benign safety profile of gamma-delta bsTCE therapeutics through excellent tolerability with low activity against healthy cells and low induction of cytokines. Based on these findings, we believe that our gamma-delta bsTCE platform may be amenable for the development of targeted therapeutics in a wide variety of tumor indications.

Based on strong preclinical data, we believe our gamma-delta bsTCE platform has the potential to generate potent and safe therapeutics that could become new standards of care in treating cancer. We are currently advancing a pipeline of multiple gamma-delta bsTCEs for the development of potential therapeutics in both hematologic malignancies and solid tumors.



Our portfolio is led by LAVA-051, a unique, humanized gamma-delta bsTCE targeting CD1d-expressing hematologic cancers, including CLL, MM, and AML. LAVA-051 is designed to be an effective anti-tumor agent against CD1d-expressing tumor cells and works via a dual mechanism of action, or MoA. Via its principal MoA, LAVA-051 cross-links CD1d-expressing tumor cells and Vg9Vd2 T cells resulting in conditional Vg9Vd2 T cell activation, the secretion of cytolytic molecules and cytokines and subsequent tumor killing. In addition, the

## [Table of Contents](#)

CD1d-binding moiety of the bsTCE is uniquely able to enhance the interaction of CD1d and the T cell receptor of invariant NKT cells, or iNKT cells, which are a population of innate-like lymphocytes that play an important role in orchestrating immune responses in cancer. As published in 2020 in *Nature Cancer*, we demonstrated that this feature led to effective iNKT cell activation and anti-tumor activity. We believe the combined V $\beta$ 9V $\delta$ 2 T cell and iNKT cell activating properties and the resulting cascade response contribute to the potential of LAVA-051 to provide rapid cytotoxicity, as well as long-term antitumor immune responses. We are also evaluating opportunities to develop LAVA-051 or derivatives thereof for the treatment of CD1d-expressing solid tumors.

In November 2020, we filed a Clinical Trial Application, or CTA, with the Competent Regulatory Authority of The Netherlands, or CCMO, to conduct a Phase 1/2a clinical trial with LAVA-051 in patients with relapsed and/or refractory CLL, MM and AML, which we expect to begin enrolling in . In addition, we expect to file an Investigational New Drug, or IND, application with the U.S. Food and Drug Administration, or FDA, in , after which patients from the U.S. will also be included in the ongoing Phase 1 part of the clinical trial.

We are also advancing a second program, LAVA-206x207, a gamma-delta bsTCE targeting PSMA for the potential treatment of prostate cancer. We expect to submit CTA or IND applications for LAVA-206x207 in and initiate a Phase 1/2a trial in metastatic castration-resistant prostate cancer in . In addition to our two named lead programs, we are advancing a portfolio of discovery programs, which we expect will provide the opportunity for additional CTA/IND submissions in .

Our platform capabilities are further validated by a research collaboration and license agreement with Janssen Biotech, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, which we entered into in May 2020. Under the terms of this agreement, we are responsible for discovering and developing novel gamma-delta bsTCEs specific for an undisclosed target for the treatment of cancer. We received an upfront payment from Janssen of \$8.0 million, have achieved the milestone necessary to receive a \$1.0 million research milestone payment, and are eligible to receive potential additional research, development, regulatory and commercial milestones, as well as tiered royalties on sales, for any licensed products.

Since our founding, we have received tranche-based commitments of approximately \$108.0 million in capital from premier investors, including Versant Ventures, Novo Holdings A/S, Sanofi Ventures, Redmile Group, LLC, Gilde Healthcare, MRL Ventures Fund, Ysios Capital and BB Pureos Bioventures, of which \$44.4 million has been funded to date.

## **Our team**

We were founded in 2016 as a spinout from the VU University in Amsterdam, the Netherlands by leaders in the field therapeutic antibodies and of immuno-oncology, with significant insights and development capabilities in the field of gamma-delta T cells and, specifically, gamma-delta bsTCEs.

We have attracted a talented group of industry experts and scientists that now comprise a highly experienced team of over 30 employees. Our executive team has extensive expertise in building successful biotech companies and R&D organizations, including Stephen Hurly, our Chief Executive Officer, who has more than 25 years of leadership experience across life science companies and investment banking; Paul Parren, Ph.D., our Executive Vice President and Head of Research and Development and professor of Molecular Immunology at the Leiden University Medical Center, who has more than 30 years of experience in antibody science and drug development. Dr. Parren has contributed to over 200 scientific publications and 100 issued U.S. and EU patents, which led to the development of four approved antibody products and two clinically translated antibody technologies; Benjamin Winograd, M.D., Ph.D., our Chief Medical Officer, who has more than 35 years of experience within the pharmaceutical industry, including R&D leadership roles that resulted in the approval of seven cancer treatments; Hans van der Vliet, M.D., Ph.D., co-founder and our Chief Scientific Officer and

## [Table of Contents](#)

professor of Medical Oncology at the Amsterdam UMC—Cancer Center Amsterdam, and lead inventor of our proprietary gamma-delta bsTCE platform; and Ton Adang, Ph.D., our Chief Development Officer, who has vast experience in drug discovery, development and project management of FDA reviews for multiple approved products. Across the leadership team, the team has been involved in the filing of more than 43 INDs and has contributed to the development of 23 approved cancer products.

In addition to our leadership team, we benefit from a distinguished Advisory Board that is actively involved in the development of our pipeline and comprised of world-renowned immuno-oncology science and medical leaders, including Nobel Laureate Prof. James P. Allison, Ph.D., University of Texas MD Anderson Cancer Center; Prof. Madhav V. Dhodapkar, MBBS, Emory University School of Medicine; Prof. Dieter Kabelitz, Ph.D., University of Kiel Institute of Immunology; Prof. Padmanee Sharma, M.D., Ph.D., University of Texas MD Anderson Cancer Center; Prof. K. Dane Wittrup, Ph.D, Koch Institute for Integrative Cancer Research at MIT; and Chair Dr. Andrea van Elsas, Ph.D., Third Rock Ventures.

## Our strategy

Our goal is to deliver gamma-delta bsTCE therapeutics that change the standard of care and improve outcomes for patients with hematologic malignancies and solid tumors. We are focused on discovering, developing and ultimately commercializing proprietary, off-the-shelf, targeted gamma-delta bsTCEs that leverage the power of gamma-delta T cells with high potency and precision to orchestrate anti-tumor immune responses. Key components of our strategy are to:

- **Establish ourselves as the leader in the gamma-delta T cell space.** We believe we are the first to develop gamma-delta bsTCE therapeutics and advance them into the clinical stage. Our extensive insights into gamma-delta T cell biology and therapeutic antibody development, cultivated through more than 20 average years of relevant research by our founders and leadership team, with 80 related patents and more than 200 peer-reviewed scientific papers, are driving the discovery and development of our innovative and differentiated therapeutic gamma-delta bsTCEs. Our targeting of Vg9Vd2 T cells affords us a level of precision that differentiates our approach from other gamma-delta approaches.
- **Advance our lead product candidate, LAVA-051, in hematologic tumors through clinical development and explore additional indications in solid tumors.** We are developing our lead dual-mechanism, CD1d gamma-delta bsTCE, LAVA-051, for the treatment of hematologic malignancies, initially focused on CLL, MM and AML. In November 2020, we filed a CTA with the CCMO and plan to initiate a Phase 1/2a dose-escalation clinical trial in . We aim to also explore the therapeutic potential of LAVA-051 in solid tumors in follow-on cohorts.
- **Advance our product candidate, LAVA-206x207, in prostate cancer through clinical development and explore additional indications in solid tumors.** Our PSMA-targeting gamma-delta bsTCE, LAVA-206x207, is designed to target and conditionally activate Vg9Vd2 T cells in PSMA-positive tumors and induce a cascade response resulting in immune activation. Prostate cancer is an “immunologically cold” tumor that does not typically respond to immune checkpoint therapy. We believe LAVA-206x207 has the potential to be effective in this tumor type based on data showing Vg9Vd2 T cell infiltration in prostate cancer. Proof-of-concept with LAVA-206x207 may position our gamma-delta bsTCEs as potential immuno-oncology treatments for patients where current immune checkpoint therapy-based approaches have not been effective. We plan to submit a CTA and an IND application in , followed by a Phase 1/2a dose-escalation clinical trial with LAVA-206x207 for the treatment of metastatic castration-resistant prostate cancer, or mCRPC, that we expect to initiate in .
- **Leverage our platform to continue to advance and expand our earlier stage pipeline while broadening the potential applications of the platform to additional targets and patient populations.** We intend to preserve

and extend our pioneering position in gamma-delta T cells by continuing to invest in our platform research to further broaden its potential and maximize the clinical utility of our gamma-delta bsTCEs. Our platform is designed to enable facile incorporation of any existing tumor-targeting antibodies. We are exploring additional tumor targets and patient populations for our gamma-delta bsTCE platform, in both hematologic malignancies and solid tumors, and proof-of-principle has been obtained for a number of bispecifics, including EGFR and CD40. We believe the modularity of our platform will allow us to rapidly discover and develop novel gamma-delta bsTCE candidates.

- **Enhance our pipeline and platform through strategic partnership and collaboration opportunities.** In 2020, we entered into a research collaboration and license agreement with Janssen, which we will continue to execute. Given the breadth of opportunities that our gamma-delta bsTCEs present in treating cancer, we will continue to explore additional strategic partnerships that enable us to expand and accelerate development of our gamma-delta bsTCEs, including through combinations with other oncology treatments.

## 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 things, specific effector T cell engagement and activation at the tumor site, often made ineffective in cancer patients due to 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 able to generate anti-tumor activity *de novo*, independent of a pre-existing response.

In the bispecific antibody concept, the cytotoxic potential of effector T cells is redirected against the tumor. Through this approach, T cells are physically linked with tumor cells via bispecific antibodies that are composed of a T cell-binding domain and a tumor-binding domain. These TCEs primarily activate T cells through binding of CD3 $\epsilon$  in the T cell receptor complex and can thereby trigger broad activation of CD3 expressing T cells. These cells would otherwise individually require the specific recognition of a unique antigen in the context of polymorphic major histocompatibility complex, or 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  $\times$  B lymphocyte antigen CD19), sparked renewed interest and



investment in this approach. This is reflected in about 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 then results in activation of the CAR-T cells and tumor cell killing. To date, multiple CAR-T therapies have generated promising clinical data, and two CAR-T cell therapies targeting CD19 have been approved, including KYMRIAH® and YESCARTA®, with many more 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 expensive technologies and procedures, in which a patient's own T cells are initially extracted and then re-administered after being modified. 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 in clinical settings, but have also been limited in their use due to several key challenges, including:

- **Limited therapeutic window** with severe side effects and dose-limiting toxicities, most prominently related to cytokine release syndrome and on-target, off-tumor related toxicities observed in both early-stage TCEs and CAR-T approaches.
- **High variability in effectiveness:** CD3 TCEs dampen the antitumor efficacy of cytotoxic T cells by co-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.
- **Burdensome dosing:** The only currently approved CD3 TCE requires burdensome, continuous dosing via an intravenous infusion pump as a result of short T cell engager pharmacokinetic half-life.
- **Manufacturing and logistics complexity:** CAR-T manufacturing complexities to date means that products cannot always be successfully produced for patients, and lengthy processes result in lag times for treatment administration, resulting in a long vein-to-vein time and a limited addressable patient population.

### 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 cells responses as a therapeutic strategy to improve cancer patients' outcomes. The large number of oncology trials with bispecific TCEs in particular is further testimony to how this approach is, among the two described above, the most promising one both from a clinical and commercial perspective, also due to its advantages around manufacturing and its off-the-shelf characteristics. To reach its full potential additional research is needed to address the current products' challenges, which limit wider patient use and optimize these products profiles. We have identified the engagement of gamma-delta T cells as the next-generation application of TCEs and believe our platform will address limitations of current TCEs to improve patient outcomes in both hematologic malignancies and solid tumors.

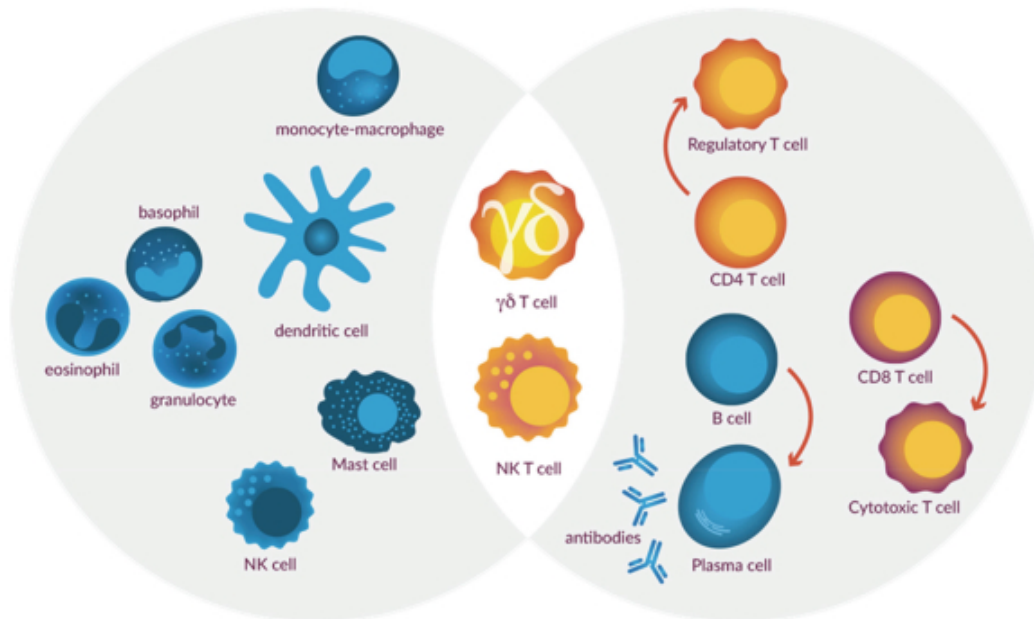
## Background on Vg9Vd2 T cells

T lymphocytes are divided into two main categories based on T cell receptor type:  $\alpha\beta$ , or alpha-beta, and  $\gamma\delta$ , or gamma-delta, T cells. Human gamma-delta T cells are further classified based on the combination of their V<sub>g</sub> and V<sub>d</sub> receptor chains, with Vg9Vd2 T cells being relatively abundant in circulation, typically representing about 1-5% of all T cells in circulation. In addition, these gamma-delta T cells have been observed to infiltrate tumors.

Although the majority of human T cells express an alpha-beta T cell receptor, or TCR, a smaller proportion of T cells expresses 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+ T cells, and MHC class I in the case of CD8+ T cells. In contrast, gamma-delta T cells typically recognize their ligands independent of antigen processing and MHC restriction. The gamma-delta T cell population can be roughly divided into two large sub-populations: Vd1 and Vd2 TCR expressing gamma-delta T cells. The Vd2 population is the largest population in peripheral blood, representing approximately 90-95% of circulating gamma-delta T cells. These gamma-delta T cells associate almost invariably with the Vg9-chain, resulting in a very homogeneous effector cell population. This population has a monomorphic TCR with a well-defined specificity for phosphoantigens presented in the context of butyrophilin molecules, or BTN3A1/2A1, and also has a well-defined proinflammatory functional profile and a unique capacity to also act as antigen-presenting cells upon their activation. Conversely, Vd1 T cells constitute a heterogeneous population of cells in part because the Vd1 chain can pair with several V<sub>g</sub> chains, such as Vg4,5,9, and also with  $\alpha\beta$ -TCR, and has more variability in TCR CDRs. Similarly, Vd1 T cell subsets recognize various antigen presenting molecules and can recognize various antigens. Vd1 T cells also present with substantial functional diversity as have been shown to be able to exert cytotoxic effects, but also roles in tissue homeostasis and repair. 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 Vd1 T cells, and in various tumor types infiltration of Vd1 has been demonstrated to be related to poorer patient outcome, while Vd2 tumor infiltration has been shown to correlate to positive prognosis

When these Vg9Vd2 T cells are activated, they secrete pro-inflammatory cytokines that trigger downstream immune cells from the innate and adaptive immune system, including alpha-beta T cells, NK cells and dendritic cells, as represented in the graphic below. Activated Vg9Vd2 T cells have a distinct ability to process and present the antigen 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.

### Simplified overview of cells involved in innate and adaptive immunity



Adapted from Dranoff G., Nature Rev. Cancer 2004; 4: 11-22

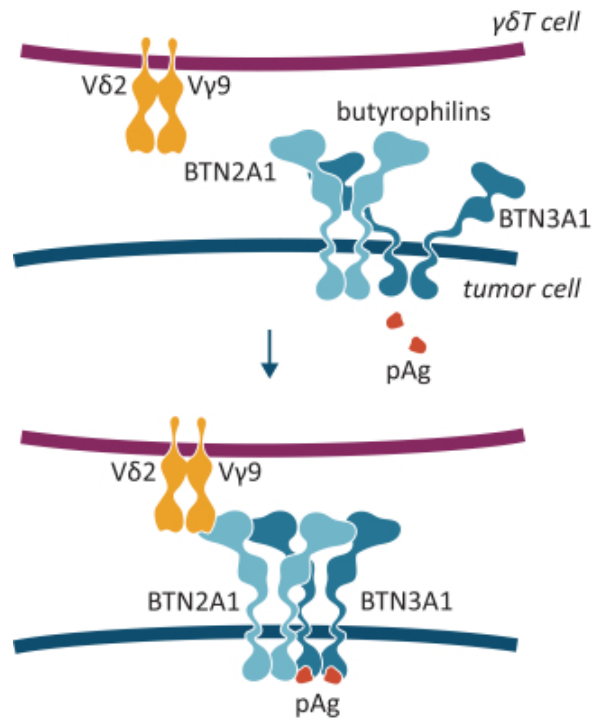
#### Targeting V $\gamma$ 9V $\delta$ 2 T cells for cancer treatments

As mentioned above, V $\gamma$ 9V $\delta$ 2 T cells have been observed to infiltrate 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. As such, V $\gamma$ 9V $\delta$ 2 T cells represent a potent and relatively homogeneous class of proinflammatory immune effector cells with an immune surveillance function.

Because V $\gamma$ 9V $\delta$ 2 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.

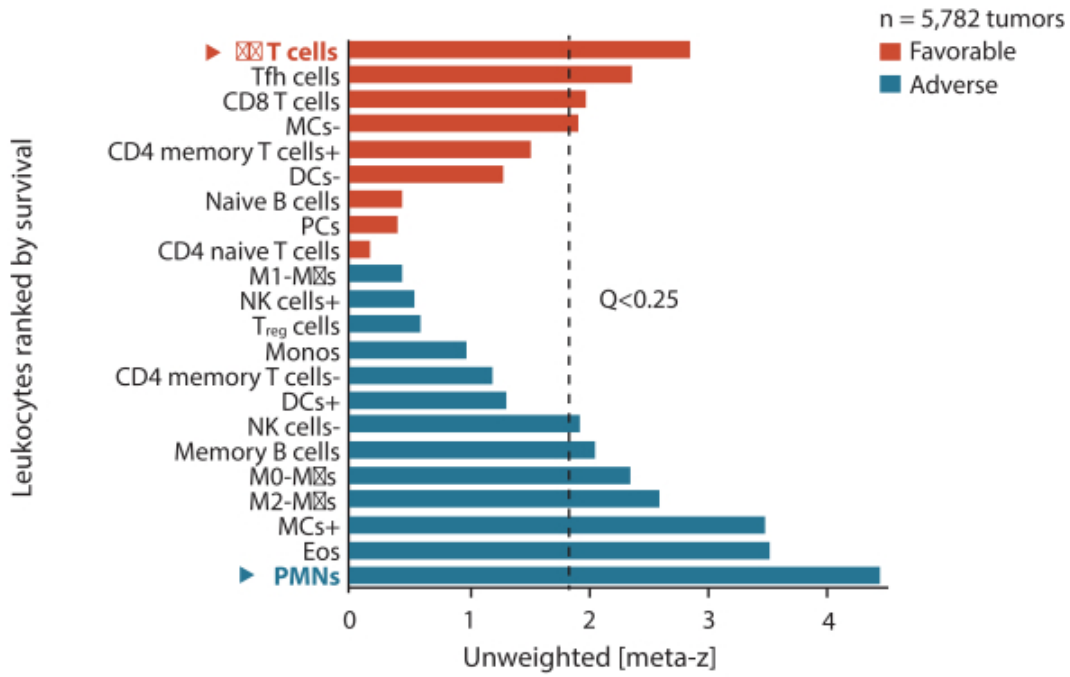
As depicted in the graphic below, V $\gamma$ 9V $\delta$ 2 T cells detect and kill tumor cells by indirectly detecting specific metabolites, called phosphoantigens, which often accumulate intracellularly at relatively high levels in tumor cells. These phosphoantigens bind to an intracellular domain of the cell-surface receptor, butyrophilin, triggering a conformational change and the recognition of butyrophilin receptors on tumor cells by V $\gamma$ 9V $\delta$ 2 T cells. Upon this interaction with tumor cells, V $\gamma$ 9V $\delta$ 2 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.

**Model of natural Vg9Vd 2 T cells activation upon Vg9Vd 2 -TCR sensing of phosphoantigen/butyrophilin complexes**



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, as reported in a landmark publication in *Nature Medicine* in 2015 and depicted in the figure below.

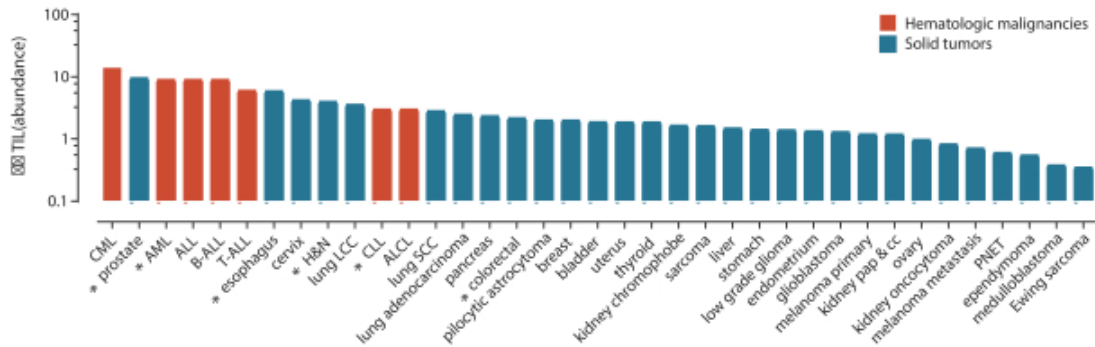
**Global Prognostic Associations for 22 Leukocyte Types Across 25 Cancers**



Adapted from Gentles A. et al, Nature Medicine 2015; 21: 938-945]

Further, as reported in *Oncoimmunology* in 2017 and depicted in malignancies Vg9Vd2 T cells was confirmed in a large set of different tumors, including cancers that are low for alpha-beta T cell infiltration.

**Abundance of tumor-infiltrating Vg9Vd2 T cells**



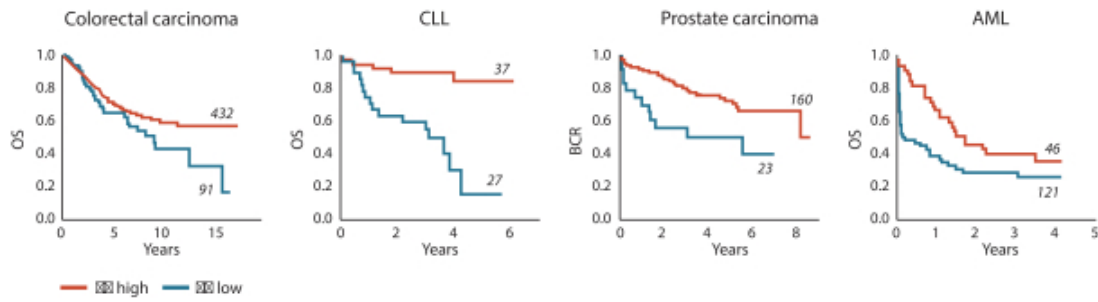
\*: In vitro/ex vivo data generated using LAVA's γδ-bstCEs

Adapted from Tosolini M et al. Oncoimmunology 2017, vol 6, e1284723

[Table of Contents](#)

As reflected in the figure below, higher tumor-infiltrating Vg9Vd2 T cell abundance correlated with increased survival and favorable outcomes in several hematologic and solid tumors.

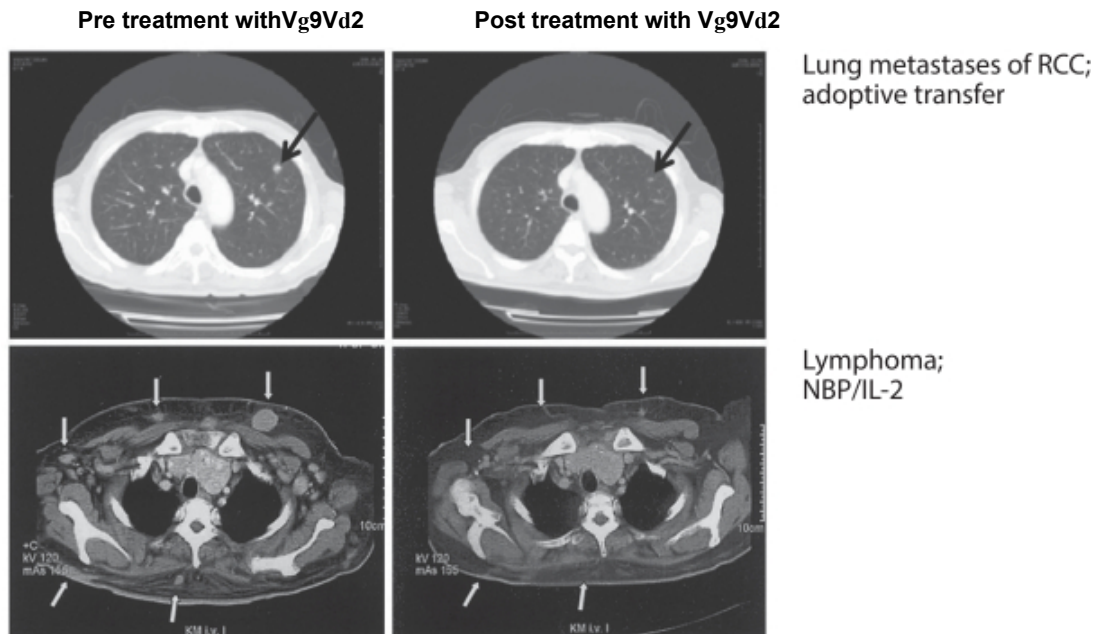
**Improved clinical outcome in patients with higher number of Vg9Vd2 T cells**



Tasolini M, et al. *Oncol Immunology*, 2017, vol 6, e1284723

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. A 2014 report summarizing the results of thirteen clinical trials of patients with advanced or metastatic cancer treated with Vg9Vd2 T cell-based immunotherapy showed that the adoptive transfer and/or *in vivo* activation of gamma-delta T cells demonstrated clinical benefit with low toxicity grade. An example of this clinical benefit was reported by Buccheri, S et al. *J Biol Regul Homeost Agents* 2014; 28: 81-90, as shown by the reduction of cancerous masses in the patient scans below.

**Examples of anti-tumor activity of Vy9Vd2-T cells in patients with hematologic malignancies and solid tumors**



Kobayashi H, et al. *Cancer Immunol Immunother* 2011;60:1075-1084

Wilhelm M, et al. *Blood* 2003;102:200-206

However, the results from these prior trials were not consistent or robust enough to support further development. A lack of a 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 Vg9Vd2 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 gamma-delta bsTCE approach

Gamma-delta bsTCEs represent an emerging new class of targeted immuno-oncology treatments. By engaging only Vg9Vd2 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 gamma-delta bsTCEs specifically engage the proinflammatory immune effector Vg9Vd2 T cell population, unlike pan T cell engagers that also result in co-activation of immunosuppressive T cell populations that would otherwise impair the inherent tumor specificity of gamma-delta T cells. Our technology is designed to retain and leverage the natural ability of Vg9Vd2 T cells to distinguish tumor cells from healthy cells.
- **Conditional activation with high precision.** Our gamma-delta bsTCEs only trigger activation of Vg9Vd2 T cells upon simultaneous binding of the gamma-delta T cell receptor and the cognate antigen on tumor cells. This conditional activation provides a tumor-targeting mechanism and avoids a broad systemic, or non-tumor specific, activation of Vg9Vd2 T cells. Tumor-targeted activation, by design, avoids systemic exhaustion, which is commonly observed after repeated generalized gamma-delta T cell triggering in phosphoantigen-based approaches applied by others.
- **Driving a cascade response that includes both innate and adaptive immune responses.** Activated Vg9Vd2 T cells have the ability to 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 gamma-delta bsTCEs, with an average EC50 in the low picomolar range. This suggests that clinical antitumor activity may be triggered using relatively low doses of our gamma-delta bsTCEs.
- **Low Risk of Cytokine Release Syndrome.** Our highly targeted gamma-delta bsTCEs did not result in any instance of CRS in non-human primate studies. This is consistent with earlier clinical studies of gamma-delta T cell-based therapeutic approaches, including those that triggered systemic activation of the entire gamma-delta T cell population, were not accompanied by CRS. 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 gamma-delta bsTCEs can trigger activation of both peripheral blood and tumor-infiltrating Vg9Vd2 T cells, allowing access to and activity against both hematologic malignancies and solid tumors, potentially including those that have not been successfully addressed using checkpoint inhibitors.
- **Broad therapeutic window.** Vg9Vd2 T cells have an inherent ability to distinguish cancerous from normal cells, which by design is retained in our gamma-delta bsTCE 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 gamma-delta bsTCEs, in combination with the low risk of CRS, may provide a broad therapeutic window.

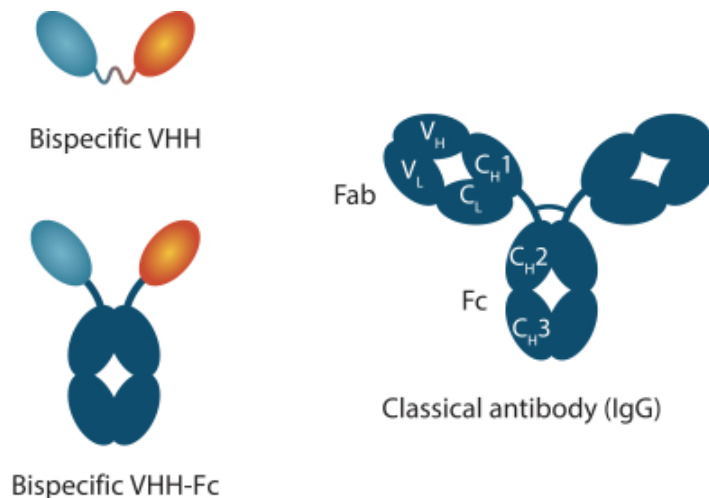
## [Table of Contents](#)

- **Fully modular, allowing for the use of approved or in-development tumor-targeting antibodies.** Our platform is fully modular, enabling existing antibodies or antibody fragments to be incorporated into our gamma-delta bsTCE platform. This allows us to expedite the discovery and development of clinical candidates since no 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 gamma-delta bsTCEs 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.
- **Possible combination with checkpoint inhibitors and other oncology approaches.** Because of their distinct MoA and targeted nature, our gamma-delta bsTCEs 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 gamma-delta bsTCEs 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. As depicted in the graphic below, the variable region of VHH antibodies only contains a heavy chain domain, whereas the variable region of classic or conventional antibodies consists of a heavy and a light chain domain. VHH antibodies have been shown to be able to access unique epitopes that may not be accessible for conventional antibodies.

#### Structure of LAVA's gamma-delta bsTCEs versus that of a classical monoclonal antibody



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 antibodies and their therapeutic potential have been validated by, for example, the approval of caplacizumab for patients with acquired thrombotic thrombocytopenic purpura.



## [Table of Contents](#)

We are developing a novel proprietary platform in two relatively small formats: a bispecific format in which a V<sub>g</sub>9Vd2 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-, or Fc, domain, or 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, or CHO, manufacturing platform and knobs-into-holes, or 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.

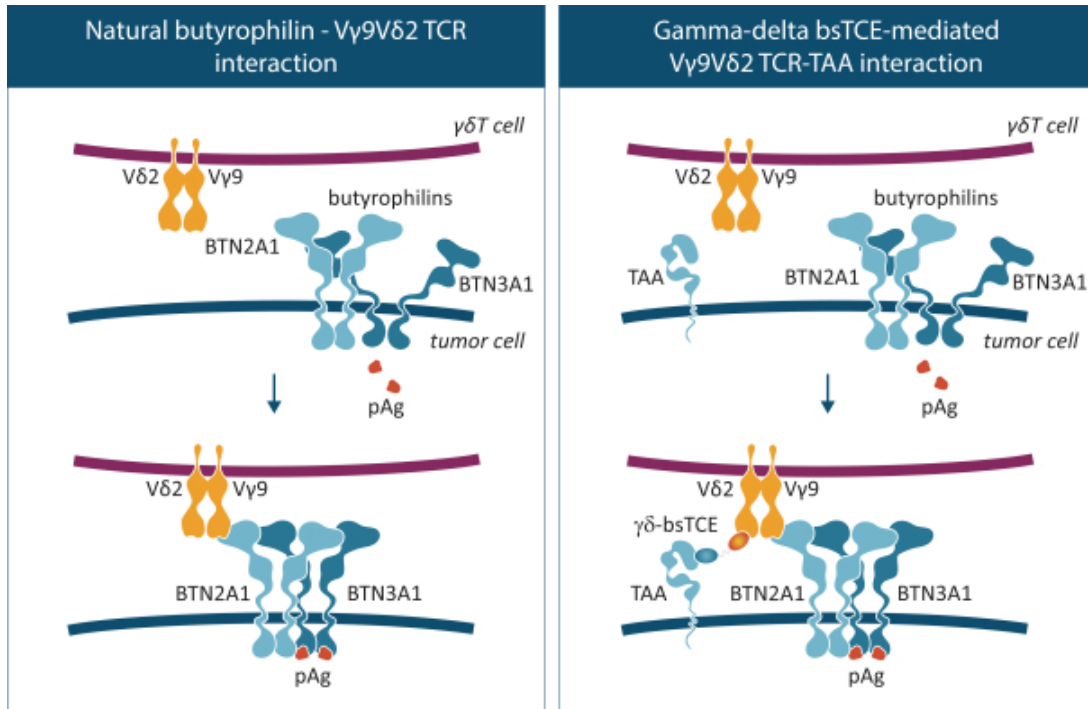
### **Our gamma-delta bsTCE platform**

We have developed a proprietary gamma-delta bsTCE platform that optimizes tumor-targeted activation of V<sub>g</sub>9Vd2 T cells for tumor cell killing, retains and leverages the inherent tumor cell recognition and killing capabilities of these cells and drives a downstream immune response cascade against tumor cells. As such, our platform combines the power and natural selectivity of V<sub>g</sub>9Vd2 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.

## [Table of Contents](#)

As depicted in the graphic below, the left panel shows the natural activation mechanism of V $\gamma$ 9V $\delta$ 2 T cells, which, through recognition of phosphoantigen-activated butyrophilins, leads to tumor cell killing. The right panel depicts our approach using a gamma-delta bsTCE that features a humanized domain antibody specific for the V $\delta$ 2 chain of the V $\gamma$ 9V $\delta$ 2 T cell receptor. This bsTCE binds V $\gamma$ 9V $\delta$ 2 T cells and a tumor-antigen of choice. Crosslinking via our bsTCEs leads to activation of V $\gamma$ 9V $\delta$ 2 T cells and potent tumor cell killing. While our approach bypasses the requirement of interactions between the V $\gamma$ 9V $\delta$ 2 TCR and phosphoantigen-activated butyrophilins, our gamma-delta bsTCEs do not block this cognate interaction, and thereby retain the inherent tumor specificity of V $\gamma$ 9V $\delta$ 2 T cells. We have shown in our preclinical work that this results in strong activity against tumor cells, but only limited activity against healthy cells expressing the same target.

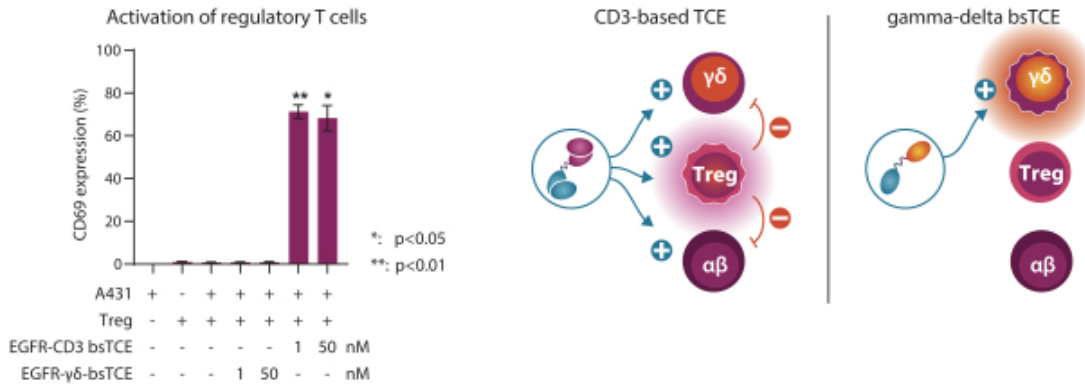
### **LAVA's proprietary gamma-delta bsTCE platform engages V $\gamma$ 9V $\delta$ 2 T cells for targeted cancer treatment**



We believe that the tumor preference of our gamma-delta bsTCEs is the result of several factors. Our approach targets antigens expressed on tumor cells at higher levels 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. This is illustrated below in an *in vitro* experiment where we 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 gamma-delta bsTCE. Since our platform does not activate immune suppressive cells like Tregs, we believe this dampening effect is unlikely to occur with gamma-delta bsTCEs, increasing their potential efficacy compared to CD3-based TCEs.

**CD3-based TCE but not gamma-delta bsTCE activate immunosuppressive regulatory T cells**



The bar graph on the left shows an experiment in which tumor (A431) cells and regulatory T cells were incubated with an EGFR CD3-based bsTCE or with our EGFR gamma-delta bsTCE. The expression of the activation-marker CD69 on the regulatory T cells was determined.

The infographic on the right illustrated the conclusion that can be drawn from this experiment: gamma-delta bsTCE did not activate regulatory T cells, whereas the CD3-based TCE induced significant levels of regulatory T cell activation.

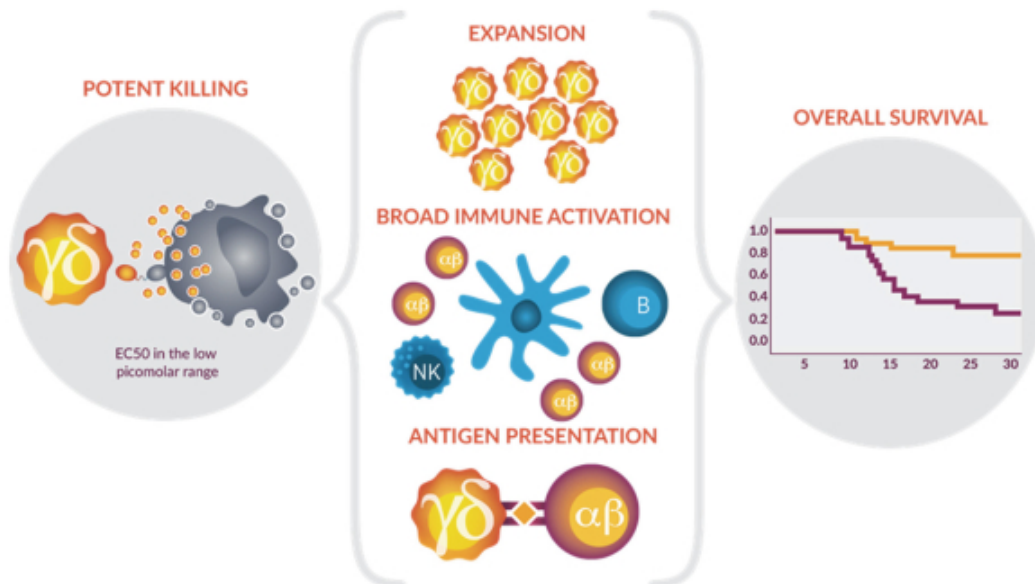
## [Table of Contents](#)

As depicted below, we believe our platform-derived gamma-delta bsTCEs drive a cascade response that provides potentially for enhanced anti-tumor efficacy. After the initial activation of Vg9Vd2 T cells is mediated through our gamma-delta bsTCEs, the activated Vg9Vd2 T cells are designed to rapidly kill tumor target cells, and also have the potential for:

- **Expansion.** The Vg9Vd2 T cells proliferate, resulting in an increased number of anti-tumor Vg9Vd2 T cells.
- **Broad immune activation.** The Vg9Vd2 T cells trigger the activation and antitumor activity of other immune cells, such as NK cells, tumor-specific alpha-beta T cells and dendritic cells.
- **Antigen presentation.** The Vg9Vd2 T cells process and present tumor antigens and acquire dendritic cell-like antigen presenting functions to trigger the development of “classical” naïve CD4<sup>+</sup> and CD8<sup>+</sup> alpha-beta T cell responses against the tumor.

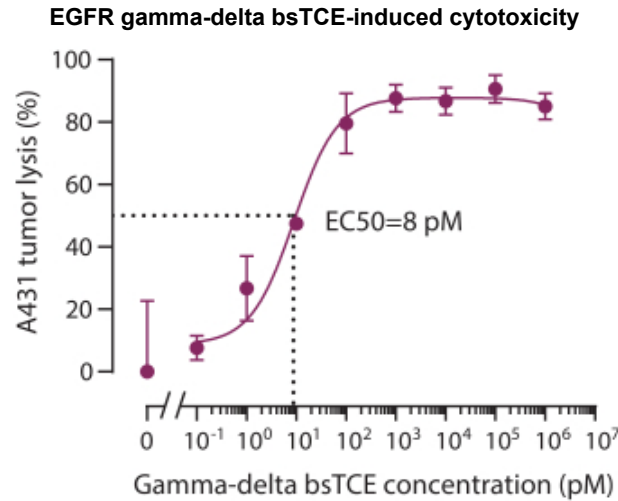
We believe that this cascade of events may enhance potency and lead to a more durable immune response.

### **Gamma-delta bsTCE have the potential to drive broad and effective anti-cancer activity**



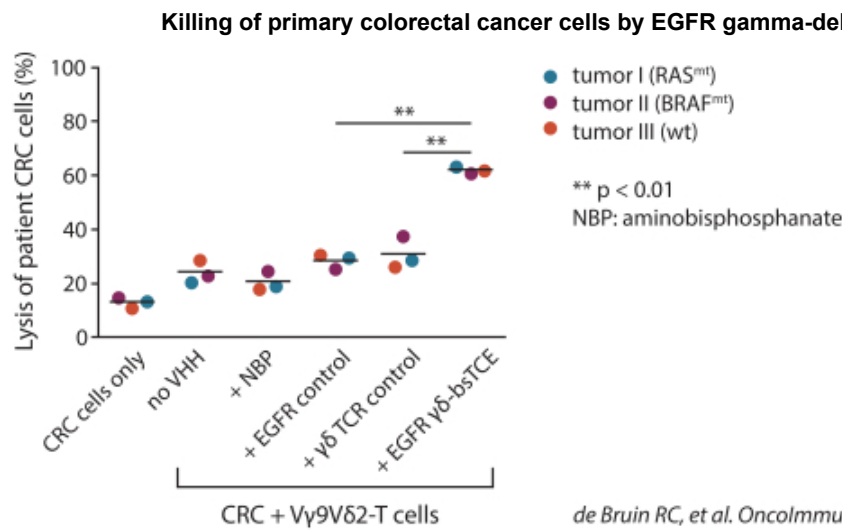
**Preclinical support for our mechanism of action**

We believe that our gamma-delta bsTCEs possess features that have the potential to address a number of shortcomings of current TCE approaches for cancer. The figure below highlights the potent cytotoxicity with a picomolar, or pM, EC50 of an EGFR specific gamma-delta bsTCE for killing of EGFR-expressing A431 tumor cells and expanded Vg9Vd2 T cells during a 24-hour co-culture (n=3). A picomolar potency resulted in activation of Vg9Vd2 T cells at low receptor occupancy, supporting evidence of maximal activity of our gamma-delta bsTCE at low concentration. In this dose response experiment, all datapoints contained an equal number of tumor cells and gamma-delta T cells. Very limited killing, up to a maximum of approximately 20%, of tumor cells by gamma-delta T cells without the gamma-delta bsTCE was observed. The killing increased as we added the gamma-delta bsTCE, with about 0.2nM being sufficient to induce near complete tumor cell killing.



*EGFR-expressing (A431) tumor cells were co-cultured with Vg9Vd 2 T cells in the presence of increasing concentrations of EGFR gamma-delta bsTCE. After 24 hours, the killing (lysis) of tumor cells was determined.*

We have demonstrated that killing of tumor cells is conditional, as it requires the gamma-delta bsTCE to engage both the Vg9Vd2 TCR as well as the tumor cell simultaneously. This is shown in the figure below, in which our EGFR gamma-delta bsTCE induced Vg9Vd2 T cells to significantly kill patient-derived primary colorectal cancer, or CRC, cells in a four-hour co-culture. The gamma-delta bsTCE-mediated killing of CRC cells was shown to be significantly higher than in the presence of controls or gamma-delta T cells alone.

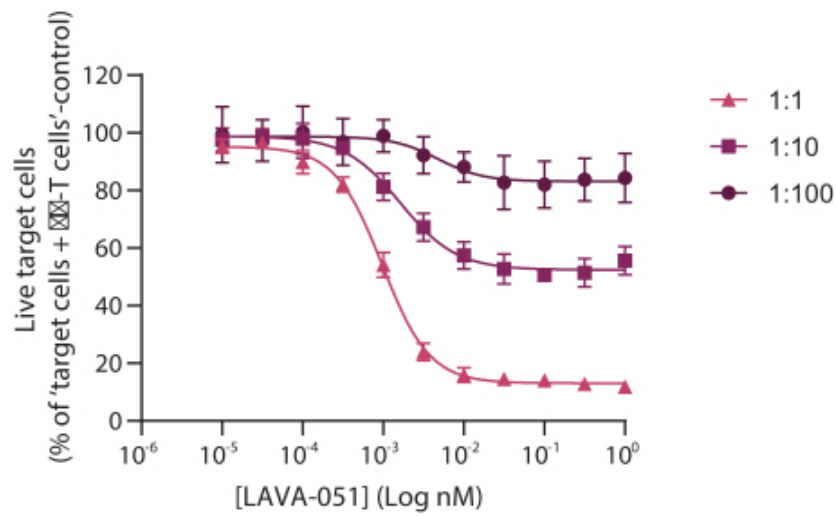


*Colorectal cancer cells, derived from patients, were cultured together with Vg9Vd 2 T cells from healthy donors in the presence of EGFR gamma-delta bsTCE, or aminobisphosphonate, or NBP or monospecific EGFR- or gdTCR-control molecules. After 4 hours, killing of the tumor cells was determined.*

Notably, tumor cell killing of primary colorectal cancer cells by our gamma-delta bsTCE occurred irrespective of downstream RAS or BRAF mutations. This is of potential importance as the conventional anti-EGFR monoclonal antibodies, cetuximab and panitumumab, have not shown relevant clinical activity as monotherapy in CRC patients with tumors harboring a RAS or BRAF mutation.

Vg9Vd2 T cells triggered by gamma-delta bsTCEs can mediate serial killing of tumor cells. The figure below shows killing of CCRF-CEM tumor cells, a T-ALL cell line naturally expressing the antigen CD1d, by Vg9Vd2 T cells at different effector-to-tumor target cell ratios using our CD1d gamma-delta bsTCE, LAVA-051, after 24 hours.

**CD1d gamma-delta bsTCE triggered lysis of CCRF-CEM tumor cells**

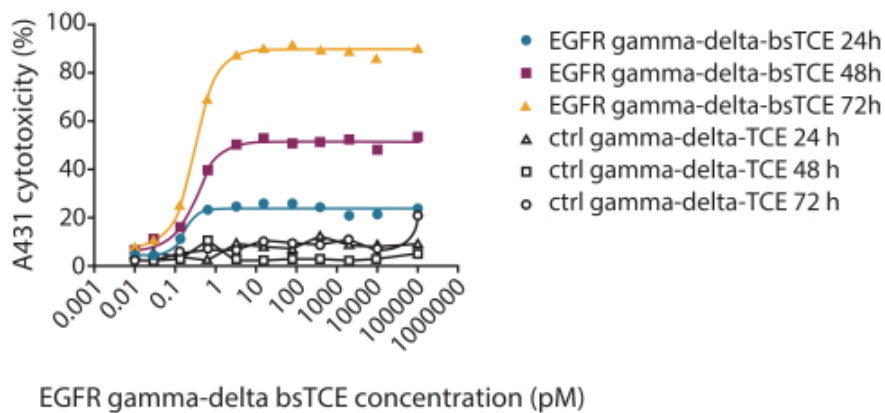


*A tumor cell line derived from T-ALL (CCRF-CEM cells) was cultured with Vg9Vd2 T cells at various Vg9Vd2 T cell-to-tumor cell-ratio's (1:1, 1:10 and 1:100) in the presence of increasing concentrations of CD1d gamma-delta bsTCE. Killing of tumor cells was determined.*

## [Table of Contents](#)

Our platform has shown the ability to induce sustained killing of tumor cells over time. Increasing the exposure time between tumor cells and effector Vg9Vd2 T cells resulted in an increase in killing, illustrated with the blue, purple and yellow lines, respectively, using EGFR-expressing A431 tumor cells and an EGFR-gamma-delta-bsTCE, as shown in the chart below. Each data point has the same number of tumor cells and gamma-delta T cells. Very limited killing (up to a maximum of approximately 10% during 72 hours of exposure) was observed when gamma-delta T cells were incubated with tumor cells in the presence of controls. Killing was increased to approximately 90% in this experiment as we added our gamma-delta bsTCE.

### Sustained EGFR gamma-delta bsTCE mediated killing of tumor cells by Vg9Vd2 T cells

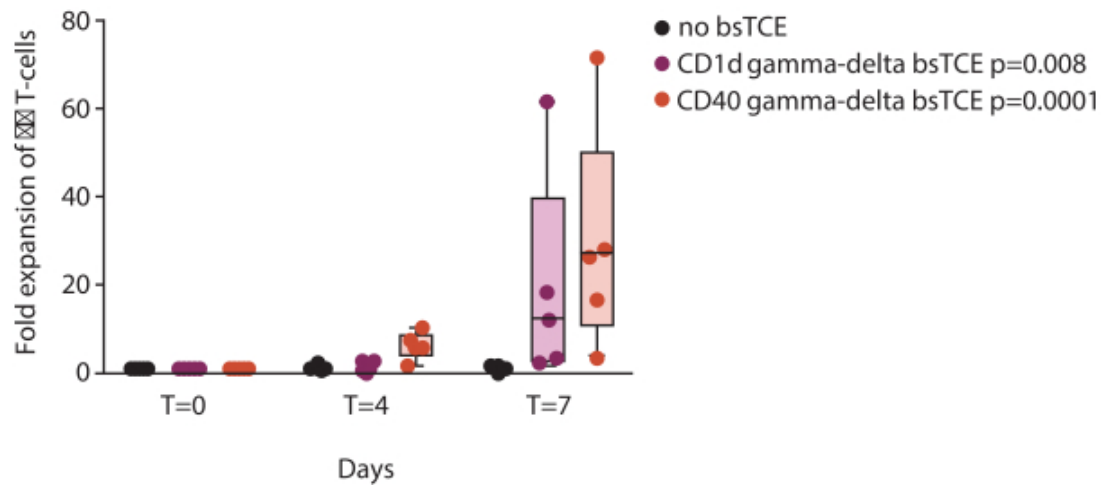


*EGFR-expressing (A431) tumor cells were cultured with Vg9Vd2 T cells in the presence of increasing concentrations of EGFR gamma-delta bsTCE. Killing of the tumor cells was determined after 24, 48 and 72 hours.*



Our preclinical work has shown the potential to drive substantial expansion of the Vg9Vd2 T cell population in assays where peripheral blood mononuclear cells are co-cultured with target expressing tumor cells for seven days. The figure below shows the expansion of Vg9Vd2 T cells by two different gamma-delta bsTCEs, a CD40-gamma-delta bsTCE and a CD1d-gamma-delta bsTCE.

**Gamma-delta bsTCE mediated expansion of Vg9Vd2 T cells**

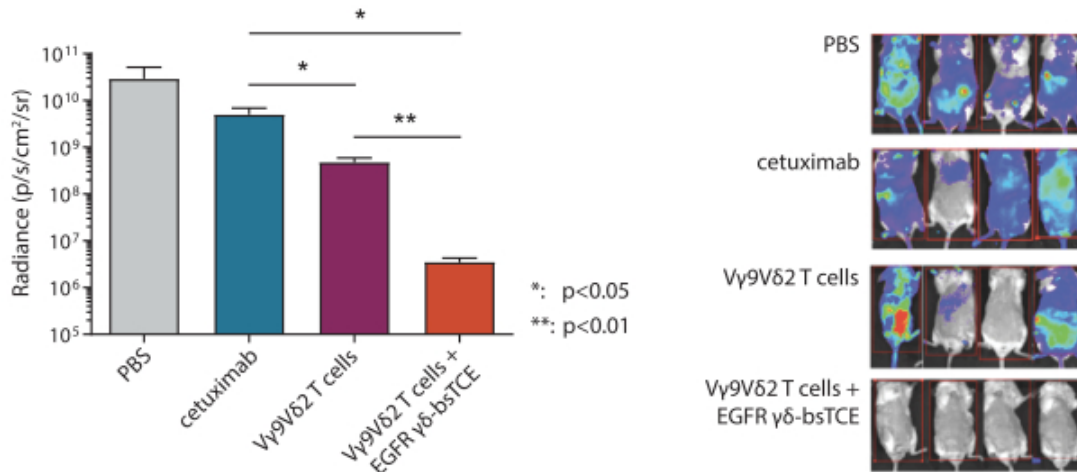


Mononuclear cells derived from the blood of healthy donors were cultured with CD1d and CD40 expressing tumor cells in the presence of CD1d gamma-delta bsTCE or CD40 gamma-delta bsTCE. The number of Vg9Vd2 T cells present in the culture was determined at the start of the experiment (T=0) and after 4 and 7 days.

## Table of Contents

The *in vivo* activity of our approach has been demonstrated with various gamma-delta bsTCEs in several tumor models. We have demonstrated the antitumor activity of an EGFR gamma-delta bsTCE in immunodeficient mice inoculated with RAS mutant colorectal cancer cells using either expanded V $\gamma$ 9V $\delta$ 2 T cells or human peripheral blood mononuclear cells, or PBMCs, as effector cells. In both settings, relevant antitumor activity was observed, as illustrated by reduced bioluminescence radiance, which reflects tumor load, reduced growth of subcutaneously implanted tumor and increased survival. In the upper panel below, using SW480 tumor cells, treatment consisted of either the anti-EGFR monoclonal antibody cetuximab, adoptive transfer of V $\gamma$ 9V $\delta$ 2 T cells alone or in combination with the EGFR gamma-delta bsTCE on days 1, 4, and 7. In the lower panel below of HCT116 tumor cells, treatment consisted of intravenous placebo or 5 mg/kg or 0.5 mg/kg of the EGFR gamma-delta bsTCE. Our gamma-delta bsTCE demonstrated better outcomes than all other approaches in this preclinical setting, as shown in the figure below.

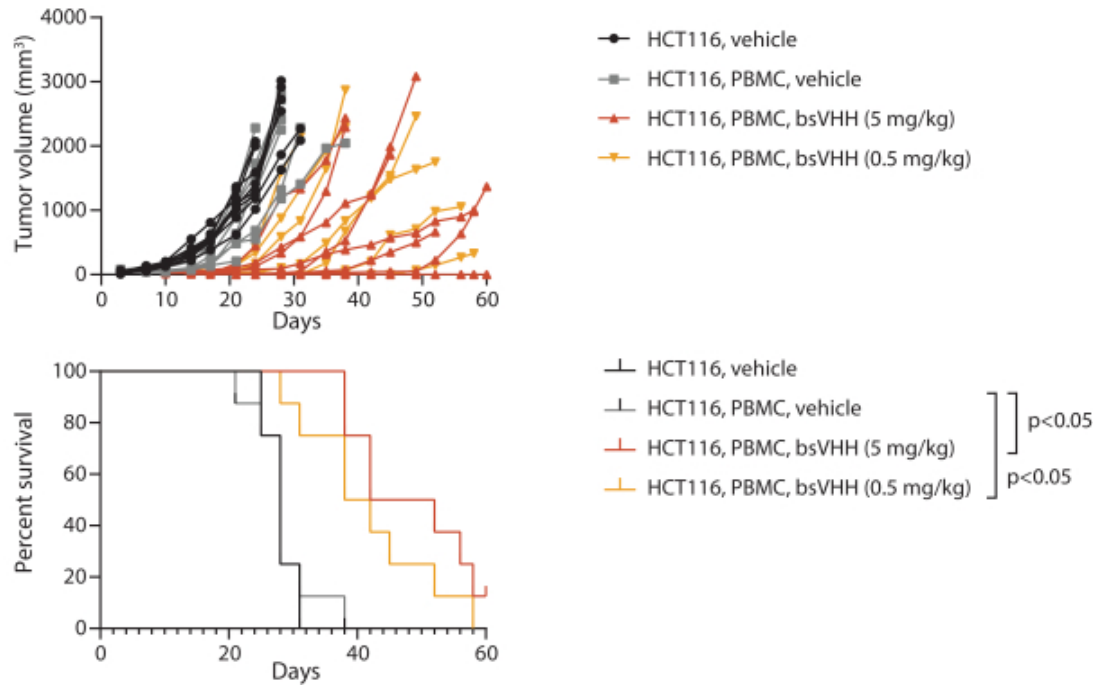
### EGFR gamma-delta bsTCE induces anti-tumor activity of expanded V $\gamma$ 9V $\delta$ 2 T cells against RAS-mutant colorectal cancer in immunodeficient mice



de Bruin RC, et al. *Oncol Immunology* 2017; 7(1):e1375641

Cells from the colorectal cancer cell line SW480, which contain a RAS mutation, were transfected to stably express luciferase. These cells were injected intravenously into immunodeficient mice on day 0. The mice were treated with 3 intravenous injections (days 1, 4, 7) of either the anti-EGFR monoclonal antibody cetuximab, V $\gamma$ 9V $\delta$ 2 T cells alone or V $\gamma$ 9V $\delta$ 2 T cells plus EGFR gamma-delta bsTCE. Bioluminescence imaging was performed after 35 days, to determine the tumor load in the mice. The bar graph shows the quantification of bioluminescence, the heat map indicates the sites and relative level of tumor cell activity in individual mice.

**EGFR gamma-delta bsTCE induced anti-tumor activity of human PBMCs against RAS-mutant colorectal cancer in immunodeficient mice**

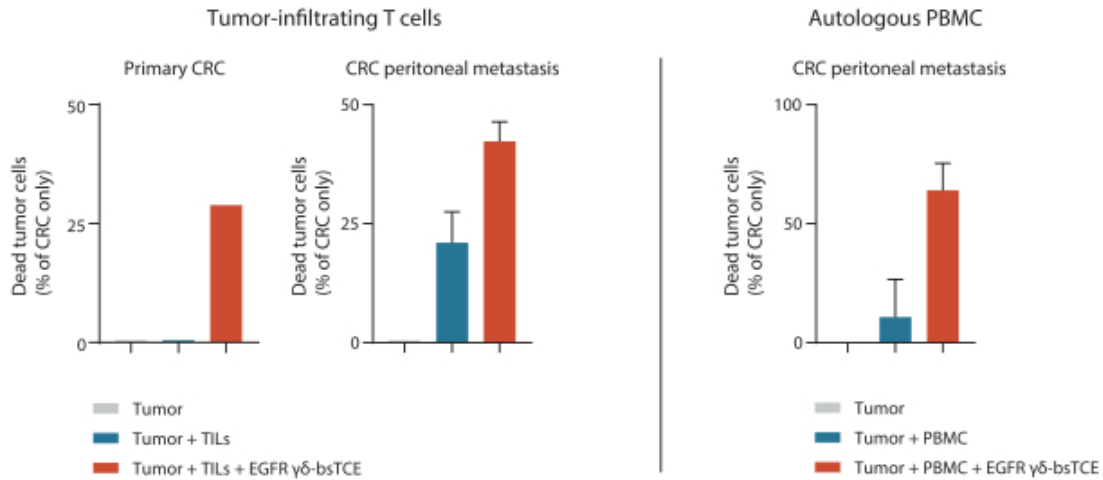


Cells from the colorectal cancer cell line HCT116, which contain a RAS mutation, and PBMCs derived from the blood of healthy donors were injected subcutaneously into immunodeficient mice. The mice were treated with intravenous injections of EGFR gamma-delta bsTCE at two dose levels during the first 14 days. Tumor volume (top graph) and percent survival of mice (bottom graph) were determined over time.

**Table of Contents**

Potent activity of our platform was also demonstrated using a combination of patient tumor cells and patient Vg9Vd2 T cells from the tumor infiltrating T cell population or in autologous PBMC. As illustrated below, an overnight co-culture of dissociated patient derived CRC cells, from either the primary tumor in the colon or from peritoneal metastases, and tumor infiltrating T cells, with a T cell-to-tumor cell ratio of 1:1, or autologous patient PBMC, with a PBMC-to-tumor cell ratio of 10:1, triggered lysis of the tumor cells in the presence of an EGFR gamma-delta bsTCE.

**EGFR gamma-delta bsTCE induced lysis of patient colorectal cancer cells by autologous patient tumor-infiltrating T cells or PBMC**



*Colorectal cancer cells, derived from the primary tumor or from metastases in the peritoneum, were cultured with tumor infiltrating lymphocytes (TILs; one TIL per tumor cell) or with autologous PBMC (10 PBMCs per tumor cell), in the presence or absence of EGFR gamma-delta bsTCE. Killing of tumor cells was determined after over-night culture.*

Our preclinical work has shown that gamma-delta bsTCEs result in preferential activity of Vg9Vd2 T cells towards cancer cells. This is illustrated in the figure below for two different gamma-delta bsTCEs. In figure A below, a concentration range of a CD20 gamma-delta bsTCE was shown to induce killing of a CD20 expressing C1R tumor cell line but not of CD20 expressing human healthy donor-derived B cells during a 24-hour co-culture (E:T ratio 2:1). In figure B below, a PSMA-gamma-delta bsTCE was shown to trigger Vg9Vd2 T cells, in an overnight assay, to lyse prostate cancer cells but not healthy prostate cells in paired dissociated tissue samples of patients undergoing radical prostatectomy for localized prostate cancer.

**Gamma-delta bsTCE triggered preferential activity against tumor cells**



*Cells from the C1R tumor cell line or B cells from healthy donors, both expressing similar levels of CD20, were cultured alone or with Vg9Vd2 T cells in the presence of increasing concentrations of CD20 gamma-delta bsTCE. Killing of CD20-positive target cells was determined after 24 hours.*

*Patient-derived cells derived from dissociated prostate cancer or healthy prostate tissue were cultured alone or with Vg9Vd2 T cells in the presence of PSMA gamma-delta bsTCE. Killing of cells was determined after over-night culture.*

**Preclinical safety**

In our studies in non-human primates, or NHPs, gamma-delta bsTCEs were well-tolerated. NHP studies were performed in cynomolgus monkeys with fully cross-reactive surrogate gamma-delta bsTCEs targeting EGFR, CD20 and CD1d. The gamma-delta bsTCEs used were designed to trigger human and monkey gamma-delta T cells with similar potency. The cross-reactive gamma-delta bsTCEs were infused intravenously four times during the course of a week at doses up to 10 mg/kg without clinical, biochemical, hematologic and histopathological signs of toxicity. Cytokines were observed in the plasma after the first administration, but at low levels that did not induce CRS. These results compare highly favorably to data reported on an EGFR- CD3-based TCE which, in stark contrast, was highly toxic at 100 times lower doses, inducing up to 3-logs higher cytokine levels. Based on these data, we anticipate our gamma-delta bsTCEs to have a significantly improved safety profile and therapeutic window than corresponding CD3-based TCEs.

**Our pipeline of gamma-delta bsTCEs**

Supported by strong preclinical data, we are developing our gamma-delta bsTCEs to become a new standard for potent and safe T cell engager cancer treatment. We are currently advancing a pipeline of multiple gamma-delta bsTCEs for the potential treatment of hematologic malignancies and solid tumors. We plan to develop each of these as a single agent or in combination with other therapies. The following table depicts our current pipeline:



Our lead product candidate is LAVA-051, a humanized gamma-delta bsTCE targeting CD1d-expressing hematologic cancers, including CLL, MM and AML. We have achieved preclinical proof-of-concept with LAVA-051, demonstrating its ability as the first antibody-based compound targeting CD1d to activate both Vg9Vd2 and iNKT cells, in a target-dependent manner. In addition, we are advancing a second product candidate, LAVA-206x207, a gamma-delta bsTCE targeting PSMA for the potential treatment of prostate cancer, as well as a portfolio of discovery programs that we expect will provide the opportunity for additional INDs in

**LAVA-051 for hematologic malignancies**

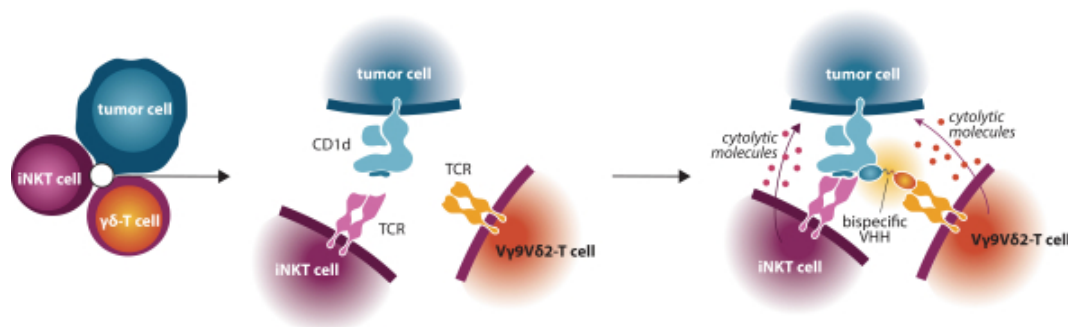
LAVA-051 is a humanized gamma-delta bsTCE that engages Vg9Vd2 T cells to kill tumor cells in a tumor target-dependent manner. We are starting a Phase 1/2a clinical trial of LAVA-051 in CLL, MM and AML patients in . LAVA-051 consists of two VHH domain antibody fragments linked via a short, five amino acid

## [Table of Contents](#)

glycine-serine linker. One arm recognizes the V $\delta$ 2 chain of the V $\gamma$ 9V $\delta$ 2 TCR and the other arm is specific for the tumor antigen CD1d. CD1d is a glycoprotein involved in the presentation of lipid antigens to iNKT cells and is expressed on a wide range of hematologic malignancies, including CLL, MM and AML. CD1d has also been shown to be expressed by several solid tumors, including prostate, cervical, breast, renal cell and colorectal cancers.

We believe LAVA-051 has the potential to be an effective therapy against CD1d-expressing tumor cells thanks to its unique mechanism of action that can trigger both gamma-delta- and iNKT-mediated cell killing responses, as illustrated in the figure below. As its principal MoA, LAVA-051 cross-links CD1d-expressing tumor cells and V $\gamma$ 9V $\delta$ 2 T cells resulting in conditional V $\gamma$ 9V $\delta$ 2 T cell activation, the secretion of cytolytic molecules and cytokines and subsequent tumor killing. In addition, the CD1d-binding moiety of the bispecific antibody uniquely enhances the interaction of CD1d and iNKT cells. iNKT cells constitute a population of innate-like lymphocytes that recognize lipid antigens presented by CD1d and play an important role in orchestrating immune responses in cancer and infection. As published in 2020 in *Nature Cancer*, we demonstrated that this feature led to effective iNKT cell activation and additional anti-tumor activity.

### **Model illustrating the capacity of LAVA-051 to trigger activation and cytolytic activity of both iNKT cells and V $\gamma$ 9V $\delta$ 2 T cell**



Activated iNKT cells can exert direct cytotoxicity against CD1d-positive tumor cells and also produce pro-inflammatory cytokines that promote the cytotoxic activity of other immune cells, including V $\gamma$ 9V $\delta$ 2 T cells, to induce subsequent tumor cell lysis. These combined MoAs contribute to the high anti-cancer potential of LAVA-051 and the potential to provide rapid cytotoxicity, as well as long-term antitumor immune responses.

CD1d is expressed by tumor cells in the majority of patients with CLL, MM and AML. Despite current treatment options, there remains an unmet need for patients with these cancers, as the vast majority will become refractory to or develop resistance to existing therapies.

In preclinical studies, 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 CD1d-positive CLL, MM and AML patients.

### **Chronic lymphocytic leukemia (CLL)**

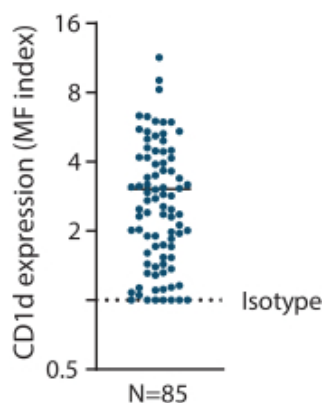
Chronic lymphocytic leukemia, or CLL, is the most common leukemia in the U.S. and Europe. CLL has an incidence of approximately 4.7 cases per 100,000 people in the U.S., and an increasing incidence in Western Europe including up to 5.27 per 100,000 in the UK. The disease has a male predominance and a median age of 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. The majority of 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 no single agreed-upon, 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 mostly chemotherapy-based treatments: the BCL-2 inhibitor venetoclax and the Bruton's tyrosine kinase, or BTK, inhibitors are now broadly evaluated at different stages of disease and in different patient segments and combinations. When disease progression occurs, especially after treatment with DNA-damaging agents, 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. Such patients, for whom no standard of care treatment currently exists will initially be included in our clinical trial with LAVA-051.

### **CD1d expression on CLL cells**

We analyzed CD1d expression on CLL cells by calculating the mean fluorescence, or MF, intensity of CD1d divided by the MF intensity of the isotype control, resulting in the MF index. The MF index correlates positively with the expression levels of CD1d. Assessment of the CD1d expression levels on patient-obtained CD19+CD5+ CLL cells showed that the CD1d MF index ranged between 1.0 and 11.9 with a mean MF index of 3.1 (n=85), as shown in the figure below.

**CD1d expression on patient CLL cells**



*CD1d expression levels on CLL cells from 85 patients was determined by flow cytometry. Expression was calculated as MF index: the mean fluorescence, or MF, intensity of CD1d staining divided by the MF intensity of staining with an isotype control.*

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 Vg9Vd2 T cells in CLL immunotherapy.

### **Multiple myeloma (MM)**

Multiple myeloma, or 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 or symptoms related to the high levels of M-protein including a reduced immune function.

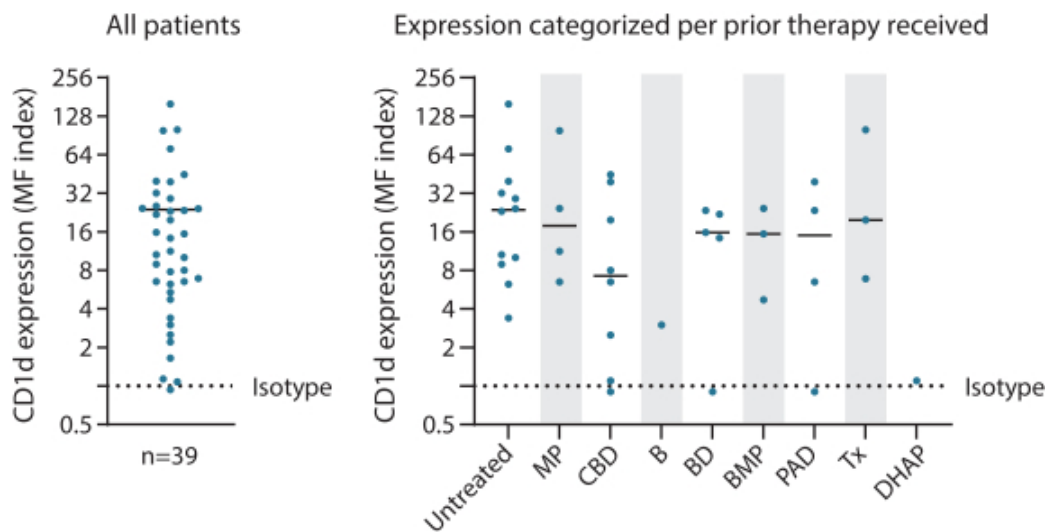
Even though the treatment landscape for MM has evolved considerably, MM remains an incurable disease. Patients typically receive combination therapy consisting of two or more different classes of drugs; combinations of different drugs are used upon failure of the previous treatment and disease progression. Upon relapse, typically the disease 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 have shown MM cells to be susceptible to the cytolytic activity of both iNKT cells and gamma-delta T cells. 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* models and *ex vivo* patient malignant cells, support the potential of targeting CD1d using LAVA-051 in MM.

**CD1d expression on MM cells**

We assessed CD1d expression on patient-obtained MM cells by flow cytometry. In general, MM cells were observed to be positive for CD1d with MF index levels ranging between 0.9 and 159.2, with a mean of 23.9 (n=39), as shown in figure A below. CD1d expression levels did not differ between untreated MM patients and MM patients that had undergone various pre-treatments prior to taking the bone marrow aspirate, indicating that there was no significant effect of the type of treatment for MM on CD1d expression levels, as shown in figure B below.

**CD1d expression on patient multiple myeloma cells**



The left graph shows CD1d expression levels on MM cells from 39 patients, determined by flow cytometry. Expression was calculated as MF index: the mean fluorescence, or MF, intensity of CD1d staining divided by the MF intensity of staining with an isotype control.

The right panel shows the CD1d expression categorized per type of treatment the patients received.

Legend for pretreatment received: MP: Melphalan, Prednisone; CBD: Cyclophosphan, Bortezomib, Dexamethasone; B: Bortezomib; BD: Bortezomib, dexamethasone; BMP: Bortezomib, melphalan, prednisone; PAD: Bortezomib, doxorubicin, dexamethasone; Tx: Auto-HSC transplantation; DHAP: Dexamethasone, cytarabine, cisplatin



### **Acute myeloid leukemia (AML)**

AML is the most common form of acute leukemia in adults. The median age of 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 younger patients under 50 years of age, to approximately 5-10% in older patients. Prognosis is also worse in patients with secondary AML, or with relapsed and/or refractory disease.

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.

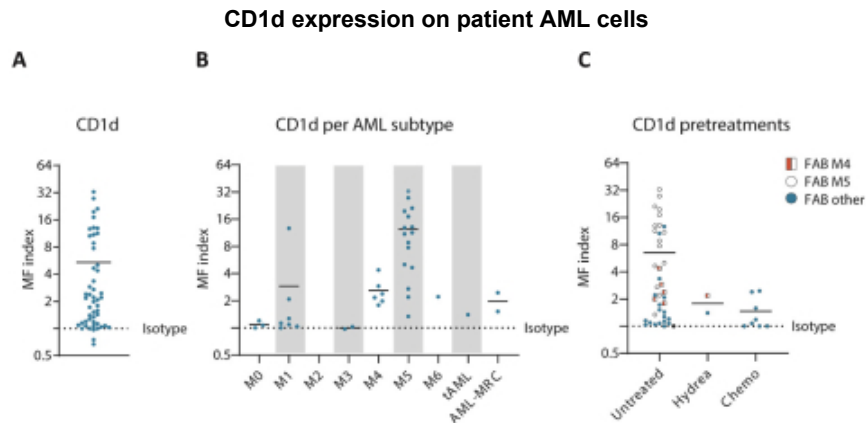
The mainstay of AML treatment for patients under approximately 60 years of age and medically fit patients consists of intensive induction chemotherapy. For patients who are not eligible for intensive regimens, therapy includes best-supportive care, low-dose cytarabine and hypomethylating agents decitabine 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 to most of these drug classes, underscoring the urgent need for efficacious therapies with novel MoAs.

CD1d+ AML cells have been shown to be susceptible to lysis by both 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 myelomonocytic subtypes, which was confirmed in the patient series that we studied as described under "CD1d Expression on AML Cells." 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.

**CD1d expression on AML cells**

We assessed CD1d expression on patient-obtained AML blast cells, which is illustrated in the graphs below. AML bone marrow mononuclear cells, or BMNCs, were gated according to each respective AML phenotype, after which the expression of CD1d was analyzed on the blast cells. As shown in figure A below, the findings demonstrated that the mean fluorescent, or MF, index levels ranged between 0.7 and 32.7, with a mean of 5.4 (n=51). Subdividing the AML samples based on the French–American–British, or FAB, classification showed that AML FAB M4 and M5 displayed relatively high expression levels of CD1d, with a mean MF index of 2.6 and 12.4, respectively, as shown in Figure B below (n=38). In addition, the CD1d expression levels were determined on samples of untreated (n=41) vs treated patients (n=10), as shown in figure C below. High expression levels of CD1d in specific classifications of AML, including FAB M4 and M5, may inform our clinical development strategy in AML.



The left graph shows CD1d expression levels on AML blast cells from 51 patients, determined by flow cytometry. Expression was calculated as MF index: the mean fluorescence, or MF, intensity of CD1d staining divided by the MF intensity of staining with an isotype control.

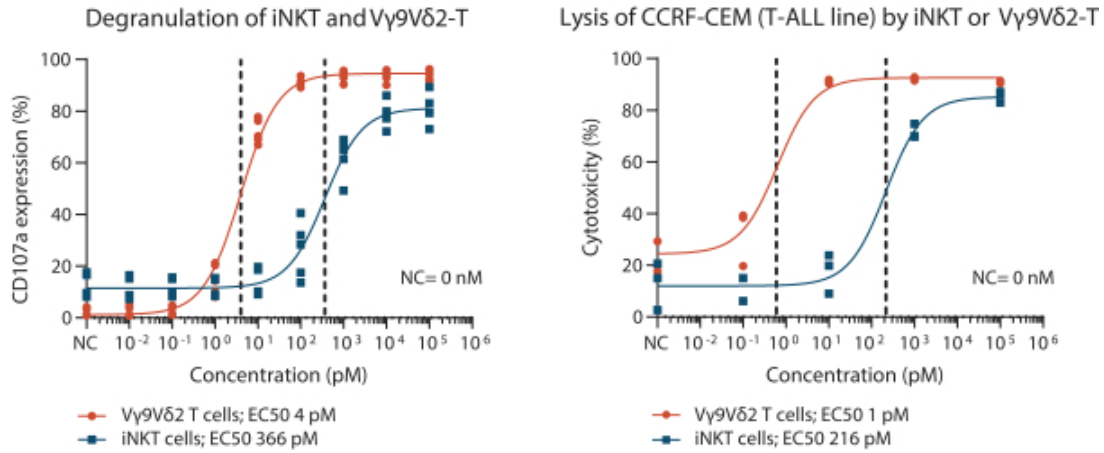
The middle panel shows the CD1d expression categorized per FAB subtype.

The right panel shows the CD1d expression categorized per type of treatment the patients received. Hydrea: Hydroxycarbamide. Chemo: Chemotherapy (unspecified).

**LAVA-051 preclinical evidence targeting CD1d**

In addition to inducing target-dependent V $\gamma$ 9V $\delta$ 2 T cell activation and subsequent target cell lysis, LAVA-051 showed a capacity to induce activation of iNKT cells by strengthening the interaction of and stabilizing the binding between the iNKT TCR with its natural ligand CD1d. iNKT cells are activated through presentation of glycolipids in the groove of the MHC class I-like molecule CD1d. This complex is recognized by the iNKT TCR which triggers a signaling cascade that results in iNKT cell activation. The anti-CD1d VHH arm used in LAVA-051 is designed to recognize its ligand CD1d, and in the presence of iNKT cells, can strengthen the interaction between the iNKT TCR and CD1d. This caused increased activation of iNKT cells, including degranulation, or release of granules containing cytolytic molecules, as shown on the left-hand figure below, and induced target-dependent lysis of malignant CD1d expressing cells, specifically CCRF-CEM in our dataset, as shown in the right-hand figure below.

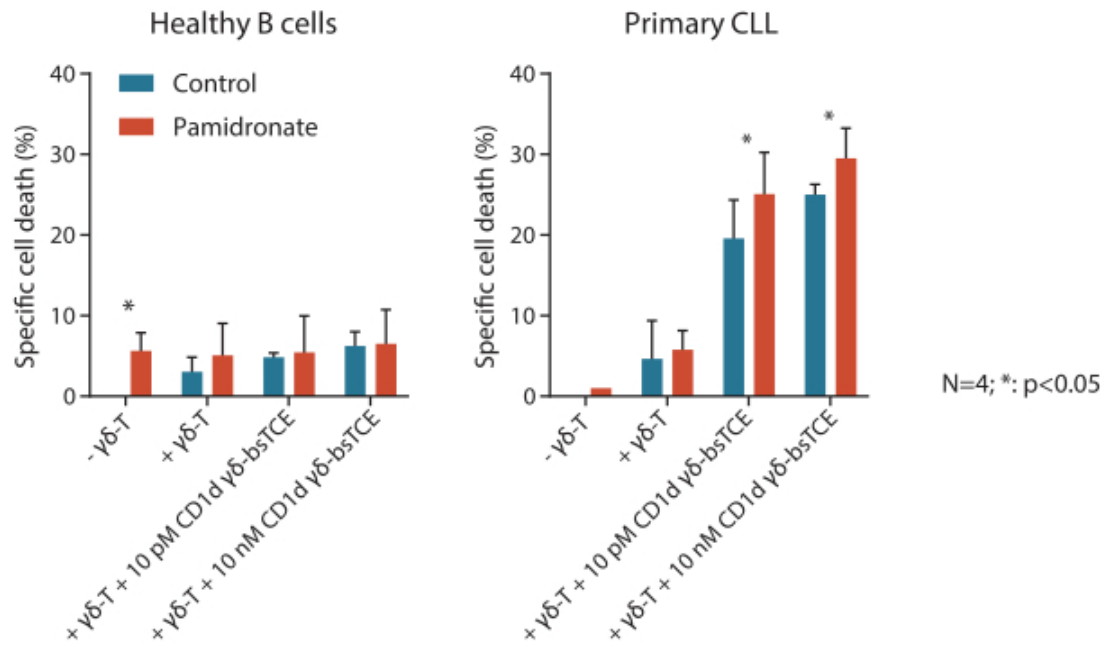
**LAVA-051 triggered degranulation and cytotoxic activity of both iNKT cells and V $\gamma$ 9V $\delta$ 2 T cells**



iNKT or V $\gamma$ 9V $\delta$ 2 T cells were cultured with CD1d-positive tumor cells in the presence of increasing concentrations of CD1d gamma-delta bsTCE. Degranulation was determined by measuring the degranulation-marker CD107a by flow cytometry after 4 hours (left graph). The ability to kill tumor cells was determined after 18 hours (right graph).

Further, CD1d gamma-delta bsTCEs caused preferential activity of V $\gamma$ 9V $\delta$ 2 T cells against cancer cells expressing CD1d.

**CD1d gamma-delta bsTCE triggered preferential activity of V $\alpha$ 9V $\beta$ 2 T cells against patient-derived CLL cells sparing healthy B cells**

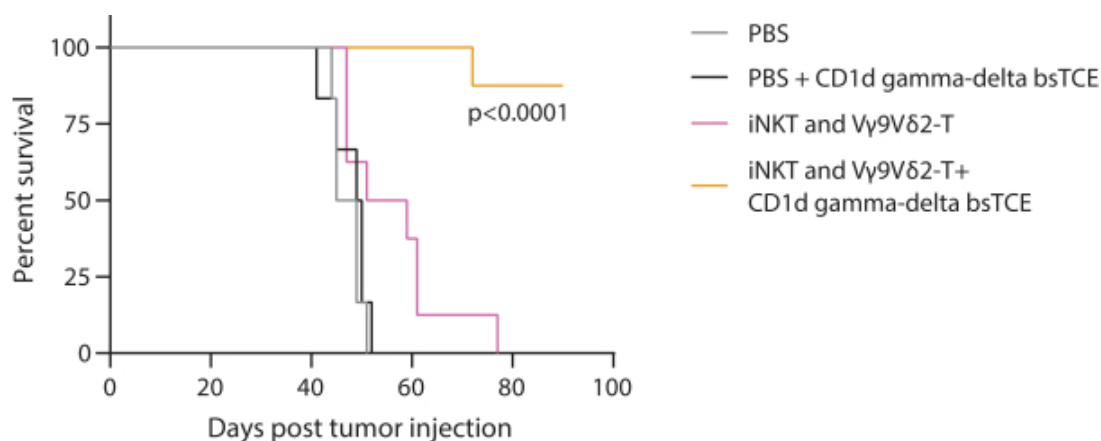


de Weerd *et al. Clin Cancer Res* 2021; doi: 10.1158/1078-0432.CCR-20-4576

Healthy B cells, known to express CD1d, and CD1d+ primary patient-derived CLL cells were pre-incubated for 2 hours in the presence or absence of pamidronate. Thereafter, the cells were co-cultured in a 1:1:1 ratio with healthy donor derived V $\alpha$ 9V $\beta$ 2 T cells for 6 hours in the absence or presence of CD1d gamma-delta bsTCEs, after which specific killing of the healthy B cells (left graph) or CLL cells (right graph) was determined.

In an *in vivo* model in immunodeficient mice, we showed that CD1d gamma-delta bsTCEs triggered iNKT and V $\gamma$ 9V $\delta$ 2 T cell activity to control CD1d+ MM tumor cell growth and thereby resulted in strong improvement of survival, as illustrated in the figure below.

**CD1d gamma-delta bsTCE induced anti-tumor activity of iNKT cells and V $\gamma$ 9V $\delta$ 2 T cells against CD1d-expressing MM in immunodeficient mice**



*CD1d expressing MM.1S, (multiple myeloma-derived) tumor cells were injected intravenously into immunodeficient mice. The mice were treated with phosphate buffered saline, or PBS control, solution or iNKT and V $\gamma$ 9V $\delta$ 2 T cell transfer and/or with CD1d gamma-delta bsTCE. The percent survival of mice was determined over time.*

Based on preclinical data in models of CLL, MM and AML, we are preparing to initiate clinical development of LAVA-051 in

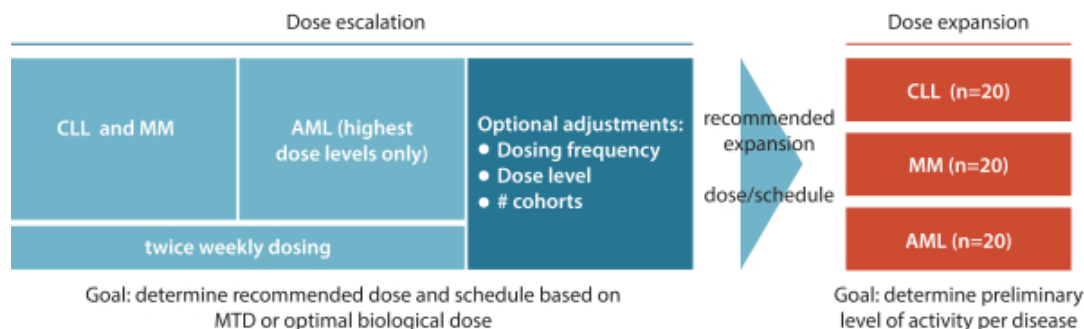
**Phase 1/2a clinical trial**

We plan to develop LAVA-051 initially for the treatment of patients with relapsed and/or refractory CD1d-positive hematologic malignancies. We have successfully completed Scientific Advice meetings with the Dutch and Swedish competent health authorities and obtained written feedback from the FDA regarding the early clinical development plan for LAVA-051. We gained alignment with all three regulatory authorities on the appropriateness to initiate clinical studies and on the principle that a safe starting dose (based on minimal anticipated biological effect level, or MABEL, can be selected for our planned first-in-human study. This open-label, multi-center, Phase 1/2a proof-of-concept clinical trial will evaluate the safety, tolerability, pharmacokinetics, or PK, pharmacodynamics, or PD, immunogenicity and antitumor activity of LAVA-051 in patients with relapsed and/or refractory CD1d-positive CLL, MM or AML.

## [Table of Contents](#)

The initial Phase 1 study will determine the safety and recommended Phase 2 dose, or RPD2, of LAVA-051. As AML is a rapidly progressing disease, patients with AML will be enrolled only once the RP2D is defined. The clinical trial design for the Phase 1 portion is shown below. The Phase 1 clinical trial will utilize an adaptive design, initially with single CLL and/or MM patient cohorts; subsequent dose escalation will be determined on clinical safety, PK, and PD.

### Schematic of our Phase 1 trial for LAVA-051 in Blood CLL, MM, and AML



Patients enrolled in the Phase 1 portion will receive LAVA-051 as a 2-hour intravenous infusion at the same dose level on days 1, 8, 11, 15, 18, 22 and 25 in the first treatment cycle of 28 days, and then twice weekly thereafter.

The selection of the initial dose and schedule for the Phase 1 portion of the clinical trial with LAVA-051 is based on our preclinical pharmacology studies, mechanistic *ex vivo* and *in vitro* investigations and PK and PD modeling approaches. In aggregate, these data have provided the information required for the calculation of the MABEL, definition of a safe starting dose and escalation schedule for the clinical trial with LAVA-051.

Once a RP2D has been established, the trial will expand into the Phase 2a portion, which will enroll patients in disease specific cohorts, with 20 patients per cohort, for relapsed and/or refractory CLL, MM and AML, to confirm safety and evaluate antitumor activity per disease cohort.

#### **Next steps with LAVA-051**

In November 2020, we filed a CTA with the CCMO to conduct a Phase 1/2a clinical trial with LAVA-051 in patients with relapsed and/or refractory CLL, MM and AML, which we expect to begin enrolling in . In addition, we expect to file an IND application with the FDA in , after which patients from the U.S. will also be included in the ongoing Phase 1 part of the clinical trial.

Based on the preliminary level of activity observed in either of the disease-oriented expansion cohorts of our Phase 1/2a study, we will be able to decide on the value of further expanding the Phase 2 in any of the three disease populations with high unmet medical need. Based on meeting disease-specific efficacy thresholds in the Phase 2 setting, we will consider applying for an accelerated approval pathway; in each of these three diseases novel drugs have been approved via the accelerated approval pathway.

We are also considering the potential to expand the evaluation of LAVA-051 into solid tumors, given the expression of CD1d in solid tumors, including prostate, cervical, breast, renal cell, and colorectal cancers.

#### **LAVA 206x207 for the Treatment of Solid Tumors**

Our second most advanced program is LAVA-206x207, which we have designed as a novel humanized gamma-delta bsTCE for the treatment of metastatic castration-resistant prostate cancer. LAVA-206x207 is a

first-in-class, humanized gamma-delta bsTCE that targets PSMA and the Vd2 domain of the TCR. Importantly, it contains an Fc domain that provides for a longer half-life. LAVA-206x207 has a molecular weight of 78kD which is about half that of a conventional IgG-based antibody, potentially supporting better tumor penetration. An IND for LAVA-206x207 is expected to be submitted in

### **Prostate cancer**

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 metastatic castration-resistant prostate cancer, or 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 Vg9Vd2 T cells. This high abundance correlates with a lower biochemical recurrence, or BCR rate, which in turn is related to an improved patient prognosis.

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 and carcinomas make PSMA an important target for immunotherapies with this form of cancer and has been clinically validated.

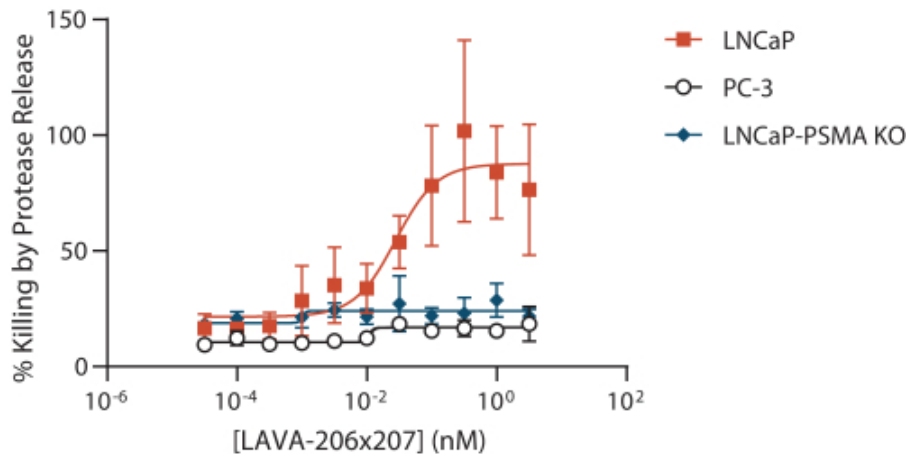
### **LAVA-206x207 for prostate cancer**

LAVA-206x207 has been demonstrated to be highly specific and potent in its ability to induce Vg9Vd2-T cell mediated killing of PSMA-positive tumor cells. We validated the extended half-life of the lead molecule in relevant animal models *in vivo*.

In preclinical models, LAVA-206x207 has shown high potency in Vg9Vd2 T cell-dependent target cell lysis of PSMA-positive cells. We assessed LAVA-206x207 for potency in inducing Vg9Vd2 T cell-dependent cytotoxicity of the PSMA positive LNCaP cell line, which are androgen-sensitive human prostate adenocarcinoma cells. We demonstrated potent cell killing, with an average EC50 of 15 pM against PSMA-positive LNCaP prostate tumor cells and that this killing was targeted to PSMA-expressing cells, as we observed no cytotoxicity against the PSMA-negative cell line PC-3 or an LNCaP-based cell line in which PSMA was knocked out.

**LAVA-206x207 triggered V<sub>g</sub>9Vd2 T cell mediated lysis of PSMA+ LNCaP prostate cancer cells**

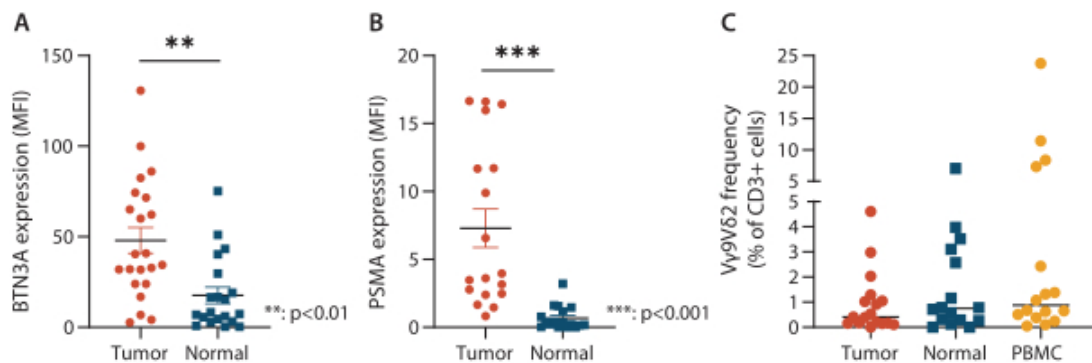
**Cytotoxicity assay using gamma-delta T cells**



Cells from the prostate cancer cell lines LNCaP, which express PSMA, and PC-3, which did not express detectable PSMA, were cultured with V<sub>g</sub>9Vd2 T cells in the presence of increasing concentrations of PSMA gamma-delta bsTCE, and killing of tumor cells was determined. To further determine PSMA-specificity, LNCaP cells in which PSMA expression was abolished (LNCaP-PSMA-KO) were used.

In order to demonstrate the relevance of targeting PSMA and V<sub>g</sub>9Vd2 T cells in prostate cancer, we analyzed tumor and healthy tissue obtained from prostatectomy from primary prostate cancer patients. We observed that prostate cancer cells have a significantly higher expression of BTN3A compared to healthy prostate cells, which is expected to facilitate the specific recognition of tumor cells by V<sub>g</sub>9Vd2 T cells and trigger their cytotoxic activity, as shown in panel A below. Furthermore, we confirmed that these tumor cells express higher levels of PSMA compared to healthy prostate cells, indicating that tumor cells are more likely to be targeted by LAVA-206x207, as shown in panel B below. As the presence of circulating and tissue-infiltrating V<sub>g</sub>9Vd2 T cells is key for this therapy to be successful, we also confirmed the presence of these effector cells both in blood and tissue derived from prostate cancer patients, shown in panel C below.

**Expression of BTN3A and PSMA and V<sub>g</sub>9Vd2 T cell frequency in samples of prostate cancer patients**



Prostate cancer tumor samples were obtained from patients undergoing radical prostatectomy. Analyses were performed on dissociated prostate tumor samples and, where available, dissociated non-malignant "normal" prostate cells. BTN3A expression, PSMA expression and V<sub>g</sub>9Vd2-T cell frequency, were assessed using flow-cytometry.

Prostate cancer (PCa)tumor samples were obtained from patients undergoing radical prostatectomy. Analyses were performed on dissociated prostate tumor samples and, where available, dissociated non-malignant "normal" prostate cells. V<sub>g</sub>9Vd2-T cell frequency (PCa n=17, normal n=16), BTN3A expression (PCa n=22, normal



n=20), and PSMA expression (PCa n=18, normal n=17) was assessed using flow-cytometry. \*\*: p<0.01; \*\*\*: p<0.001

BTN3A is butyrophilin 3A; conformational changes in BTN3A1 upon binding of this receptor to intracellular phosphoantigens are sensed by the Vg9Vd2-T cell receptor and facilitate their interactions with tumor cells.

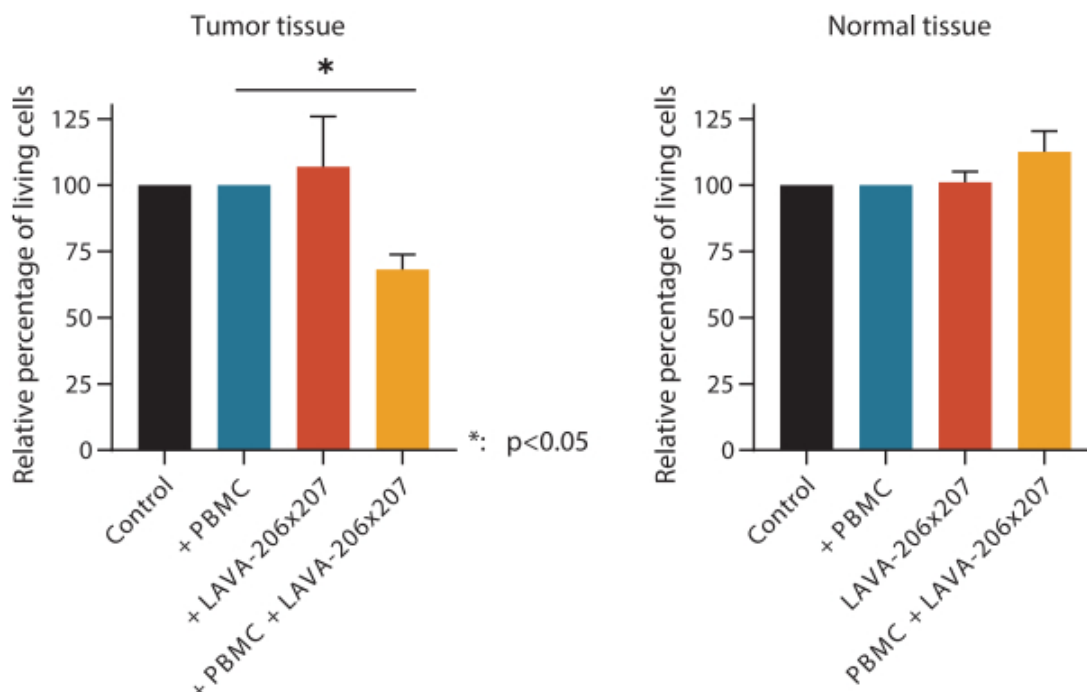
To mimic the *in vivo* setting of a cancer patient treated with LAVA-206x207, we performed an *ex vivo* assay using primary prostate cancer tissue. Single cell suspensions derived from prostate tumor tissue or healthy prostate tissue were incubated overnight with LAVA-206x207, or predecessor compounds, LAVA-014, a non-humanized bispecific VHH, and LAVA-205, a humanized bispecific VHH, after which expression of CD107a, a marker indicating degranulation of cytotoxic granules, was assessed on Vg9Vd2-T cells using flowcytometry. Each compound showed a high potency to induce degranulation of Vg9Vd2 T cells present specifically in prostate tumor tissue, as shown below, and not in healthy prostate tissue, which is not shown.

Further, using flowcytometry, we analyzed lysis of tumor cells mediated by our PSMA specific gamma-delta bsTCEs in an overnight co-culture experiment of dissociated patient prostate tissue samples and expanded allogeneic Vg9Vd2 T cells.

LAVA-206x207 cytotoxic activity directed towards tumor cells in an autologous setting was assessed using a 24-hour co-culture of patient PBMCs containing non-enriched non-stimulated Vg9Vd2 T cells, (n=4) and dissociated patient prostate tumor cells, as shown in panel A below, where we also observed that normal, non-malignant, prostate cells were spared, as shown in panel B below.

**LAVA-206x207 triggered preferential activity of patient PBMC towards autologous prostate cancer cells**

**Killing of prostate cells in tumor non-malignant tissue**



Patient-derived cells derived from dissociated prostate cancer or non-malignant prostate were cultured alone or with patient PBMCs in the presence of LAVA-206x207. Killing of cells was determined after 24 hours.

## [Table of Contents](#)

Altogether, these data support that LAVA-206x207 is able to effectively activate autologous tumor infiltrating V $\beta$ 9V $\delta$ 2 T cells and induce highly specific tumor cell cytotoxicity using autologous V $\beta$ 9V $\delta$ 2 T cells. Based on the preclinical data demonstrated with LAVA-206x207, we believe our novel approach may offer a new therapeutic opportunity for late-stage prostate cancer patients with an unmet medical need.

LAVA-206x207 was evaluated for risk of CRS by performing an *in vitro* cytokine release assay in fresh whole blood from 30 different human donors. Different concentrations of LAVA-206x207, ranging from 280 to 8.75 nM, were tested and the levels of seven pro-inflammatory and anti-inflammatory cytokines (IL-2, IL-4, IL-6, IL-8, IL-10, IFN $\gamma$  and TNF $\alpha$ ) in plasma were measured using an immunoassay. Two control antibodies, Erbitux<sup>®</sup> (cetuximab) and Campath<sup>®</sup> (alemtuzumab), were also included in the assay, as low and high response comparators, respectively. LAVA-206x207 induced the release of only IL-8 and IFN $\gamma$ , but not the other cytokines. The IFN $\gamma$  levels induced by LAVA-206x207 were slightly higher as compared to the levels induced by Erbitux<sup>®</sup>, but the highest IFN $\gamma$  release observed was more than 50 times lower than induced by Campath<sup>®</sup>, an antibody clinically associated with CRS. Importantly, LAVA-206x207 did not induce any IL-6 release, a prominent cytokine in CRS. The CRS risk profile for LAVA206x207 was therefore concluded to be low.

### **Planned LAVA-206x207 phase 1 clinical trial**

We expect to submit CTA/IND applications for LAVA-206x207 in \_\_\_\_\_, and to initiate a Phase 1/2a trial in metastatic castration-resistant prostate cancer in the \_\_\_\_\_. Based on the half-life established, we expect to administer LAVA-206x207 intravenously on a bi-weekly dosing schedule and based on its low potential for CRS, we are starting our clinical study without premedication or step-dosing.

### **Future programs**

Our goal is to become the world leader in antibody-based gamma-delta T cell engager therapies for the treatment of patients with cancer. Given the modularity and reach of our platform, we plan to develop gamma-delta bsTCE therapeutics addressing a wide range of hematologic malignancies and solid tumors.

In addition, behind our two named lead programs, we are advancing a pipeline of discovery programs, including gamma-delta bsTCEs that target EGFR and CD40, that we will prioritize and advance based on a number of criteria, including established unmet medical need for the selected indication, target expression in cancer cells vs healthy tissue, clinically validated TCE or monoclonal antibody approaches, favorable clinical and regulatory development pathways, and evidence that gamma-delta bsTCEs may offer compelling advantages for patients over currently available standards-of-care and therapeutic modalities in development. We expect these programs will provide the opportunity for additional INDs beginning in \_\_\_\_\_.

We also intend to pursue combination therapy, as outlined above in our strategies, with our lead programs, once their respective safety has been established in our initial clinical studies. Standard of care therapy, particularly in hematologic malignancies, is based on combination treatments; the expected good tolerance of our gamma-delta bsTCEs and their MoA makes them ideal candidates for combination with other existing therapies.

## **License agreements**

### **VUmc agreement**

In January 2017, we entered into a license and assignment agreement, or the VUmc Agreement, with Stichting VUmc, or VUmc, and we amended the VUmc Agreement in January 2018 to clarify certain of our financial obligations and in July 2020 to agree on an adapted scope of the rights retained by VUmc and to agree to negotiate a future amendment with respect to certain other financial obligations. Under the VUmc Agreement, VUmc granted us an exclusive, although non-exclusive with respect to certain intangible know-how, worldwide,

## [Table of Contents](#)

sublicensable license under certain patent rights and know-how owned by VUmc 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.

Pursuant to the terms of the VUmc Agreement, in July 2017 VUmc conditionally assigned to us its rights and title to all of the patent rights licensed under the VUmc Agreement. Although we now own all such patent rights, we cannot sell, transfer, or assign such rights (other than in the case of an Exit, as defined in the VUmc Agreement) without VUmc's prior written consent and we must exercise our rights in the assigned patents consistent with the VUmc Agreement. If we intend to abandon any patent or patent application assigned to us under the VUmc Agreement, VUmc has a right to reacquire such patent rights.

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. We are also obligated to pay VUmc a tiered percentage of our value upon the listing of majority of our shares on a stock exchange or other change of control, or an Exit, less certain deductions. The Exit payment is capped at a specified amount in the high-teens of millions of Euros and is subject to an offset in the amount of the royalties that we have paid or that have accrued under the VUmc Agreement as of the date of the Exit.

We are obligated to use commercially reasonable efforts to develop, manufacture, and sell licensed products directly or through our sublicensees during the term or until the second anniversary of an Exit, if earlier.

The VUmc Agreement expires on a country-by-country basis upon the expiration of the last to expire valid claim of the assigned patents in such country. The VUmc Agreement automatically terminates in the case of our bankruptcy or if we cease our present business prior to an Exit. VUmc may terminate the VUmc Agreement for our uncured material breach following a certain cure period. We may terminate the VUmc Agreement for convenience following a certain notice period. Upon any termination of the VUmc Agreement, we are obligated to transfer back to VUmc the assigned patent rights, to cease use of those patent rights and the licensed know-how, and to offer VUmc a right of first negotiation to obtain a license to or acquire relevant intellectual property developed and owned by us for the purpose of continuing the development and commercialization of the patent rights and licensed know-how for a payment to be agreed by us and VUmc in good faith.

### **Janssen collaboration and license agreement**

In May 2020, we entered into a research collaboration and license agreement, or the Janssen Agreement, with Janssen Biotech, Inc., or Janssen, 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

## [Table of Contents](#)

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.

We received an upfront fee of \$8.0 million and have achieved the milestone necessary to receive \$1.0 million research milestone fee 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.

## **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 our own global commercialization and distribution capabilities over time in certain geographies 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.

## 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 gamma-delta bispecific T cell 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, and we 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 Adaptate Biotherapeutics Ltd, Adicet Bio, Inc., Editas Medicine, Inc., GammaDelta Therapeutics Ltd, ImCheck Therapeutics SAS, Immatics Biotechnologies GmbH, Leucid Bio Ltd, PhosphoGam Inc., Shattuck Labs Inc., and 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 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.

As of December 31, 2020, we own, co-own or exclusively license two issued U.S. patents, two pending U.S. patent applications, four pending European regional-phase patent applications four pending PCT patent application, four issued patents in other territories and 17 pending patent applications in other territories that are important to the development of our business.

Our policy is to file patent applications to protect proprietary technology, inventions and improvements to inventions and other intellectual property that may be commercially important to the development of our

## [Table of Contents](#)

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 the section titled “Business—License Agreements.”

### *Our patent portfolio*

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

#### **LAVA-051**

Pursuant to the VUmc Agreement, we have contingent ownership rights to two issued U.S. patents, two U.S. pending patent applications, two pending European patent applications, four foreign issued patents and 17 pending foreign patent applications containing claims or supporting disclosures directed to the LAVA-051 composition of matter and to methods of treating diseases of interest using LAVA-051. We also own one pending PCT patent application related to 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-206x207**

Pursuant to the VUmc Agreement, we have contingent ownership rights to one issued U.S. patent, one U.S. pending patent application, and one pending European patent application, three foreign issued patents and eight foreign pending patent applications containing claims or supporting disclosures directed to the LAVA-206x207 composition of matter and to methods of treating diseases of interest using LAVA-206x207. We also own one pending European patent application related to LAVA-206x207. 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.

For more information on the VUmc Agreement, see the section titled “Business – License Agreements.”

### **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. In addition, in certain instances, the term of a U.S. patent can be extended to recapture a portion of the United States Patent and Trademark Office, or the USPTO, delay in issuing the patent as well as, in the case of a patent that covers an FDA-approved drug or biologic, a portion of the term effectively lost as a result of the FDA regulatory review period. 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

## [Table of Contents](#)

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.

PCT applications are not eligible to become an issued patent until, among other things, we file one or more national stage patent applications within, depending on the country, 30 to 32 months of the PCT application's priority date in the countries in which we seek patent protection. If we do not timely file any national stage patent applications, we may lose our priority date with respect to our PCT patent applications and any patent protection on the inventions disclosed in such patent applications. While we intend to timely file national stage patent applications relating to our PCT patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

The actual protection afforded by a patent may vary on a product-by-product basis, from country to country, and can depend upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

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, as well as in 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 Institutional Review Board, or 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**

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND 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 must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial. Supervision



## [Table of Contents](#)

of human gene transfer trials includes evaluation and assessment by an Institutional Biosafety Committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

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.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called 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

## [Table of Contents](#)

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.

### **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. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured, including, as applicable, for compliance with Good Tissue Practices. 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. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. 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. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. 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. The FDA may require one or more Phase 4 post market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.

### **Expedited development and review programs**

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product 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. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

In 2017, FDA established a new regenerative medicine advanced therapy, or RMAT, designation as part of its implementation of the 21st Century Cures Act. The RMAT designation is intended to fulfill the 21st Century Cures Act requirement that FDA facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. 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. Once approved, when appropriate, the FDA can permit fulfillment of post-approval requirements under accelerated approval through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence such as electronic health records; through the collection of larger confirmatory datasets; or through post-approval monitoring of all patients treated with the therapy prior to approval.

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. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. 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. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee.

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. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. 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. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. 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. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

### **Biosimilars and reference product exclusivity**

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, 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.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

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. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

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.

#### **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 laws, transparency laws, the health information privacy and security laws, and similar state laws, 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 reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers and purchasers on the other. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

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, the federal healthcare programs, including Medicare and Medicaid, 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. A claim includes "any request or demand" for money or property presented to the U.S. government. For instance, historically, pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Additionally, companies have been prosecuted for, among other things, causing false claims to be submitted because of the companies' marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses. Further, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA.

The Health Insurance Portability and Accountability, or HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and



## [Table of Contents](#)

Clinical Health Act, or HITECH, and their 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.

State and foreign laws may also govern the privacy and security of health information in some circumstances. These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts. For example, 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. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose to data subjects (in concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of personal data, defines pseudonymized (i.e., key-coded) data, introduces mandatory data breach notification requirements, and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. Fines for certain breaches of the GDPR are significant: up to the greater of €20 million or 4% of total global annual turnover. Further, following the withdrawal of the United Kingdom from the EU on January 31, 2020, pursuant to the transitional arrangements agreed between the United Kingdom and the EU, we will have to comply with the GDPR and separately the GDPR as implemented in the United Kingdom, each regime having the ability to fine up to the greater of €20 million/£17 million or 4% of global turnover. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, including how data transfers between EU member states and the United Kingdom will be treated. 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, or EEA. Recent developments in the EU have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. In July 2020, the Court of Justice of the European Union, or CJEU, invalidated the EU-US Privacy Shield Framework, or Privacy Shield, under which personal data could be transferred from the EEA to U.S. entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy, subject to certain conditions, of the standard contractual clauses (a standard form contract approved by the European Commission as an adequate personal data transfer mechanism), future regulatory guidance could result in changes to the use of standard contractual clauses. 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.



## [Table of Contents](#)

In addition, California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling certain personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. The CCPA became effective on January 1, 2020 and the California Attorney General may bring enforcement actions for violations beginning July 1, 2020. In addition, California voters recently approved the California Privacy Rights Act of 2020, or CPRA, which goes into effect on January 1, 2023. As currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. It is expected that the CPRA would, among other things, give California residents the ability to limit the use of their personal information, further restrict the use of cross-contextual advertising, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action, provide for increased penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the new law. Moreover, laws in all 50 U.S. states require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

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 also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

In addition, many states and foreign jurisdictions have enacted analogous versions of these laws. For example, many states have similar, and typically more prohibitive, fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts. Further, some states require

## [Table of Contents](#)

pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and relevant federal government compliance guidance and restrict marketing practices or require disclosure of marketing expenditures and pricing information.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. In addition, our activities are potentially subject to federal and state consumer protection and unfair competition 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. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, we cannot be sure that the level of

## [Table of Contents](#)

reimbursement will be adequate. 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. Therefore, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party payor reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. 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.

### **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 has 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 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% 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 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 to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

## [Table of Contents](#)

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- 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 drug samples that manufacturers and distributors provide to physicians;
- 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
- a licensure framework for follow on biologic products.

There have been executive, legal and political challenges to certain aspects of the ACA. Since January 2017, President Trump has signed several executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. In December 2017, the Tax Act was enacted which repealed, effective January 1, 2019, the tax penalty for an individual's failure to maintain ACA-mandated health insurance, commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case, although it is unclear when or how the Supreme Court will rule.

Other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will stay in effect through 2030, other than a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

## [Table of Contents](#)

Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. 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 Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Further, at the states level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. We expect that additional healthcare reform measures will be adopted in the future, particularly in light of the recent U.S. presidential election. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

### **The foreign corrupt practices act**

The Foreign Corrupt Practices Act, or 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 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.

### **Employees**

As of December 31, 2020, we had 31 employees (including 28 full time employees), sixteen of whom hold M.D. or Ph.D. degrees. Twenty-five of our employees work in research and development and six 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.

## **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 believe that our facilities are adequate to meet our current needs and that additional space can be obtained on commercially reasonable terms as needed.

## **Legal proceedings**

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We are not currently aware of any such proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

# Management

## Board structure

Prior to the consummation of this offering, we will continue to have a two-tier board structure consisting of a management board (*bestuur*) and a separate supervisory board (*raad van commissarissen*). Stephen Hurly and Paul Parren are currently the only two members of our management board. Stefan E. Luzi, Guido Magni, Reza Halse, Erik J. van den Berg, Laia Crespo Martin, Nanna L. Lüneborg and Joël J.P. Jean-Mairet currently serve on our supervisory board. As part of our reorganization and immediately prior to the consummation of this offering, we will transition from a two-tier board structure to a one-tier board structure consisting of a board of directors consisting of executive and non-executive directors, as outlined below. There are no family relationships among any of our directors.

## Board of directors

Upon completion of our reorganization and immediately prior to the consummation of this offering, our board of directors is expected to be composed of \_\_\_\_\_ members, comprised of \_\_\_\_\_ executive directors, whom we consider to be one of our executive officers, and \_\_\_\_\_ non-executive directors. We are currently reviewing the composition of our board of directors and our corporate governance practices in light of this offering and applicable requirements of the SEC and Nasdaq. In subsequent filings with the SEC, we will update any relevant disclosures herein as appropriate. Following the closing of this offering, each of our directors will hold office for the term set by our general meeting (as set forth in the table below), 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.

The following table lists our current directors, as well as their ages, term served, the year of expiration of their term as directors following the closing of this offering and position:

Name	Age	Term served	Year in which term expires	Position
Erik J. van den Berg	48	January 2017—Present		Chairperson
Joël J.P. Jean-Mairet	49	September 2020—Present		Director
Nanna Lüneborg	45	September 2020—Present		Director
Stefan Luzi	37	January 2018—Present		Director
Guido Magni	67	May 2018—Present		Director

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

**Erik J. van den Berg** has served as one of our supervisory directors since January 2017 and as Chairperson of our supervisory board since March 2018, and will continue to serve as a non-executive director following the closing of this offering. 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 Masters 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 one of our supervisory directors since 2019 and will continue to serve as a non-executive director following the closing of this offering. 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 Lüneborg, Ph.D.**, has served as one of our supervisory directors since September 2020 and will continue to serve as a non-executive director following the closing of this Offering. She has 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. Lüneborg 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. Lüneborg 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 one of our supervisory directors since January 2018 and will continue to serve as a non-executive director following the closing of this offering. 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 one of our supervisory directors since May 2018 and will continue to serve as a non-executive director following the closing of this offering. 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, Piquor Therapeutics AG 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.



## Executive officers

The following table presents information about our current executive officers, including their ages as of the date of this prospectus:

Name	Age	Position
Stephen Hurly	53	Chief Executive Officer
Benjamin Winograd	65	Chief Medical Officer
Hans van der Vliet	47	Chief Scientific Officer
Ton Adang	60	Chief Development Officer
Paul Parren	57	Head of R&D
Peter Ros	49	Vice President, Finance

## Executive officers

The following is a brief summary of the business experience of certain of our key employees.

**Stephen Hurly** has served as our President, Chief Executive Officer and as one of our management directors 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.

**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 pomalidomide (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.

**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

## [Table of Contents](#)

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.

**Paul W.H.I. Parren, Ph.D.**, has served as our Executive Vice President and Head of Research & 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.

**Peter Ros** has served as our Vice President of Finance since January 2020. Prior to joining Lava Therapeutics, he served in various roles at Genmab, including as Senior Director of Accounting and Finance from October 2018 to December 2019, Senior Director of Finance and Accounting, R&D Operations from July 2015 to September 2018, and Senior Director of Finance from November 2001 to June 2015. Mr. Ros also served as an Accountant at PricewaterhouseCoopers from September 1993 to April 1999. He received a RA in accountancy from VU Amsterdam and his HEAO RA in accountancy from Windesheim University.

## Committees

### **Audit committee**

The audit committee is expected to consist of \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_. The audit committee will assist the board of directors in overseeing our accounting and financial reporting processes and the audits of our financial statements. \_\_\_\_\_ will serve as chairperson of the audit committee. In addition, the audit committee will be 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 \_\_\_\_\_ satisfies the "independence" requirements set forth in Rule 10A-3 under the Exchange Act and qualifies as an "audit committee financial expert," as such term is defined in the rules of the SEC.

We intend to rely on the phase-in rules of the SEC and Nasdaq with respect to the independence of our audit committee. These rules require that all members of our audit committee must meet the independence standard for audit committee membership within one year of the effectiveness of the registration statement of which this prospectus forms a part. The audit committee will be governed by a charter that complies with applicable Nasdaq rules, which charter will be posted on our website prior to the listing of our common shares on Nasdaq.

### **Compensation committee**

The compensation committee is expected to consist of \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_. The compensation committee will assist the board of directors in determining compensation for our executive officers and our directors. \_\_\_\_\_ will serve as chairperson of the compensation committee.

## [Table of Contents](#)

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 will opt out of Nasdaq Listing Rule 5605(d), which requires that a compensation committee consist entirely of independent directors. The compensation committee will be governed by a charter that will be posted on our website prior to the listing of our common shares on Nasdaq.

### ***Nomination and corporate governance committee***

The nomination and corporate governance committee is expected to consist of \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_. The nomination and corporate governance committee will assist 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. \_\_\_\_\_ will serve as chairperson of the nomination and corporate governance committee.

As permitted by the listing requirements of Nasdaq, we will opt out of Nasdaq Listing Rule 5605(e), which requires independent director oversight of director nominations. The nominating and corporate governance committee will be governed by a charter that will be posted on our website prior to the listing of our common shares on Nasdaq.

### **Code of business conduct and ethics**

Prior to the closing of this offering, we will adopt a written code of business conduct and ethics, or code of conduct, which outlines the principles of legal and ethical business conduct under which we do business. The code of conduct will apply to all of our directors and employees. Upon the closing of this offering, the full text of the code of conduct will be available on our website at [www.lavatherapeutics.com](http://www.lavatherapeutics.com). The information and other content appearing on our website are not part of this prospectus.

### **Executive officer employment agreements**

Each of our executive officers has entered into an employment agreement with us for an indefinite period of time. We plan to enter into amended employment agreements with each of our executive officers in connection with this offering.

### **Compensation of board of directors and certain executive officers**

The aggregate compensation, including benefits in kind, accrued or paid to our senior management with respect to the year ended December 31, 2020, for services in all capacities was € \_\_\_\_\_. In 2020, we granted \_\_\_\_\_ options under our Employee Stock Option Plan to our senior management.

Dutch law provides that we must establish a policy in respect of the remuneration of our directors. Such policy addresses the following topics: the fixed and variable components of the remuneration (if any), remuneration in the form of shares and severance payments. Prior to the consummation of this offering, our general meeting of shareholders will adopt such a policy to be proposed by the board of directors. The board of directors determines the remuneration of the directors in accordance with the remuneration policy. Our executive directors may not participate in the discussions or decision-making regarding the remuneration of our executive directors. A proposal by the board of directors with respect to remuneration schemes in the form of shares or rights to shares in which directors may participate must be submitted by the board of directors to the general meeting for its approval. This proposal must set out at least the maximum number of shares or rights to shares to be granted to the directors and the criteria for granting or amendment.

## [Table of Contents](#)

The aggregate compensation, including benefits in kind, accrued or paid to our directors with respect to the year ended December 31, 2020 for services in all capacities was approximately € . As of December 31, 2020, we have no amounts set aside or accrued to provide pension, retirement or similar benefits to our directors.

### **Insurance and indemnification**

Following the consummation of this offering and subject to certain exemptions, our current and former directors and other current and former officers and employees as designated by our board of directors will have the benefit of indemnification provisions set forth in our articles of association. These provisions give our current and former directors and other current and former officers and employees as designated by our board of directors the right, to the extent permitted by applicable law, to recover from us amounts, including but not limited to any financial losses or damages and any expense reasonably paid or incurred by such indemnified person in connection with any threatened, pending or completed suit, action or legal proceedings of a civil, criminal, administrative or other nature, formal or informal, in which such indemnified person became involved, to the extent this relates to its current or form position with us and/or our group companies and in each case to the extent permitted by applicable law. However, no indemnification shall be given to an indemnified person; (i) if a competent court or arbitral tribunal has established, without having (or no longer having) the possibility for appeal, that the acts or omissions of such indemnified person that led to the financial losses, damages, expenses, suit, claim, action or legal proceedings as described above are of an unlawful nature (including acts or omissions which are considered to constitute malice, gross negligence, intentional recklessness and/or serious culpability attributable to such indemnified person); (ii) to the extent that his or her financial losses, damages and expenses are covered under insurance and the relevant insurer has settled, or has provided reimbursement for, these financial losses, damages and expenses (or has irrevocably undertaken to do so); (iii) in relation to proceedings brought by such indemnified person against our company, except for proceedings brought to enforce indemnification to which he is entitled pursuant to our articles of association, pursuant to an agreement between such indemnified person and our company which has been approved by our board of directors or pursuant to insurance taken out by our company for the benefit of such indemnified person; and (iv) for any financial losses, damages or expenses incurred in connection with a settlement of any proceedings effected without our prior consent. There is generally no entitlement to indemnification for acts or omissions that amount to willful (*opzettelijk*), intentionally reckless (*bewust roekeloos*) or seriously culpable (*ernstig verwijtbaar*) conduct. In addition, upon the consummation of this offering, we intend to enter into agreements with our directors to indemnify them against expenses and liabilities to the fullest extent permitted by law. These agreements will also provide, subject to certain exceptions, for indemnification for related expenses including, among other expenses, attorneys' fees, judgments, penalties, fines and settlement amounts incurred by any of these individuals in any action or proceeding. In addition to such indemnification, we provide our directors with directors' and officers' liability insurance.

### **Compensation committee interlocks and insider participation**

None of our senior management has served as a member of a compensation committee (or if no committee performs that function, the board of directors) of any other entity that has a member of key management serving as a member of our board of directors.

### **Remuneration and other benefits to directors for the year ended December 31, 2020**

As a foreign private issuer, in accordance with Nasdaq listing requirements, we will 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

---

## [Table of Contents](#)

compensation paid to our directors, provided that such compensation is consistent with our compensation policy. Such compensation policy will be adopted by our general meeting prior to the closing of this offering. Changes to such compensation policy will require a vote of our general meeting by simple majority of votes cast. The board of directors determines the remuneration of individual directors with due observance of the compensation policy. A proposal with respect to remuneration schemes in the form of shares or rights to shares in which directors may participate is subject to approval by our general meeting by simple majority of votes cast. Such a proposal must set out at least the maximum number of shares or rights to subscribe for shares to be granted to the directors and the criteria for granting or amendment.

Our compensation policy will authorize our board of directors 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.

### **Long-term incentive plan**

In connection with this offering, we intend to establish a long-term incentive plan, or the Plan, pursuant to which we may grant options, restricted stock, restricted stock units, share appreciation rights and other equity and equity-based awards. The maximum number of common shares underlying awards granted pursuant to the Plan will in total not exceed % of our issued share capital from time to time. The Plan will be administered by our board of directors (where appropriate on the basis of a recommendation of our compensation committee). We may grant awards under the Plan to our officers, directors, employees, consultants or other advisors. We may condition awards under the Plan upon the achievement or satisfaction of performance criteria and we will determine the vesting conditions for awards under the Plan. The Plan will provide for special provisions for good leavers and bad leavers as well as for a change in control of our company.

## Principal shareholders

As of the date of this prospectus, our authorized share capital amounts to € \_\_\_\_\_, divided into \_\_\_\_\_ common shares and \_\_\_\_\_ preferred shares, each with a nominal value of €0.12.

The following table sets forth information relating to the beneficial ownership of our common shares as of June 30, 2020 after giving effect to the conversion of all of our outstanding preferred shares into an aggregate of \_\_\_\_\_ common shares immediately prior to the consummation of this offering, as adjusted to reflect the sale of common shares in this offering, by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding common shares;
- each of our board members; and
- all board members as a group.

The number of common shares beneficially owned by each entity, person, board member 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 shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of December 1, 2020 through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all common shares held by that person.

The percentage of shares beneficially owned before the offering is computed on the basis of \_\_\_\_\_ of our common shares as of \_\_\_\_\_, 2020, after giving effect to the conversion of all of our outstanding preferred shares into an aggregate of \_\_\_\_\_ common shares immediately prior to the consummation of this offering. The percentage of shares beneficially owned after the offering is based on the number of our common shares to be outstanding after this offering, including the \_\_\_\_\_ of our common shares that we are selling in this offering, and assumes no exercise of the underwriters' option to purchase additional common shares from us. Common shares that a person has the right to acquire within 60 days of December 31, 2020 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all board members as a group. As of December 31, 2020, after giving effect to the conversion of all of our outstanding preferred shares into an aggregate of \_\_\_\_\_ common shares immediately prior to the consummation of this offering, \_\_\_\_\_ common shares, representing \_\_\_\_\_ % of our issued and outstanding common shares, were held by \_\_\_\_\_ U.S. record holders. Unless otherwise indicated below, the address for each beneficial owner listed is c/o LAVA Therapeutics, at Yalelaan 60, 3584 CM Utrecht, the Netherlands.

[Table of Contents](#)

Name and address of beneficial owner	Shares beneficially owned before the offering		Shares beneficially owned after the offering	
	Number	Percent	Number	Percent
<b>5% or Greater Shareholders</b>				
Coöperatieve Gilde Healthcare IV U.A.			%	%
Versant Venture Capital VI, L.P.				
Novo Holdings A/S(1)				
Sanofi Foreign Participations B.V.				
Entities affiliated with Redmile Group, LLC				
Ysios BioFund III FCRE				
MRL Ventures Fund, LLC				
<b>Board Members and Senior Management</b>				
Stephen Hurly				
Paul Parren				
Benjamin Winograd				
Ton Adang				
Hans van der Vliet				
Peter Ros				
Erik van den Berg				
Joël Jean-Mairet				
Nanna Lüneborg(2)				
Stefan Luzi				
Guido Magni				
<b>All board members and senior management as a group (  persons)</b>				

\* Indicates beneficial ownership of less than 1% of the total outstanding common shares.

- (1) Consists of shares held by Novo Holdings A/S (Novo). The board of directors of Novo (the Novo Board) has shared voting and investment power with respect to the shares held by Novo and may exercise such control only with the support of a majority of the members of the Novo Board. As such, no individual member of the Novo Board is deemed to hold any beneficial ownership or reportable pecuniary interest in the shares held by Novo. Dr. Lüneborg, a member of our board of directors, is employed as a Partner at Novo and is not deemed to have beneficial ownership of the shares held by Novo. The address for Novo is Tuborg Havnevej 19, DK-2900 Hellerup, Denmark.
- (2) Dr. Lüneborg, a member of our board of directors, is employed as a partner at Novo Holdings A/S. Dr. Lüneborg is not deemed to hold any beneficiary ownership or reportable pecuniary interest in the shares held by Novo Holdings A/S.

## Related party transactions

The following is a description of related party transactions we have entered into since January 1, 2018 with any members of our board of directors and the holders of more than 5% of our common shares.

### Preferred Series A financing

In June 2017, we issued an aggregate of 7,945 shares of Preferred Series A at a price per share of €134.04 for an aggregate purchase price of €1.07 million.

The following table sets forth the aggregate number of our shares of Preferred Series A purchased by our board members and 5% shareholders and their affiliates. Each share of Preferred Series A identified in the following table will be converted into one (1) common shares in connection with this offering.

	<b>Shares of Preferred Series A</b>
<b>Participants(1)</b>	
Erik van den Berg	245

(1) Additional details regarding these shareholders and their equity holdings is provided in "Principal Shareholders."

### Preferred Series B financing

In January 2018, we issued an aggregate of 17,646 shares of Preferred Series B at a price per share of €906.78 for an aggregate purchase price of €16.0 million.

The following table sets forth the aggregate number of our shares of Preferred Series B purchased by our board members and 5% shareholders and their affiliates. Each share of Preferred Series B identified in the following table will be converted into one (1) common share in connection with this offering.

	<b>Shares of Preferred Series B</b>
<b>Participants(1)</b>	
Coöperatieve Gilde Healthcare IV U.A.	7,720
Versant Venture Capital VI, L.P.	7,720
MRL Ventures Fund, LLC	2,206

(1) Additional details regarding these shareholders and their equity holdings is provided in "Principal Shareholders".



## Preferred Series C financing

In September 2020, we issued an aggregate of 18,705 shares of Preferred Series C at a price per share of €1019.67 for an aggregate purchase price of €19.0 million.

The following table sets forth the aggregate number of our shares of Preferred Series C purchased by our board members and 5% shareholders and their affiliates. Each share of Preferred Series C identified in the following table will be converted into one (1) common share in connection with this offering.

<b>Participants(1)</b>	<b>Shares of Preferred Series C</b>
MRL Ventures Fund, LLC	791
Coöperatieve Gilde Healthcare IV U.A.	3,164
Entities affiliated with Versant Venture Capital VI, L.P.	3,164
Novo Holdings A/S	3,956
Sanofi Foreign Participations B.V.	2,373
Ysios BioFund III FCRE	1,582
Entities affiliated with Redmile Group, LLC	2,357

(1) Additional details regarding these shareholders and their equity holdings is provided in "Principal Shareholders".

## Shareholders' agreement

We and all of our then-existing shareholders entered into a shareholders' agreement on September 15, 2020. While the shareholders' agreement will terminate upon the consummation of this offering, certain provisions of this agreement, including our obligation to enter into a registration rights agreement with certain of our existing shareholders upon the consummation of this offering, will survive upon the consummation of the offering.

## Indemnification agreements

Our articles of association, as they will be effective upon the closing of the offering, will require us to indemnify our current and former directors to the fullest extent permitted by law, subject to certain exceptions. Prior to the closing of this offering, we will enter into indemnification agreements with all of our directors.

## Related person transaction policy

Upon to the consummation of this offering, we will adopt a related person transaction policy. Under this policy, related person transactions (as defined by the policy) must be reviewed by, and will be 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.

# Description of share capital and articles of association

## General

We were incorporated under the laws of the Netherlands on February 15, 2016, as a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*), and prior to the consummation of this offering, we intend to convert into a Dutch public company with limited liability (*naamloze vennootschap*). See “Corporate Reorganization”. Our principal executive offices are located at Yalelaan 60, 3584 CM Utrecht, the Netherlands. Our telephone number at this address is +31 6 3000 3035.

The following is a summary of material information concerning our share capital and our articles of association as they will read upon the closing of this offering. The summaries of our articles of association as set forth herein are qualified in their entirety by reference to the full text of our articles of association. This summary does not constitute legal advice regarding those matters and should not be regarded as such.

## Share capital

As of the date of this prospectus, we have an issued share capital in the amount of € , divided into common shares, each with a nominal value of €0.12.

Under Dutch law, our authorized share capital is the maximum capital that we may issue without amending our articles of association. An amendment of our articles of association would require a resolution of the general meeting upon proposal by our board of directors. Upon the closing of this offering, our authorized share capital will amount to € , divided into common shares and preferred shares, each with a nominal value of €0.12.

We intend to apply to list our common shares on Nasdaq under the symbol “LVRX.”

Initial settlement of our common shares issued in this offering will take place on the closing date of this offering through The Depository Trust Company, or DTC, in accordance with its customary settlement procedures for equity securities. Each person owning common shares held through DTC must rely on the procedures thereof and on institutions that have accounts therewith to exercise any rights of a holder of the common shares.

Upon the closing of this offering, our articles of association will provide that, for as long as any of our common shares are admitted to trading on Nasdaq, the New York Stock Exchange or on any other regulated stock exchange operating in the United States, the laws of the State of New York shall apply to the property law aspects of our common shares reflected in the register administered by our transfer agent, subject to certain overriding exceptions under Dutch law.

## Common shares

The following summarizes the main rights of holders of our common shares:

- each holder of common shares is entitled to one vote per share on all matters to be voted on by shareholders generally, including the appointment of directors;
- there are no cumulative voting rights;
- the holders of our common shares are entitled to dividends and other distributions as may be declared from time to time by us out of funds legally available for that purpose, if any, following payment of the preferred dividend if any preferred shares are or have been outstanding (to the extent holders or former holders of preferred shares are entitled to such distribution under our articles of association);

## Table of Contents

- upon our liquidation and dissolution, the holders of common shares will be entitled to share ratably in the distribution of all of our assets remaining available for distribution after satisfaction of all our liabilities, following payment of the preferred dividend if any preferred shares are or have been outstanding (to the extent holders or former holders of preferred shares are entitled to such distribution under our articles of association); and
- the holders of our common shares have pre-emption rights in case of share issuances or the grant of rights to subscribe for shares, except if such rights are limited or excluded by the corporate body authorized to do so and except in such cases as provided by Dutch law and our articles of association.

### **Shareholders' register**

Pursuant to Dutch law and our articles of association, we must keep our shareholders' register accurate and current. The board of directors keeps our shareholders' register and records names and addresses of all holders of registered shares, showing the date on which the shares were acquired, the date of the acknowledgement by or notification of us as well as the amount paid on each share. The register also includes the names and addresses of those with a usufruct (*vruchtgebruik*) on registered shares belonging to another or a pledge (*pandrecht*) in respect of such shares. The common shares offered in this offering will be held through DTC. Therefore, DTC or its nominee will be recorded in the shareholders' register as the holder of those common shares. Our common shares and preferred shares, if any, shall be in registered form (op naam). We may issue share certificates (*aandeelbewijzen*) for registered shares in such form as may be approved by our board of directors.

### **Corporate objectives**

Pursuant to the articles of association as they will read upon the closing of this offering, our main corporate objectives are:

- to, either individually or jointly or with other entities, engage in cellular therapy, immunotherapy and other oncological therapies and the fight against cancer (cells), as well as the development of products, intellectual property, the acquiring thereof and to register patentable findings and the performing of medical, commercial and industrial activities in the widest sense of the word;;
- to incorporate, to cooperate with, to participate in, to hold any other interest in, to take over and to manage or supervise companies and other legal entities, partnerships and businesses;
- to finance companies and other legal entities, partnerships and businesses also by providing securities or guarantees, by warranting performance in any other way and by assuming liability, whether jointly and severally or otherwise, in respect of obligations;
- to acquire, manage and alienate registered property and items of property in general, securities and other valuable papers, to borrow and to lend funds and to grant guarantees on behalf of third parties;
- to make periodic payments, to administer pension schemes and to arrange for annuity contracts,
- to do anything which, in the widest sense, is connected with or may be conducive to the objectives described above.

### **Limitations on the rights to own securities**

Our common shares may be issued to individuals, corporations, trusts, estates of deceased individuals, partnerships and unincorporated associations of persons. Our articles of association contain no limitation on the rights to own our shares and no limitation on the rights of non-residents of the Netherlands or foreign shareholders to hold or exercise voting rights. Following the closing of this offering, it is our intention that our preferred shares shall only be issued to the protective foundation, if and when incorporated.

### **Limitation on liability and indemnification matters**

Under Dutch law, our directors may be held liable for damages in the event of improper or negligent performance of their duties. They may be held jointly and severally liable for damages to our company and to third parties for infringement of our articles of association or of certain provisions of Dutch law. In certain circumstances, they may also incur additional specific civil and criminal liabilities. Subject to certain exceptions, our articles of association provide for indemnification of our current and former directors and other current and former officers and employees as designated by our board of directors. No indemnification under our articles of association shall be given to an indemnified person:

- if a competent court or arbitral tribunal has established, without having (or no longer having) the possibility for appeal, that the acts or omissions of such indemnified person that led to the financial losses, damages, expenses, suit, claim, action or legal proceedings as described above are of an unlawful nature (including acts or omissions which are considered to constitute malice, gross negligence, intentional recklessness and/or serious culpability attributable to such indemnified person);
- to the extent that his or her financial losses, damages and expenses are covered under insurance and the relevant insurer has settled, or has provided reimbursement for, these financial losses, damages and expenses (or has irrevocably undertaken to do so);
- in relation to proceedings brought by such indemnified person against our company, except for proceedings brought to enforce indemnification to which he is entitled pursuant to our articles of association, pursuant to an agreement between such indemnified person and our company which has been approved by our board of directors or pursuant to insurance taken out by our company for the benefit of such indemnified person; and
- for any financial losses, damages or expenses incurred in connection with a settlement of any proceedings effected without our prior consent.

Under our articles of association, our board of directors may stipulate additional terms, conditions and restrictions in relation to the indemnification described above.

### **Shareholders' meetings**

General meetings may be held in Amsterdam, Arnhem, Assen, The Hague, Haarlem, 's-Hertogenbosch, Groningen, Leeuwarden, Lelystad, Maastricht, Middelburg, Rotterdam, Schiphol (*Haarlemmermeer*), Utrecht or Zwolle, all in the Netherlands. The annual general meeting must be held within six months of the end of each financial year. Additional extraordinary general meetings may also be held, whenever considered appropriate by our board of directors and shall be held within three months after our board of directors has considered it to be likely that our shareholders' equity (*eigen vermogen*) has decreased to an amount equal to or lower than half of our paid-in and called up share capital, in order to discuss the measures to be taken if so required.

Pursuant to Dutch law, one or more shareholders or others with meeting rights under Dutch law who jointly represent at least one-tenth of our issued share capital may request us to convene a general meeting, setting out in detail the matters to be discussed. If we have not taken the steps necessary to ensure that such meeting can be held within six weeks after the request, the proponent(s) may, on their application, be authorized by the competent Dutch court in preliminary relief proceedings to convene a general meeting. The court shall disallow the application if it does not appear that the proponent(s) has/have previously requested our board of directors to convene a general meeting and our board of directors has not taken the necessary steps so that the general meeting could be held within six weeks after the request.

General meetings must be convened by an announcement published in a Dutch daily newspaper with national distribution. The notice must state the agenda, the time and place of the meeting, the record date (if any), the

## [Table of Contents](#)

procedure for participating in the general meeting by proxy, as well as other information as required by Dutch law. The notice must be given at least 15 calendar days prior to the day of the meeting. The agenda for the annual general meeting shall include, among other things, the adoption of our statutory annual accounts, appropriation of our profits and proposals relating to the composition of the board of directors, including the filling of any vacancies. In addition, the agenda shall include such items as have been included therein by our board of directors. The agenda shall also include such items requested by one or more shareholders or others with meeting rights under Dutch law representing at least 3% of our issued share capital. These requests must be made in writing or by electronic means and received by us at least 60 days before the day of the meeting. No resolutions shall be adopted on items other than those that have been included in the agenda.

In accordance with the DCGC and our articles of association, shareholders having the right to put an item on the agenda under the rules described above shall exercise such right only after consulting the board of directors in that respect. If one or more shareholders intend to request that an item be put on the agenda that may result in a change in our strategy (for example, the dismissal of directors), our board of directors must be given the opportunity to invoke a reasonable period to respond to such intention. Such period shall not exceed 180 days (or such other period as may be stipulated for such purpose by Dutch law and/or the DCGC from time to time). If invoked, our board of directors must use such response period for further deliberation and constructive consultation, in any event with the shareholder(s) concerned, and shall explore the alternatives. At the end of the response time, our board of directors shall report on this consultation and the exploration of alternatives to the general meeting. The response period may be invoked only once for any given general meeting and shall not apply: (a) in respect of a matter for which a response period has been previously invoked; or (b) if a shareholder holds at least 75% of our issued share capital as a consequence of a successful public bid. The response period may also be invoked in response to shareholders or others with meeting rights under Dutch law requesting that a general meeting be convened, as described above.

The general meeting is presided over by the chairperson of our board of directors. If no chairperson has been elected or if he or she is not present at the meeting, the general meeting shall be presided over by the vice-chairperson of our board of directors. If no vice-chairperson has been elected or if he or she is not present at the meeting, the general meeting shall be presided over by a person designated in accordance with our articles of association. Directors may always attend a general meeting. In these meetings, they have an advisory vote. The chairperson of the meeting may decide at his or her discretion to admit other persons to the meeting.

All shareholders and others with meeting rights under Dutch law are authorized to attend the general meeting, to address the meeting and, in so far as they have such right, to vote pro rata to his or her shareholding. Shareholders may exercise these rights, if they are the holders of shares on the record date, if any, as required by Dutch law, which is currently the 28th day before the day of the general meeting. Under our articles of association, shareholders and others with meeting rights under Dutch law must notify us in writing or by electronic means of their identity and intention to attend the general meeting. This notice must be received by us ultimately on the seventh day prior to the general meeting, unless indicated otherwise when such meeting is convened.

Each common and each preferred share, if any are outstanding, share confers the right on the holder to cast one vote at the general meeting. Shareholders may vote by proxy. No votes may be cast at a general meeting on shares held by us or our subsidiaries or on shares for which we or our subsidiaries hold depository receipts. Nonetheless, the holders of a usufruct (*vruchtgebruik*) and the holders of a right of pledge (*pandrecht*) in respect of shares held by us or our subsidiaries in our share capital are not excluded from the right to vote on such shares, if the usufruct (*vruchtgebruik*) or the right of pledge (*pandrecht*) was granted prior to the time such shares were acquired by us or any of our subsidiaries. Neither we nor any of our subsidiaries may cast votes in respect of a share on which we or such subsidiary holds a usufruct (*vruchtgebruik*) or a right of pledge (*pandrecht*). Shares which are not entitled to voting rights pursuant to the preceding sentences will not be

## [Table of Contents](#)

taken into account for the purpose of determining the number of shareholders that vote and that are present or represented, or the amount of the share capital that is provided or that is represented at a general meeting.

Decisions of the general meeting are taken by a simple majority of votes cast, except where Dutch law or our articles of association provide for a qualified majority or unanimity and/or a quorum.

### **Directors**

#### *Appointment of directors*

Our directors will be appointed by the general meeting upon binding nomination by our board of directors. However, the general meeting may at all times overrule a binding nomination by a resolution adopted by at least a two-thirds majority of the votes cast, provided such majority represents more than half of the issued share capital. If the general meeting overrules a binding nomination, the board of directors has the exclusive right to make a new nomination.

Prior to the closing of this offering, our board of directors shall adopt a diversity policy for the composition of our board of directors, as well as a profile for the composition of our board of directors. The board of directors shall make any nomination for the appointment of a director with due regard to the rules and principles set forth in such diversity policy and profile, as applicable.

At a general meeting, a resolution to appoint a director can only be passed in respect of candidates whose names are stated for that purpose in the agenda of that general meeting or in the explanatory notes thereto.

#### *Duties and liabilities of directors*

Under Dutch law, the board of directors is charged with the management of the company, subject to the restrictions contained in our articles of association. Our executive directors manage our day-to-day business and operations and implement our strategy. Our non-executive directors focus on the supervision on the policy and functioning of the performance of the duties of all of our directors and our general state of affairs. The directors may divide their tasks among themselves in or pursuant to internal rules and in accordance with Dutch law. Each director has a statutory duty to act in the corporate interest of our company and its business. Under Dutch law, the corporate interest extends to the interests of all corporate stakeholders, such as shareholders, creditors, employees, customers and suppliers. The duty to act in the corporate interest of our company also applies in the event of a proposed sale or break-up of our company, provided that the circumstances generally dictate how such duty is to be applied and how the respective interests of various groups of stakeholders should be weighed.

Our board of directors is entitled to represent our company. The power to represent our company also vests in our Chief Executive Officer acting individually or any two other executive directors acting jointly.

#### *Dividends and other distributions*

Under Dutch law, we may only pay dividends and other distributions from our reserves to the extent our shareholders' equity (eigen vermogen) exceeds the sum of our paid-in and called-up share capital plus the reserves we must maintain under Dutch law or our articles of association and (if it concerns a distribution of profits) after adoption of our statutory annual accounts by our general meeting from which it appears that such dividend distribution is allowed.

Under our articles of association as they will read upon the closing of this offering, if any preferred shares are or have been outstanding, a dividend is first paid out of our profits, if available for distribution, to the holders

## [Table of Contents](#)

or former holders, as applicable, of those preferred shares to the extent they are entitled to such distribution under our articles of association, which we refer to as our preferred dividend. Thereafter, our board of directors, may decide that all or part of the remaining profits shown in our adopted statutory annual accounts will be added to our reserves. After reservation of any such profits, any remaining profits will be at the disposal of the general meeting at the proposal of our board of directors for distribution on our common shares, subject to applicable restrictions of Dutch law as set out in the previous paragraph. Our board of directors, is permitted, subject to certain requirements and applicable restrictions of Dutch law, to declare interim dividends without the approval of our general meeting. Dividends and other distributions shall be made payable no later than a date determined by us. Claims to dividends and other distributions not made within five years from the date that such dividends or distributions became payable will lapse and any such amounts will be considered to have been forfeited to us (*verjaring*).

### *Exchange controls*

Under Dutch law, there are no exchange controls applicable to the transfer to persons outside of the Netherlands of dividends or other distributions with respect to, or of the proceeds from the sale of, shares of a Dutch company, subject to applicable restrictions under sanctions and measures, including those concerning export control, pursuant to European Union regulations, the Sanctions Act 1977 (*Sanctiewet 1977*) or other legislation, applicable anti-boycott regulations, applicable anti-money-laundering regulations and similar rules. There are no special restrictions in our articles of association or Dutch law that limit the right of shareholders who are not citizens or residents of the Netherlands to hold or vote shares.

### *Squeeze out procedures*

A shareholder who holds at least 95% of our issued share capital for his or her own account, alone or together with group companies, may initiate proceedings against our other shareholders jointly for the transfer of their shares to such shareholder. The proceedings are held before the Enterprise Chamber of the Amsterdam Court of Appeal, or the Enterprise Chamber (*Ondernemingskamer*), and can be instituted by means of a writ of summons served upon each of the other shareholders in accordance with the provisions of the Dutch Code of Civil Procedure (*Wetboek van Burgerlijke Rechtsvordering*). The Enterprise Chamber may grant the claim for squeeze-out in relation to the other shareholders and will determine the price to be paid for the shares, if necessary, after appointment of one or three experts who will offer an opinion to the Enterprise Chamber on the value to be paid for the shares of the other shareholders. Once the order to transfer becomes final before the Enterprise Chamber, the person acquiring the shares shall give written notice of the date and place of payment and the price to the holders of the shares to be acquired whose addresses are known to him. Unless the addresses of all of them are known to the acquiring person, such person is required to publish the same in a Dutch daily newspaper with a national circulation.

### *Dissolution and liquidation*

Under our articles of association, we may be dissolved by a resolution of the general meeting, subject to a proposal of our board of directors. In the event of a dissolution, the liquidation shall be effected by our board of directors, unless the general meeting decides otherwise. During liquidation, the provisions of our articles of association will remain in force as far as possible. To the extent that any assets remain after payment of all of our liabilities, if any preferred shares are or have been outstanding, a liquidation distribution equal to the preferred dividend is first paid out to the holders or former holders of those preferred shares (to the extent they are entitled to such distribution under our articles of association). Thereafter, any remaining assets shall be distributed to our shareholders in proportion to their number of shares.

## **Dutch corporate governance codes**

Upon the closing of this offering, we will be subject to the Dutch Corporate Governance Code, or the DCGC. The DCGC contains principles and best practice provisions on corporate governance that regulate relations between the board of directors and the general meeting and matters in respect of financial reporting, auditors, disclosure, compliance and enforcement standards. The DCGC is based on a “comply or explain” principle. Accordingly, companies must disclose in their statutory annual reports whether they comply with the provisions of the DCGC. If a company subject to the DCGC does not comply with those provisions, that company would be required to give the reasons for such non-compliance. We do not comply with all best practice provisions of the DCGC. As of the date of this prospectus, our main deviations from the DCGC are summarized below, but we cannot exclude the possibility of deviating from additional provisions of the DCGC after the date hereof, including in order to follow market practice or governance practices in the United States.

Under our articles of association, directors are to be appointed on the basis of a binding nomination prepared by our board of directors. This means that the nominee will be appointed unless the general meeting removes the binding nature of the nomination (in which case a new nomination will be prepared by the board of directors for a subsequent general meeting). Our articles of association provide that the general meeting can only pass such resolution by a two-thirds majority representing more than half of the issued share capital. However, the DCGC recommends that the general meeting can pass such a resolution by simple majority, representing no more than one-third of the issued share capital.

Under our articles of association, directors can only be dismissed by the general meeting by simple majority, provided that our board of directors proposes the dismissal. In other cases, the general meeting can only pass such resolution by a two-thirds majority representing more than half of the issued share capital. The DCGC recommends that the general meeting can pass a resolution to dismiss a director by a simple majority, representing no more than one-third of the issued share capital.

The DCGC recommends against providing equity awards as part of the compensation of a non-executive director. However, we may deviate from this recommendation and grant equity awards to our non-executive directors, consistent with U.S. market practice.

The Plan allows us to set the terms and conditions of equity awards granted thereunder. Under the Plan, we may grant shares that are not subject to a lock-up period of at least five years after the date of grant, and we may grant options without restricting the exercisability of those options during the first three years after the date of grant. In those cases, this would cause additional deviations from the DCGC.

### ***Dutch financial reporting supervision act***

On the basis of the Dutch Financial Reporting Supervision Act (*Wet toezicht financiële verslaggeving*), or the FRSA, the Dutch Authority for the Financial Markets (*Stichting Autoriteit Financiële Markten*), or AFM, supervises the application of financial reporting standards by Dutch companies whose securities are listed on a Dutch or foreign stock exchange.

Pursuant to the FRSA, the AFM has an independent right to (i) request an explanation from us regarding our application of the applicable financial reporting standards if, based on publicly known facts or circumstances, it has reason to doubt that our financial reporting meets such standards and (ii) recommend to us the making available of further explanations. If we do not comply with such a request or recommendation, the AFM may request that the Enterprise Chamber (*Ondernemingskamer*) order us to (i) make available further explanations as recommended by the AFM, (ii) provide an explanation of the way we have applied the applicable financial reporting standards to our financial reports or (iii) prepare or restate our financial reports in accordance with the Enterprise Chamber’s orders.



### **Public offer rules**

Dutch public offer rules will not apply to us, as these rules only apply to Dutch companies listed on a regulated market in a member state of the European Economic Area.

### **Comparison of Dutch corporate law and our articles of association and U.S. corporate law**

The following comparison between Dutch corporate law, which applies to us, and Delaware corporation law, the law under which many publicly listed corporations in the United States are incorporated, discusses additional matters not otherwise described in this prospectus. Although we believe this summary is materially accurate, the summary is subject to Dutch law, including Book 2 of the Dutch Civil Code and the DCGC and Delaware corporation law, including the Delaware General Corporation Law.

### **Corporate governance**

#### *Duties of directors*

*The Netherlands.* Prior to the consummation of this offering, we will continue to have a two-tier board structure consisting of a management board (*bestuur*) and a separate supervisory board (*raad van commissarissen*). As part of our reorganization and immediately prior to the offering, we will adopt a one-tier board structure consisting of a board of directors consisting of executive and non-executive directors.

Under Dutch law, the board of directors is charged with the management of the company, subject to the restrictions contained in our articles of association. Our executive directors manage our day-to-day business and operations and implement our strategy. Our non-executive directors focus on the supervision on the policy and functioning of the performance of the duties of all of our directors and our general state of affairs. The directors may divide their tasks among themselves in or pursuant to internal rules and in accordance with Dutch law. Each director has a statutory duty to act in the corporate interest of our company and its business. Under Dutch law, the corporate interest extends to the interests of all corporate stakeholders, such as shareholders, creditors, employees, customers and suppliers. The duty to act in the corporate interest of our company also applies in the event of a proposed sale or break-up of our company, provided that the circumstances generally dictate how such duty is to be applied and how the respective interests of various groups of stakeholders should be weighed.

Any resolution of our board of directors regarding a material change in our identity or character requires approval of the general meeting. The absence of the approval of the general meeting shall result in the relevant resolution being null and void but shall not affect the powers of representation of the board or of the directors vis-à-vis third parties.

Our board of directors is entitled to represent our company. The power to represent our company also vests in our Chief Executive Officer acting individually or any two other directors acting jointly.

*Delaware.* The board of directors bears the ultimate responsibility for managing the business and affairs of a corporation. In discharging this function, directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its stockholders. Delaware courts have decided that the directors of a Delaware corporation are required to exercise informed business judgment in the performance of their duties. Informed business judgment means that the directors have informed themselves of all material information reasonably available to them. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation. In addition, under Delaware law, when the board of directors of a Delaware corporation

## [Table of Contents](#)

approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the stockholders.

### *Director terms*

*The Netherlands.* The DCGC provides the following best practice recommendations on the terms for tenure of directors:

- executive directors should be appointed for a maximum period of four years, without limiting the number of consecutive terms executive directors may serve; and
- non-executive directors should be appointed for two consecutive periods of no more than four years. Thereafter, non-executive directors may be reappointed for a maximum of two consecutive periods of no more than two years, provided that the reasons for any reappointment after an eight-year term of office should be disclosed in our statutory annual management report.

The general meeting shall at all times be entitled to suspend or dismiss a director. Under our articles of association as they will read upon the closing of this offering, the general meeting may only adopt a resolution to suspend or dismiss a director by at least a two-thirds majority of the votes cast, provided that such majority represents more than half of our issued share capital, unless the resolution is passed at the proposal of our board of directors, in which latter case a simple majority of the votes cast is sufficient. If a director is suspended and the general meeting does not resolve to dismiss him or her within three months from the date of such suspension, the suspension shall lapse.

*Delaware.* The Delaware General Corporation Law generally provides for a one-year term for directors, but permits directorships to be divided into up to three classes with up to three-year terms, with the years for each class expiring in different years, if permitted by the certificate of incorporation, an initial bylaw or a bylaw adopted by the stockholders. A director elected to serve a term on a "classified" board may not be removed by stockholders without cause. There is no limit in the number of terms a director may serve.

### *Director vacancies*

*The Netherlands.* Our board of directors can temporarily fill vacancies in its midst caused by temporary absence or incapacity of directors without requiring a shareholder vote. If all of our directors are absent or incapacitated, our management shall be attributed to the person who most recently ceased to hold office as the chairperson of our board of directors, provided that if such former chairperson is unwilling or unable to accept that position, our management shall be attributed to the person who most recently ceased to hold office as our Chief Executive Officer. If such former Chief Executive Officer is also unwilling or unable to accept that position, our management shall be attributed to one or more persons whom the general meeting. The person(s) charged with our management in this manner may designate one or more persons to be charged with our management instead of, or together with, such person(s).

Under Dutch law, directors are appointed and re-appointed by the general meeting. Under our articles of association as they will read upon the closing of this offering, our directors will be appointed by the general meeting upon binding nomination by our board of directors. However, the general meeting may at all times overrule a binding nomination by a resolution adopted by at least a two-thirds majority of the votes cast, provided such majority represents more than half of the issued share capital. If the general meeting overrules a binding nomination, the board of directors has the exclusive right to make a new nomination.

*Delaware.* The Delaware General Corporation Law provides that vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) unless (i) otherwise

provided in the certificate of incorporation or bylaws of the corporation or (ii) the certificate of incorporation directs that a particular class of shares is to elect such director, in which case any other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.

### ***Conflict-of-interest transactions***

*The Netherlands.* Under Dutch law and our articles of association, our directors shall not take part in any discussion or decision-making that involves a subject or transaction in relation to which he or she has a direct or indirect personal conflict of interest with us. Such a conflict of interest would generally arise if the director concerned is unable to serve our interests and the business connected with our company with the required level of integrity and objectivity due to the existence of the conflicting personal interest. Our articles of association provide that if as a result of conflicts of interests no resolution of the board of directors can be adopted, the resolution may nonetheless be adopted by the board of directors as if none of the directors had a conflict of interest. In that latter case, each director is entitled to participate in the discussion and decision-making process and to cast a vote.

The DCGC provides the following best practice recommendations in relation to conflicts of interests in respect of directors:

- A director should report any conflict of interest or potential conflict of interest in a transaction that is of material significance to the company and/or to such person to the chairperson of the board of directors without delay and should provide all relevant information in that regard, including the relevant information pertaining to his or her spouse, registered partner or other life companion, foster child and relatives by blood or marriage up to the second degree. If the chairperson of the board of directors has a conflict of interest or potential conflict of interest, he or she should report this to the vice-chairperson of the board of directors without delay.
- The board of directors should decide, outside the presence of the director concerned, whether there is a conflict of interest.
- All transactions in which there are conflicts of interest with directors should be agreed on terms that are customary in the market.
- Decisions to enter into transactions in which there are conflicts of interest with directors that are of material significance to the company and/or to the relevant directors should require the approval of the board of directors. Such transactions should be published in our statutory annual report, together with a description of the conflict of interest and a declaration that the relevant best practice provisions of the DCGC have been complied with.

*Delaware.* The Delaware General Corporation Law generally permits transactions involving a Delaware corporation and an interested director of that corporation if:

- the material facts as to the director's relationship or interest are disclosed and a majority of disinterested directors consent;
- the material facts are disclosed as to the director's relationship or interest and a majority of shares entitled to vote thereon consent; or
- the transaction is fair to the corporation at the time it is authorized by the board of directors, a committee of the board of directors or the stockholders.

**Proxy voting by directors**

*The Netherlands.* An absent director may issue a proxy for a specific meeting of the board of directors but only to another director in writing or by electronic means.

*Delaware.* A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

**Dutch corporate governance code**

Upon the consummation of this offering, we will be subject to the Dutch Corporate Governance Code, or the DCGC. The DCGC contains both principles and best practice provisions on corporate governance that regulate relations between the board of directors and the general meeting and matters in respect of financial reporting, auditors, disclosure, compliance and enforcement standards. The DCGC is based on a "comply or explain" principle. A copy of the DCGC can be found on [www.mccg.nl/english](http://www.mccg.nl/english). Accordingly, we are required to disclose in our annual board report, filed in the Netherlands, to what extent we comply with the principles and best practice provisions of the DCGC, and where we do not (for example, because of a conflicting Nasdaq requirement or otherwise), we must state why and to what extent we deviate in our annual board report.

We do not comply with all principles and best practice provisions of the DCGC. As of the date of this prospectus, our main deviations from the DCGC are summarized below, but cannot exclude the possibility of deviating from additional provisions of the DCGC after the date hereof, including in order to follow market practice or governance practices in the United States.

Under our articles of association as they will read following our corporate reorganization, our directors will be appointed by the general meeting on the basis of a binding nomination prepared by our board of directors. This means that the nominee will be appointed to board of directors, unless the general meeting removes the binding nature of the nomination (in which case a new nomination will be prepared by our board of directors for a subsequent general meeting). Our articles of association as they will read following our corporate reorganization, will provide that the general meeting can only pass such resolution by a two-thirds majority representing more than half of the issued share capital. However, the DCGC recommends that the general meeting can pass such a resolution by simple majority, representing no more than one-third of the issued share capital.

Under our articles of association as they will read following our corporate reorganization, directors can only be dismissed by the general meeting by simple majority, provided that our board of directors proposes the dismissal. In other cases, the general meeting can only pass such resolution by a two-thirds majority representing more than half of the issued share capital. However, the DCGC recommends that the general meeting can pass such a resolution to dismiss a director by simple majority, representing no more than one-third of the issued share capital.

The DCGC recommends against providing equity awards as part of the compensation of a non-executive director. However, we may deviate from this recommendation and grant equity awards to our non-executive directors, consistent with U.S. market practice.

Our Plan allows us to set the terms and conditions of awards granted thereunder. Under the Plan, we may grant common shares that are not subject to a lock-up period of at least five years after the date of grant, and we may grant options without restricting the exercisability of those options during the first three years after the date of grant. In those cases, this would cause a deviation from the DCGC.

## **Shareholder rights**

### *Voting rights*

*The Netherlands.* In accordance with Dutch law and our articles of association, each issued common share and preferred share, if any are outstanding, confers the right to cast one vote at the general meeting. No votes may be cast at a general meeting on shares held by us or our subsidiaries or on shares for which we or our subsidiaries hold depository receipts. Nonetheless, the holders of a usufruct (*vruchtgebruik*) and the holders of a right of pledge (*pandrecht*) in respect of shares held by us or our subsidiaries in our share capital are not excluded from the right to vote on such shares, if the usufruct (*vruchtgebruik*) or the right of pledge (*pandrecht*) was granted prior to the time such shares were acquired by us or any of our subsidiaries. Neither we nor any of our subsidiaries may cast votes in respect of a share on which we or such subsidiary holds a usufruct (*vruchtgebruik*) or a right of pledge (*pandrecht*). Shares which are not entitled to voting rights pursuant to the preceding sentences will not be taken into account for the purpose of determining the number of shareholders that vote and that are present or represented, or the amount of the share capital that is provided or that is represented at a general meeting.

For each general meeting, the board of directors may determine that a record date will be applied in order to establish which shareholders are entitled to attend and vote at the general meeting. Such record date shall be the 28th day prior to the day of the general meeting. The record date and the manner in which shareholders can register and exercise their rights will be set out in the notice of the meeting which must be published in a Dutch daily newspaper with national distribution at least 15 calendar days prior to the meeting (and such notice may therefore be published after the record date for such meeting). Under our articles of association, shareholders and others with meeting rights under Dutch law must notify us in writing or by electronic means of their identity and intention to attend the general meeting. This notice must be received by us ultimately on the seventh day prior to the general meeting, unless indicated otherwise when such meeting is convened.

*Delaware.* Under the Delaware General Corporation Law, each stockholder is entitled to one vote per share of stock, unless the certificate of incorporation provides otherwise. In addition, the certificate of incorporation may provide for cumulative voting at all elections of directors of the corporation, or at elections held under specified circumstances. Either the certificate of incorporation or the bylaws may specify the number of shares and/or the amount of other securities that must be represented at a meeting in order to constitute a quorum, but in no event will a quorum consist of less than one-third of the shares entitled to vote at a meeting.

Stockholders as of the record date for the meeting are entitled to vote at the meeting, and the board of directors may fix a record date that is no more than 60 nor less than 10 days before the date of the meeting, and if no record date is set then the record date is the close of business on the day next preceding the day on which notice is given, or if notice is waived then the record date is the close of business on the day next preceding the day on which the meeting is held. The determination of the stockholders of record entitled to notice or to vote at a meeting of stockholders shall apply to any adjournment of the meeting, but the board of directors may fix a new record date for the adjourned meeting.

### *Shareholder proposals*

*The Netherlands.* Pursuant to Dutch law, one or more shareholders or others with meeting rights under Dutch law who jointly represent at least one-tenth of our issued share capital may request us to convene a general meeting, setting out in detail the matters to be discussed. If we have not taken the steps necessary to ensure that such meeting can be held within six weeks after the request, the proponent(s) may, on their application, be authorized by the competent Dutch court in preliminary relief proceedings to convene a general meeting. The court shall disallow the application if it does not appear that the proponent(s) has/have previously requested

## [Table of Contents](#)

our board of directors to convene a general meeting and our board of directors has not taken the necessary steps so that the general meeting could be held within six weeks after the request.

Pursuant to Dutch law, and subject to the applicable requirements, the agenda for our general meetings shall also include such items requested by one or more shareholders or others with meeting rights under Dutch law representing at least 3% of our issued share capital. These requests must be made in writing or by electronic means and received by us at least 60 days before the day of the meeting. No resolutions shall be adopted on items other than those that have been included in the agenda.

In accordance with the DCGC and our articles of association, shareholders having the right to put an item on the agenda under the rules described above shall exercise such right only after consulting board of directors in that respect. If one or more shareholders intend to request that an item be put on the agenda that may result in a change in our strategy (for example, the dismissal of directors), our board of directors must be given the opportunity to invoke a reasonable period to respond to such intention. Such period shall not exceed 180 days (or such other period as may be stipulated for such purpose by Dutch law and/or the DCGC from time to time). If invoked, our board of directors must use such response period for further deliberation and constructive consultation, in any event with the shareholders(s) concerned, and shall explore the alternatives. At the end of the response time, our board of directors shall report on this consultation and the exploration of alternatives to the general meeting. The response period may be invoked only once for any given general meeting and shall not apply: (a) in respect of a matter for which a response period has been previously invoked; or (b) if a shareholder holds at least 75% of our issued share capital as a consequence of a successful public bid. The response period may also be invoked in response to shareholders or others with meeting rights under Dutch law requesting that a general meeting be convened, as described above.

*Delaware.* Delaware law does not specifically grant stockholders the right to bring business before an annual or special meeting. However, if a Delaware corporation is subject to the SEC's proxy rules, a stockholder who owns at least €2,000 in market value, or 1% of the corporation's securities entitled to vote, and has owned such securities for at least one year, may propose a matter for a vote at an annual or special meeting in accordance with those rules.

### *Action by written consent*

*The Netherlands.* Under Dutch law, shareholders' resolutions may be adopted in writing without holding a meeting of shareholders, provided that (i) the articles of association allow such action by written consent, (ii) the company has not issued bearer shares or, with its cooperation, depository receipts for shares in its capital, and (iii) the resolution is adopted unanimously by all shareholders that are entitled to vote. Although our articles of association allow for shareholders' resolutions to be adopted in writing, the requirement of unanimity renders the adoption of shareholder resolutions without holding a meeting not feasible for us as a publicly traded company.

*Delaware.* Although permitted by Delaware law, publicly listed companies do not typically permit stockholders of a corporation to take action by written consent.

### *Appraisal rights*

*The Netherlands.* Subject to certain exceptions, Dutch law does not recognize the concept of appraisal or dissenters' rights. However, Dutch law does provide for squeeze-out procedures as described under "Dividends and Other Distributions - Squeeze-Out Procedures." Also, Dutch law provides for cash exit rights in certain situations for dissenting shareholders of a company organized under Dutch law entering into certain types of mergers. In those situations, a dissenting shareholder may file a claim with the Dutch company for

compensation. Such compensation shall then be determined by one or more independent experts. The shares of such shareholder that are subject to such claim will cease to exist as of the moment of entry into effect of the merger.

*Delaware.* The Delaware General Corporation Law provides for stockholder appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the stockholder's shares, in connection with certain mergers and consolidations.

### **Shareholder suits**

*The Netherlands.* In the event a third-party is liable to a Dutch company, only the company itself can bring a civil action against that party. The individual shareholders do not have the right to bring an action on behalf of the company. Only in the event that the cause for the liability of a third-party to the company also constitutes a tortious act directly against a shareholder does that shareholder have an individual right of action against such third-party in its own name. Dutch law provides for the possibility to initiate such actions collectively, in which a foundation or an association can act as a class representative and has standing to commence proceedings and claim damages if certain criteria are met. The court will first determine if those criteria are met. If so, the case will go forward as a class action on the merits after a period allowing class members to opt out from the case has lapsed. All members of the class who are residents of the Netherlands and who did not opt-out will be bound to the outcome of the case. Residents of other countries must actively opt in in order to be able to benefit from the class action. The defendant is not required to file defenses on the merits prior to the merits phase having commenced. It is possible for the parties to reach a settlement during the merits phase. Such a settlement can be approved by the court, which approval will then bind the members of the class, subject to a second opt-out. This new regime applies to claims brought after January 1, 2020 and which relate to certain events that occurred prior to that date. For other matters, the old Dutch class actions regime will apply. Under the old regime, no monetary damages can be sought. Also, a judgment rendered under the old regime will not bind individual class members. Even though Dutch law does not provide for derivative suits, our directors and officers can still be subject to liability under U.S. securities laws.

*Delaware.* Under the Delaware General Corporation Law, a stockholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. An individual also may commence a class action suit on behalf of himself and other similarly situated stockholders where the requirements for maintaining a class action under Delaware law have been met. A person may institute and maintain such a suit only if that person was a stockholder at the time of the transaction which is the subject of the suit. In addition, under Delaware case law, the plaintiff normally must be a stockholder at the time of the transaction that is the subject of the suit and throughout the duration of the derivative suit. Delaware law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff in court, unless such a demand would be futile.

### **Repurchase of shares**

*The Netherlands.* Under Dutch law, when issuing shares, a public company such as ours may not subscribe for newly issued shares in its own capital. Such company may, however, subject to certain restrictions of Dutch law and its articles of association, acquire shares in its own capital. A listed public company such as ours may acquire fully paid shares in its own capital at any time for no valuable consideration. Furthermore, subject to certain provisions of Dutch law and its articles of association, such company may repurchase fully paid shares in its own capital if (i) the company's shareholders' equity (*eigen vermogen*) less the payment required to make the acquisition does not fall below the sum of paid-in and called-up share capital plus any reserves required by Dutch law or its articles of association and (ii) the aggregate nominal value of shares of the company which the

## [Table of Contents](#)

company acquires, holds or on which the company holds a pledge (*pandrecht*) or which are held by a subsidiary of the company, would not exceed 50% of its then-current issued share capital.

An acquisition by us of shares in our capital for a consideration must be authorized by our general meeting. Such authorization may be granted for a maximum period of 18 months and must specify the number of shares that may be acquired, the manner in which shares may be acquired and the price limits within which shares may be acquired. The actual acquisition may only be effected pursuant to a resolution of our board of directors. Our board of directors will be authorized for a period of 18 months following the completion of our corporate reorganization to cause the repurchase of shares (or depository receipts for shares) by us of up to 10% of our issued share capital, for a price per share not exceeding 110% of the average market price of our common shares on Nasdaq (such average market price being the average of the closing prices on each of the five consecutive trading days preceding the date the acquisition is agreed upon by us), provided that, until our common shares are listed on a stock exchange, the maximum purchase price shall be 110% of the original issue price of the shares concerned.

No authorization of the general meeting is required if fully paid common shares are acquired by us with the intention of transferring such common shares to our employees under an applicable employee share purchase plan.

*Delaware.* Under the Delaware General Corporation Law, a corporation may purchase or redeem its own shares unless the capital of the corporation is impaired or the purchase or redemption would cause an impairment of the capital of the corporation. A Delaware corporation may, however, purchase or redeem out of capital any of its preferred shares or, if no preferred shares are outstanding, any of its own shares if such shares will be retired upon acquisition and the capital of the corporation will be reduced in accordance with specified limitations.

### **Anti-takeover provisions**

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

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

- the authorization of a class of preferred shares that may be issued to a protective foundation, in such a manner as to dilute the interest of any potential acquirer or shareholder activist, see “Risk factors—Provisions of our articles of association or Dutch corporate law might deter acquisition bids for us that might be considered favorable and prevent, delay or frustrate any attempt to replace or dismiss the members of our board of directors”;
- a provision that our directors are appointed on the basis of a binding nomination prepared by our board of directors which can only be overruled by a two-thirds majority of votes cast representing more than half of our issued share capital;
- a provision that our directors may only be dismissed by the general meeting by a two-thirds majority of votes cast representing more than half of our issued share capital, unless the dismissal is proposed by our board of directors in which latter case a simple majority of the votes cast would be sufficient;
- a provision allowing, among other matters, the former chairperson of our board of directors or our former Chief Executive Officer to manage our affairs if all of our directors are dismissed and to appoint others to be charged with our affairs, including the preparation of a binding nomination for directors as discussed above, until new directors are appointed by the general meeting on the basis of such binding nomination; and



## [Table of Contents](#)

- a requirement that certain matters, including an amendment of our articles of association, may only be resolved upon by our general meeting if proposed by our board of directors.

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

*Delaware.* In addition to other aspects of Delaware law governing fiduciary duties of directors during a potential takeover, the Delaware General Corporation Law also contains a business combination statute that protects Delaware companies from hostile takeovers and from actions following the takeover by prohibiting some transactions once an acquirer has gained a significant holding in the corporation.

Section 203 of the Delaware General Corporation Law prohibits “business combinations,” including mergers, sales and leases of assets, issuances of securities and similar transactions by a corporation or a subsidiary with an interested stockholder that beneficially owns 15% or more of a corporation’s voting stock, within three years after the person becomes an interested stockholder, unless:

- the transaction that will cause the person to become an interested stockholder is approved by the board of directors of the target prior to the transactions;
- after the completion of the transaction in which the person becomes an interested stockholder, the interested stockholder holds at least 85% of the voting stock of the corporation not including shares owned by persons who are directors and officers of interested stockholders and shares owned by specified employee benefit plans; or
- after the person becomes an interested stockholder, the business combination is approved by the board of directors of the corporation and holders of at least 66.67% of the outstanding voting stock, excluding shares held by the interested stockholder.

A Delaware corporation may elect not to be governed by Section 203 by a provision contained in the original certificate of incorporation of the corporation or an amendment to the original certificate of incorporation or to the bylaws of the company, which amendment must be approved by a majority of the shares entitled to vote and may not be further amended by the board of directors of the corporation. In most cases, such an amendment is not effective until 12 months following its adoption.

### **Inspection of books and records**

*The Netherlands.* The board of directors must provide the general meeting, within a reasonable amount of time with all information that the general meeting requires, unless this would be contrary to an overriding interest of our company. If the board of directors invokes such an overriding interest, it must give reasons.

*Delaware.* Under the Delaware General Corporation Law, any stockholder may inspect for any proper purpose certain of the corporation’s books and records during the corporation’s usual hours of business.

### **Suspension and dismissal of directors**

*The Netherlands.* Under our articles of association, directors can only be suspended or dismissed by the general meeting by simple majority, provided that our board of directors proposes the suspension or dismissal. In other cases, the general meeting can only pass such resolution by a two-thirds majority representing more than half of the issued share capital. The DCGC recommends that the general meeting can pass a resolution to dismiss a director by a simple majority, representing no more than one-third of the issued share capital.

*Delaware.* Under the Delaware General Corporation Law, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of

directors, except (i) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board is classified, stockholders may effect such removal only for cause, or (ii) in the case of a corporation having cumulative voting, if less than the entire board is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he is a part.

## **Issuance of shares**

*The Netherlands.* Under Dutch law, a company's general meeting is the corporate body authorized to resolve on the issuance of shares and the granting of rights to subscribe for shares. The general meeting can delegate such authority to another corporate body of the company for a period not exceeding five years; this authorization may only be extended from time to time for a maximum period of five years. Prior to the closing of this offering, our board of directors will be authorized for a period of five years from the completion of our corporate reorganization to issue shares or grant rights to subscribe for shares up to our authorized share capital from time to time. We may not subscribe for our own shares on issue.

*Delaware.* All creation of shares require the board of directors to adopt a resolution or resolutions, pursuant to authority expressly vested in the board of directors by the provisions of the company's certificate of incorporation.

### **Preemptive rights**

*The Netherlands.* Under Dutch law, in the event of an issuance of shares, each shareholder will have a pro rata pre-emption right in proportion to the aggregate nominal value of the shares held by such holder (except in case of an issue of shares to employees, against a contribution other than in cash or pursuant to the exercise of a previously acquired right to subscribe for shares). Under our articles of association, the pre-emption rights in respect of newly issued shares may be restricted or excluded by a resolution of the general meeting. Another corporate body may restrict or exclude the pre-emption rights in respect of newly issued shares if it has been designated as the authorized body to do so by the general meeting. Such designation can be granted for a period not exceeding five years. A resolution of the general meeting to restrict or exclude the pre-emption rights or to designate another corporate body as the authorized body to do so requires a majority of not less than two-thirds of the votes cast, if less than one-half of our issued share capital is represented at the meeting. Prior to the closing of this offering, our board of directors will be authorized for a period of five years from the completion of our corporate reorganization to limit or exclude pre-emption rights in relation to an issuance of shares or a grant of rights to subscribe for shares that the board of directors is authorized to resolve upon (see above under "Issuance of Shares").

*Delaware.* Under the Delaware General Corporation Law, stockholders have no preemptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the certificate of incorporation.

### **Dividends**

*The Netherlands.* Under Dutch law, we may only pay dividends and other distributions from our reserves to the extent our shareholders' equity (*eigen vermogen*) exceeds the sum of our paid-in and called-up share capital plus the reserves we must maintain under Dutch law or our articles of association and (if it concerns a distribution of profits) after adoption of our statutory annual accounts by our general meeting from which it appears that such dividend distribution is allowed. Subject to those restrictions, any future determination to

## [Table of Contents](#)

pay dividends or other distributions from our reserves will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors we deem relevant. See "Dividend Policy."

Pursuant to our articles of association, distributions may be made in cash, in kind or in the form of shares.

Under our articles of association as they will read upon the closing of this offering, if any preferred shares are or have been outstanding, a dividend is first paid out of our profits, if available for distribution, to the holders or former holders, as applicable, of those preferred shares to the extent they are entitled to such distribution under our articles of association, which we refer to as our preferred dividend. Thereafter, our board of directors may decide that all or part of the remaining profits shown in our adopted statutory annual accounts will be added to our reserves. After reservation of any such profits, any remaining profits will be at the disposal of the general meeting at the proposal of our board of directors for distribution on our common shares, subject to applicable restrictions of Dutch law as set out in the previous paragraph. Our board of directors is permitted, subject to certain requirements and applicable restrictions of Dutch law, to declare interim dividends without the approval of our general meeting. Dividends and other distributions shall be made payable no later than a date determined by us. Claims to dividends and other distributions not made within five years from the date that such dividends or distributions became payable will lapse and any such amounts will be considered to have been forfeited to us (*verjaring*).

**Delaware.** Under the Delaware General Corporation Law, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets). In determining the amount of surplus of a Delaware corporation, the assets of the corporation, including stock of subsidiaries, must be valued at their fair market value as determined by the board of directors, without regard to their historical book value. Dividends may be paid in the form of common shares, property or cash.

### **Shareholder vote on certain reorganizations**

**The Netherlands.** Under Dutch law, the general meeting must approve resolutions of the board of directors relating to a significant change in the identity or the character of the company or the business of the company, which includes:

- a transfer of the business or virtually the entire business to a third-party;
- the entry into or termination of a long-term cooperation of the company or a subsidiary with another legal entity or company or as a fully liable partner in a limited partnership or general partnership, if such cooperation or termination is of a far-reaching significance for the company; and
- the acquisition or divestment by the company or a subsidiary of a participating interest in the capital of a company having a value of at least one-third of the amount of its assets according to its balance sheet and explanatory notes or, if the company prepares a consolidated balance sheet, according to its consolidated balance sheet and explanatory notes in the last adopted annual accounts of the company.

The absence of such approval shall result in the relevant resolution being null and void but shall not affect the powers of representation of the board of directors or of the directors vis-à-vis third parties.

**Delaware.** Under the Delaware General Corporation Law, the vote of a majority of the outstanding shares of capital stock entitled to vote thereon generally is necessary to approve a merger or consolidation or the sale of

## [Table of Contents](#)

all or substantially all of the assets of a corporation. The Delaware General Corporation Law permits a corporation to include in its certificate of incorporation a provision requiring for any corporate action the vote of a larger portion of the stock or of any class or series of stock than would otherwise be required.

Under the Delaware General Corporation Law, no vote of the stockholders of a surviving corporation to a merger is needed, however, unless required by the certificate of incorporation, if (i) the agreement of merger does not amend in any respect the certificate of incorporation of the surviving corporation, (ii) the shares of stock of the surviving corporation are not changed in the merger, and (iii) the number of common shares of the surviving corporation into which any other shares, securities or obligations to be issued in the merger may be converted does not exceed 20% of the surviving corporation's common shares outstanding immediately prior to the effective date of the merger. In addition, stockholders may not be entitled to vote in certain mergers with other corporations that own 90% or more of the outstanding shares of each class of stock of such corporation, but the stockholders will be entitled to appraisal rights.

### **Remuneration of directors**

*The Netherlands.* 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. Such compensation policy will be adopted by our general meeting prior to the closing of this offering. Changes to such compensation policy will require a vote of our general meeting by a simple majority of votes cast. The board of directors determines the remuneration of individual directors with due observance of the compensation policy and Dutch law. A proposal with respect to remuneration schemes in the form of shares or rights to shares in which directors may participate is subject to approval by our general meeting by simple majority of votes cast. Such a proposal must set out at least the maximum number of shares or rights to subscribe for shares to be granted to the directors and the criteria for granting or amendment.

Our compensation policy will authorize our board of directors 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 of directors.

*Delaware.* Under the Delaware General Corporation Law, the stockholders do not generally have the right to approve the compensation policy for directors or the senior management of the corporation, although certain aspects of executive compensation may be subject to stockholder vote due to the provisions of U.S. federal securities and tax law, as well as exchange requirements.

### **Listing**

We intend to apply to list the common shares on Nasdaq under the symbol "LVRX ."

### **Transfer agent and registrar**

Upon the closing of this offering, the transfer agent and registrar for our common shares will be .

## Common shares eligible for future sale

Prior to this offering, there has been no market for our common shares. Future sales of substantial amounts of our common shares in the public market could adversely affect market prices prevailing from time to time. Furthermore, because only a limited number of common shares will be available for sale shortly after this offering due to existing contractual and legal restrictions on resale as described below, there may be sales of substantial amounts of our common shares in the public market after such restrictions lapse. This may adversely affect the prevailing market price of our common shares and our ability to raise equity capital in the future.

Upon consummation of this offering, we will have \_\_\_\_\_ common shares outstanding, or \_\_\_\_\_ common shares outstanding if the underwriters exercise their option in full to purchase additional common shares, and after giving effect to the conversion of all of our outstanding preferred shares into an aggregate of \_\_\_\_\_ common shares immediately prior to the consummation of this offering. Of these shares, \_\_\_\_\_ common shares, or \_\_\_\_\_ common shares if the underwriters exercise their option in full to purchase additional common shares, sold in this offering will be freely transferable without restriction or registration under the Securities Act, except for any shares purchased by one of our existing "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining common shares are "restricted shares" as defined in Rule 144. Restricted shares may be sold in the public market only if registered or if they qualify for an exemption from registration under Rules 144 or 701 of the Securities Act. As a result of the contractual \_\_\_\_\_-day lock-up period described below and the provisions of Rules 144 and 701, these shares will be available for sale in the public market as follows:

Number of shares	Date
	On the date of this prospectus.
	After 90 days from the date of this prospectus (subject, in some cases, to volume limitations).
	After _____ days from the date of this prospectus (subject, in some cases, to volume limitations).

### Rule 144

In general, a person who has beneficially owned our common shares that are restricted shares for at least six months would be entitled to sell such securities, provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned our common shares that are restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of our common shares then outstanding, which will equal approximately \_\_\_\_\_ common shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional common shares; or
- the average weekly trading volume of our common shares on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144 to the extent applicable.

## **Rule 701**

In general, under Rule 701, any of our employees, board members, officers, consultants or advisors who purchases shares from us in connection with a compensatory share or option plan or other written agreement before the effective date of this offering is entitled to resell such shares 90 days after the effective date of this offering in reliance on Rule 144, without having to comply with the holding period requirements or other restrictions contained in Rule 701.

The SEC has indicated that Rule 701 will apply to typical share options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after the date of this prospectus. Securities issued in reliance on Rule 701 are restricted securities and, subject to the contractual restrictions described below, beginning 90 days after the date of this prospectus, may be sold by persons other than “affiliates,” as defined in Rule 144, subject only to the manner of sale provisions of Rule 144 and by “affiliates” under Rule 144 without compliance with its one-year minimum holding period requirement.

## **Regulation S**

Regulation S provides generally that sales made in offshore transactions are not subject to the registration or prospectus-delivery requirements of the Securities Act.

## **Registration rights**

We are subject to certain registration rights under the definitive documentation for our Series C Preferred financing.

## **Lock-up agreements**

All of our board members and the holders of all or substantially all of our common shares have agreed, subject to limited exceptions, not to offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise dispose of, directly or indirectly, or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common shares or such other securities for a period of \_\_\_\_\_ days after the date of this prospectus, subject to certain exceptions, without the prior written consent of certain of the underwriters. See “Underwriting.”

## Material income tax considerations

*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 the U.S. dollar;

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 advisers as to the particular U.S. federal income tax consequences of holding and disposing of common shares.

## [Table of Contents](#)

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 advisers 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.

The discussion below assumes that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement and any related agreement will be complied with in accordance with their terms.

### ***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).

We have not yet determined our PFIC status. 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. Even if we were to determine that we are not a PFIC for a taxable year, 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.



## Table of Contents

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 advisers 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 advisers 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

## [Table of Contents](#)

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 adviser 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 advisers 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 advisers regarding the requirements of filing such information returns under these rules.

**WE STRONGLY URGE A U.S. HOLDER TO CONSULT YOUR TAX ADVISER 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 U.S. dollar 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 U.S. dollars. If the dividend is converted into U.S. dollars 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 U.S. dollars 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 advisers 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 U.S. dollars. 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 U.S. dollars, the amount realized will be the U.S. dollar 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 U.S. dollar value of the amount realized in a non-U.S. dollar 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

## [Table of Contents](#)

settlement date, you will recognize foreign currency gain or loss to the extent of any difference between the U.S. dollar amount realized on the date of sale or disposition and the U.S. dollar value of the currency received at the spot rate on the settlement date. U.S. Holders should consult their tax advisers 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 US 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 advisers 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 advisers 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, and in the case of individuals, such holder’s partner or certain of its relatives by blood or marriage in the direct line (including foster children), 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 speaking, 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 individuals, together with such holder’s partner (as defined in the Dutch Income Tax Act 2001), 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 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 who 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 activities performed by such holder or certain individuals related to such holder (as defined in the Dutch Income Tax Act 2001).

## 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 of redemption of common shares, or proceeds of 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*) 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 income tax or corporate income tax liability and to a refund of any residual Dutch dividend withholding tax. 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, reductions of, or full or partial refunds of, Dutch dividend withholding tax under Dutch national tax legislation, EU law, or a double taxation convention in effect between the Netherlands and such other country.

### **Remittance to the dutch tax authorities**

In general, we will be required to remit all amounts withheld as Dutch dividend withholding tax to the Dutch tax authorities. However, under certain circumstances, we are allowed to reduce the amount to be remitted to the Dutch tax authorities by the lesser of:

- 3% of the portion of the distribution paid by us that is 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 current calendar year (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 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 (*Wet op de dividendbelasting 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.

## **Taxes on income and capital gains**

### **Dutch resident entities**

Generally speaking, if the holder of common shares is an entity that is a resident or deemed to be resident of the Netherlands for Dutch corporate income tax purposes (a “Dutch Resident Entity”), any payment on the common shares or any gain or loss 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 €245,000 and 25% with respect to taxable profits in excess of that amount (rates and brackets for 2021).

### **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 payment on the common shares or any gain or loss realized on the disposal or deemed disposal of the common shares is taxable at the progressive Dutch income tax rates (with a maximum of 49.5% in 2021), 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 derives benefits from the common shares that are taxable as benefits from other activities (*resultaat uit overige werkzaamheden*).

If the above-mentioned conditions (i) and (ii) do not apply to the individual holder of common shares, such holder will be taxed annually on a deemed return (with a maximum of 5.69% in 2021) on the individual's net investment assets (*rendementsgrondslag*) for the year, insofar the individual's net investment assets for the year exceed a statutory threshold (*heffingvrij vermogen*). The deemed return on the individual's net investment assets for the year is taxed at a rate of 31%. Actual income, gains or losses in respect of the common shares are as such not subject to Dutch income tax.

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, 2021, the deemed return ranges from 1.90% up to 5.69% (depending on the aggregate amount of the net investment assets of the individual on January 1, 2021). The deemed return will be adjusted annually on the basis of historic market yields.

### ***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 taxes on income or capital gains in respect of any payment on the common shares or in respect of any gain or loss 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 derive benefits from the common shares that are taxable as benefits from other 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 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 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.

## Underwriting

We are offering the common shares described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC, Jefferies LLC and SVB Leerink LLC are acting as joint book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of common shares listed next to its name in the following table:

Name	Number of common shares
J.P. Morgan Securities LLC	
Jefferies LLC	
SVB Leerink LLC	
Wedbush Securities Inc.	
<b>Total</b>	

The underwriters are committed to purchase all the common shares offered by us if they purchase any common shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the common shares directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$ \_\_\_\_\_ per share. Any such dealers may resell common shares to certain other brokers or dealers at a discount of up to \$ \_\_\_\_\_ per share from the initial public offering price. After the initial offering of the common shares to the public, if all of the common shares are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. Sales of any common shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to \_\_\_\_\_ additional common shares from us to cover sales of common shares by the underwriters which exceed the number of common shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional common shares. If any common shares are purchased with this option to purchase additional common shares, the underwriters will purchase common shares in approximately the same proportion as shown in the table above. If any additional common shares are purchased, the underwriters will offer the additional common shares on the same terms as those on which the common shares are being offered.

The underwriting fee is equal to the public offering price per common share less the amount paid by the underwriters to us per common share. The underwriting fee is \$ \_\_\_\_\_ per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional common shares.

	Without option to purchase additional common shares exercise	With full option to purchase additional common shares exercise
Per Common Share	\$ _____	\$ _____
Total	\$ _____	\$ _____

## [Table of Contents](#)

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately \$

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of common shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations. We have also agreed to reimburse the underwriters for certain of their expenses in an amount of up to \$

We have agreed that we will not (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, or submit to, or file with, the SEC a registration statement under the Securities Act relating to, any of our common shares or securities convertible into or exercisable or exchangeable for any of our common shares, or publicly disclose the intention to make any offer, sale, pledge, loan, disposition or filing, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any common shares or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of common shares or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC, Jefferies LLC and SVB Leerink LLC for a period of days after the date of this prospectus, other than our common shares to be sold in this offering.

The restrictions on our actions, as described above, do not apply to certain transactions, including (i) the issuance of common shares or securities convertible into or exercisable for our common shares pursuant to the conversion or exchange of convertible or exchangeable securities or the exercise of warrants or options (including net exercise) or the settlement of RSUs (including net settlement), in each case outstanding on the date of the underwriting agreement and described in this prospectus; (ii) grants of stock options, stock awards, restricted stock, RSUs, or other equity awards and the issuance of our common shares or securities convertible into or exercisable or exchangeable for our common shares (whether upon the exercise of stock options or otherwise) to our employees, officers, directors, advisors, or consultants pursuant to the terms of an equity compensation plan in effect as of the closing of this offering and described in this prospectus, provided that such recipients enter into a lock-up agreement with the underwriters; or (iii) our filing of any registration statement on Form S-8 relating to securities granted or to be granted pursuant to any plan in effect on the date of the underwriting agreement and described in this prospectus or any assumed benefit plan pursuant to an acquisition or similar strategic transaction.

Our directors and executive officers, and substantially all of our shareholders (such persons, the "lock-up parties"), have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each lock-up party, with limited exceptions, for a period of days after the date of this prospectus (such period, the "restricted period"), may not (and may not cause any of their direct or indirect affiliates to), without the prior written consent of J.P. Morgan Securities, Jefferies LLC and SVB Leerink LLC, (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any of our common shares or any securities convertible into or exercisable or exchangeable for our common shares (including, without limitation, common shares or such other securities which may be deemed to be beneficially owned by such lock-up parties in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant (collectively with the common shares, the "lock-up securities")), (2) enter into any hedging, swap or other agreement or transaction

## [Table of Contents](#)

that transfers, in whole or in part, any of the economic consequences of ownership of the lock-up securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of lock-up securities, in cash or otherwise, (3) make any demand for, or exercise any right with respect to, the registration of any lock-up securities, or (4) publicly disclose the intention to do any of the foregoing. Such persons or entities have further acknowledged that these undertakings preclude them from engaging in any hedging or other transactions or arrangements (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) designed or intended, or which could reasonably be expected to lead to or result in, a sale or disposition or transfer (by any person or entity, whether or not a signatory to such agreement) of any economic consequences of ownership, in whole or in part, directly or indirectly, of any lock-up securities, whether any such transaction or arrangement (or instrument provided for thereunder) would be settled by delivery of lock-up securities, in cash or otherwise.

The restrictions described in the immediately preceding paragraph and contained in the lock-up agreements between the underwriters and the lock-up parties do not apply, subject in certain cases to various conditions, to certain transactions, including (a) transfers of lock-up securities: (i) as bona fide gifts, or for bona fide estate planning purposes, (ii) by will or intestacy, (iii) to any trust for the direct or indirect benefit of the lock-up party or any immediate family member, (iv) to a partnership, limited liability company or other entity of which the lock-up party and its immediate family members are the legal and beneficial owner of all of the outstanding equity securities or similar interests, (v) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (i) through (iv), (vi) in the case of a corporation, partnership, limited liability company, trust or other business entity, (A) to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate of the lock-up party, or to any investment fund or other entity controlling, controlled by, managing or managed by or under common control with the lock-up party or its affiliates or (B) as part of a distribution to members or stockholders of the lock-up party; (vii) by operation of law, (viii) to us from an employee upon death, disability or termination of employment of such employee, (ix) as part of a sale of lock-up securities acquired in open market transactions after the completion of this offering, (x) to us in connection with the vesting, settlement or exercise of restricted stock units, options, warrants or other rights to purchase our common shares (including "net" or "cashless" exercise), including for the payment of exercise price and tax and remittance payments, or (xi) pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction approved by our board of directors and made to all shareholders involving a change in control, provided that if such transaction is not completed, all such lock-up securities would remain subject to the restrictions in the immediately preceding paragraph; (b) exercise of the options, settlement of RSUs or other equity awards, or the exercise of warrants granted pursuant to plans described in this prospectus, provided that any lock-up securities received upon such exercise, vesting or settlement would be subject to restrictions similar to those in the immediately preceding paragraph; (c) the conversion of outstanding preferred shares, warrants to acquire preferred shares, or convertible securities into our common shares or warrants to acquire our common shares, provided that any common shares or warrant received upon such conversion would be subject to restrictions similar to those in the immediately preceding paragraph; and (d) the establishment by lock-up parties of trading plans under Rule 10b5-1 under the Exchange Act, provided that such plan does not provide for the transfer of lock-up securities during the restricted period.

J.P. Morgan Securities LLC, Jefferies LLC and SVB Leerink LLC in their sole discretion, may release the securities subject to any of the lock-up agreements with the underwriters described above, in whole or in part at any time.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

We intend to apply to have our common shares approved for listing on Nasdaq under the symbol "LVRX".

## [Table of Contents](#)

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling common shares in the open market for the purpose of preventing or retarding a decline in the market price of the common shares while this offering is in progress. These stabilizing transactions may include making short sales of common shares, which involves the sale by the underwriters of a greater number of common shares than they are required to purchase in this offering, and purchasing common shares on the open market to cover positions created by short sales. Short sales may be “covered” shorts, which are short positions in an amount not greater than the underwriters’ option to purchase additional common shares referred to above, or may be “naked” shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional common shares, in whole or in part, or by purchasing common shares in the open market. In making this determination, the underwriters will consider, among other things, the price of common shares available for purchase in the open market compared to the price at which the underwriters may purchase common shares through the option to purchase additional common shares. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common shares in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase common shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act of 1933, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common shares, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common shares in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those common shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common shares or preventing or retarding a decline in the market price of the common shares, and, as a result, the price of the common shares may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on Nasdaq, in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for our common shares. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

## [Table of Contents](#)

Neither we nor the underwriters can assure investors that an active trading market will develop for our common shares, or that the common shares will trade in the public market at or above the initial public offering price.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

### **Notice to prospective investors in the European Economic Area**

In relation to each Member State of the European Economic Area (each a “Member State”), no common shares have been offered or will be offered pursuant to the offering to the public in that Member State prior to the publication of a prospectus in relation to the common shares which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation, except that offers of common shares may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the underwriters; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

*provided* that no such offer of common shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any common shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and the Company that it is a “qualified investor” within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any common shares being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the common shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any common shares to the public other than their offer or resale in a Member State

## [Table of Contents](#)

to qualified investors as so defined or in circumstances in which the prior consent of the underwriters have been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an “offer to the public” in relation to common shares in any Member State means the communication in any form and by any means of sufficient information on the *terms* of the offer and any common shares to be offered so as to enable an investor to decide to purchase or subscribe for any common shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

### **Notice to prospective investors in the United Kingdom**

In the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the “**Order**”) and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”) or otherwise in circumstances which have not resulted and will not result in an offer to the public of the common shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

### **Notice to prospective investors in Canada**

The common shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the common shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

### **Notice to prospective investors in Switzerland**

The common shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (“SIX”) or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any

other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the common shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the common shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of common shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of common shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of common shares.

### **Notice to prospective investors in Hong Kong**

The common shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or SFO, of Hong Kong and any rules made thereunder; or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong), or CO, or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the common shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to common shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the SFO and any rules made thereunder.

### **Notice to prospective investors in Singapore**

Each joint book-running manager has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each joint book-running manager has represented and agreed that it has not offered or sold any common shares or caused the common shares to be made the subject of an invitation for subscription or purchase, and will not offer or sell any common shares or cause the common shares to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common shares, whether directly or indirectly, to any person in Singapore other than:

- (d) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA) pursuant to Section 274 of the SFA;
- (e) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA; or
- (f) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.



## [Table of Contents](#)

Where the common shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (g) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (h) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the common shares pursuant to an offer made under Section 275 of the SFA except:
  - (i) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
  - (ii) where no consideration is or will be given for the transfer;
  - (iii) where the transfer is by operation of law;
  - (iv) as specified in Section 276(7) of the SFA; or
  - (v) as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

**Singapore SFA Product Classification**—In connection with Section 309B of the SFA and the CMP Regulations 2018, unless otherwise specified before an offer of common shares, we have determined, and hereby notify all relevant persons (as defined in Section 309A(1) of the SFA), that the common shares are “prescribed capital markets products” (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

### **Notice to prospective investors in Japan**

The common shares have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the common shares nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any “resident” of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

### **Notice to prospective investors in the United Arab Emirates**

The common shares have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

## Notice to prospective investors in Israel

In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase common shares under the Israeli Securities Law, 5728—1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728—1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions, or the Addressed Investors; or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728—1968, subject to certain conditions, or the “Qualified Investors”. The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. We have not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728—1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our common shares to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728—1968. In particular, we may request, as a condition to be offered common shares, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728—1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728—1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728—1968 and the regulations promulgated thereunder in connection with the offer to be issued common shares; (iv) that the common shares that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728—1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728—1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

## Notice to prospective investors in Australia

This prospectus:

- (i) does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth) (the “Corporations Act”);
- (j) has not been, and will not be, lodged with the Australian Securities and Investments Commission (“ASIC”), as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and
- (k) may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, available under section 708 of the Corporations Act (“Exempt Investors”).

The common shares may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the common shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any common shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the common shares, you represent and warrant to us that you are an Exempt Investor.

## [Table of Contents](#)

As any offer of common shares under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the common shares you undertake to us that you will not, for a period of 12 months from the date of issue of the common shares, offer, transfer, assign or otherwise alienate those common shares to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

### **Notice to prospective investors in China**

This prospectus will not be circulated or distributed in the PRC and the common shares will not be offered or sold, and will not be offered or sold to any person for re-offering or resale directly or indirectly to any residents of the PRC except pursuant to any applicable laws and regulations of the PRC. Neither this prospectus nor any advertisement or other offering material may be distributed or published in the PRC, except under circumstances that will result in compliance with applicable laws and regulations.

### **Notice to prospective investors in Korea**

The common shares have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder (the "FSCMA"), and the common shares have been and will be offered in Korea as a private placement under the FSCMA. None of the common shares may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder (the "FETL"). Furthermore, the purchaser of the common shares shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the common shares. By the purchase of the common shares, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the common shares pursuant to the applicable laws and regulations of Korea.

### **Notice to prospective investors in Saudi Arabia**

This document may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations as issued by the board of the Saudi Arabian Capital Market Authority ("CMA") pursuant to resolution number 2-11-2004 dated 4 October 2004 as amended by resolution number 1-28-2008, as amended (the "CMA Regulations"). The CMA does not make any representation as to the accuracy or completeness of this document and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this document. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this document, you should consult an authorized financial adviser.

### **Notice to prospective investors in the Dubai International Financial Centre ("DIFC")**

This document relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority ("DFSA"). This document is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no

---

[Table of Contents](#)

responsibility for this document. The securities to which this document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this document, you should consult an authorized financial advisor.

In relation to its use in the DIFC, this document is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

**Notice to prospective investors in Bermuda**

Common shares may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

## Expenses of the offering

We estimate that our expenses in connection with this offering, other than underwriting discounts and commissions, will be as follows:

<b>Expenses</b>	<b>Amount</b>
Securities and Exchange Commission registration fee	\$ *
FINRA filing fee	*
The Nasdaq Global Market listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Miscellaneous costs	*
<b>Total</b>	<b>*</b>

\* To be filed by amendment.

All amounts in the table are estimates except the SEC registration fee, the Nasdaq listing fee and the FINRA filing fee. We will pay all of the expenses of this offering.

## Legal matters

We are being represented by Cooley LLP, New York, New York with respect to certain legal matters as to United States federal securities and New York State law. The validity of our common shares and certain other matters of Dutch law will be passed upon for us by NautaDutilh N.V. with the address of Beethovenstraat 400, 1082 PR Amsterdam, the Netherlands. Certain legal counsel to the underwriters in connection with this offering are Davis Polk & Wardwell LLP, with respect to U.S. federal law, and De Brauw Blackstone Westbroek N.V., with respect to Dutch law.

## Experts

The financial statements as of December 31, 2019 and for the year then ended included in this prospectus have been so included in reliance upon the report (which contains a qualification relating to the omission of comparative figures and transition disclosures required by IFRS 1, as discussed in Note 2 to the consolidated financial statements) of PricewaterhouseCoopers Accountants N.V., an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting. The current address of PricewaterhouseCoopers Accountants N.V. is Boschdijktunnel 10, 5611 AG Eindhoven, The Netherlands.

## Enforcement of civil liabilities

We are organized and existing under the laws of the Netherlands, and, as such, under Dutch private international law rules the rights of our shareholders and the civil liability of our directors and executive officers are governed in certain respects by the laws of the Netherlands. The ability of our shareholders in certain countries other than the Netherlands to bring an action against us, our directors and executive officers may be limited under applicable law. In addition, 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 prospectus, 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.



## Where you can find more information

We have filed with the SEC a registration statement (including amendments and exhibits to the registration statement) on Form F-1 under the Securities Act. This prospectus, which is part of the registration statement, does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. For further information, we refer you to the registration statement and the exhibits and schedules filed as part of the registration statement. If a document has been filed as an exhibit to the registration statement, we refer you to the copy of the document that has been filed. Each statement in this prospectus relating to a document filed as an exhibit is qualified in all respects by the filed exhibit.

Upon consummation of this offering, we will become subject to the informational requirements of the Exchange Act. Accordingly, we will be required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. 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](http://www.sec.gov).

As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our board members 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 will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

We will send our transfer agent a copy of all notices of our general meetings of shareholders and other reports, communications and information that are made generally available to shareholders. The transfer agent has agreed to mail to all shareholders a notice containing the information (or a summary of the information) contained in any notice of a meeting of our shareholders received by the transfer agent and will make available to all shareholders such notices and all such other reports and communications received by the transfer agent.

## Index to consolidated financial statements

	Page
<b>Six months ended June 30, 2020 (unaudited)</b>	
<a href="#">Consolidated interim statements of profit or loss and other comprehensive income</a> (loss)	F-2
<a href="#">Consolidated interim statements of financial position</a>	F-3
<a href="#">Consolidated interim statements of changes in equity</a>	F-4
<a href="#">Consolidated interim statements of cash flows</a>	F-5
<a href="#">Notes to interim financial statements</a>	F-6
<b>Year ended December 31, 2019</b>	
<a href="#">Report of independent registered public accounting firm</a>	F-26
<a href="#">Consolidated statements of profit or loss and other comprehensive income</a> (loss)	F-27
<a href="#">Consolidated statements of financial position</a>	F-28
<a href="#">Consolidated statements of changes in equity</a>	F-29
<a href="#">Consolidated statements of cash flows</a>	F-30
<a href="#">Notes to financial statements</a>	F-31

# Lava Therapeutics B.V.

## Unaudited interim consolidated statements of profit or loss and other comprehensive income (loss)

(In thousands of euros, except share and per share amounts)

	Notes	Six months ended June 30, 2020 (Unaudited)
<b>Revenue</b>		
Research and license revenue	4	€ 592
<b>Total revenue</b>		<b>592</b>
<b>Operating expenses:</b>		
Research and development	5	(6,010)
General and administrative	6	(1,353)
<b>Total operating expenses</b>		<b>(7,363)</b>
<b>Operating loss</b>		<b>(6,771)</b>
Interest expense, net	7	(108)
Foreign currency exchange loss, net		(268)
<b>Total non-operating expenses</b>		<b>(376)</b>
<b>Loss before income tax</b>		<b>(7,147)</b>
Income tax benefit (expense)	8	—
<b>Loss for the period</b>		<b>€ (7,147)</b>
<b>Total comprehensive loss for the period</b>		<b>€ (7,147)</b>
<b>Loss per share, in Euros</b>		
Basic and diluted loss per share attributable to common equity holders	9	€ (3,529.4)
Basic and diluted weighted average number of common shares		2,025

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

# Lava Therapeutics B.V.

## Unaudited interim consolidated statements of financial position

(In thousands of euros)

	Notes	June 30, 2020 (Unaudited)
<b>Assets</b>		
<b>Non-current assets:</b>		
Property and equipment, net	10	€ 833
Right-of-use assets	11	279
Non-current assets and security deposits		27
<b>Total non-current assets</b>		<b>1,139</b>
<b>Current assets:</b>		
Trade receivables and other		114
Prepaid expenses and other current assets		79
VAT receivable		115
Cash and cash equivalents	12	8,341
<b>Total current assets:</b>		<b>8,649</b>
<b>Total assets</b>		<b>€ 9,788</b>
<b>Equity and Liabilities</b>		
<b>Equity</b>		
Share capital		—
Share premium	13	€ 17,066
Equity-settled employee benefits reserve		574
Accumulated deficit		(19,326)
<b>Total equity</b>		<b>(1,686)</b>
<b>Non-current liabilities</b>		
Customer advances and deferred revenue	4	3,255
Lease liabilities	11	212
Borrowings	14	1,996
<b>Total non-current liabilities</b>		<b>5,463</b>
<b>Current liabilities</b>		
Trade payables and other	15	1,317
Lease liabilities	11	135
Accrued expenses and other current liabilities	16	1,009
Customer advances and deferred revenue	4	3,550
<b>Total current liabilities</b>		<b>6,011</b>
<b>Total liabilities</b>		<b>11,474</b>
<b>Total equity and liabilities</b>		<b>€ 9,788</b>

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

# Lava Therapeutics B.V.

## Unaudited interim consolidated statements of changes in equity

(In thousands of euros, except for per share amounts)

	Note	Preference				Common share shares	Share capital	Equity- settled employee benefits reserves	Accumulated losses	Total
		Series A shares	Series A Share premium	Series B shares	Series B Share premium					
Balance at January 1, 2020		7,945	€ 1,065	17,646	€ 16,001	2,025	—	€ 324	€ (12,179)	€ 5,211
Loss for the period (unaudited)		—	—	—	—	—	—	—	(7,147)	(7,147)
Share-based compensation expense (unaudited)	17	—	—	—	—	—	—	250	—	250
<b>Balance at June 30, 2020 (unaudited)</b>		<b>7,945</b>	<b>€ 1,065</b>	<b>17,646</b>	<b>€ 16,001</b>	<b>2,025</b>	<b>—</b>	<b>€ 574</b>	<b>€ (19,326)</b>	<b>€(1,686)</b>

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

# Lava therapeutics B.V.

## Unaudited interim consolidated statements of cash flows

(In thousands of euros)

	Notes	Six months ended June 30, 2020 (Unaudited)
<b>Cash flows from operating Activities</b>		
Loss before income tax		(€7,147)
Adjusted for:		
Depreciation and amortization of non-current assets		80
Foreign currency exchange loss, net		268
Depreciation and amortization of right of use assets	11	91
Share-based compensation expense	17	250
Changes in working capital:		
Trade receivables and other		(53)
VAT receivable		19
Other assets		(24)
Trade accounts payable and other	15	824
Deferred revenue	4	6,805
Other liabilities	16	327
<b>Net cash provided by (used in) operating activities</b>		<b>1,440</b>
<b>Cash flows from investing activities</b>		
Purchase of property and equipment	10	(143)
Change in restricted cash		(1)
<b>Net cash used in investing activities</b>		<b>(144)</b>
<b>Cash flows from financing activities</b>		
Proceeds from borrowings	14	769
Payment of principal portion of lease liabilities		(93)
<b>Net cash provided by financing activities</b>		<b>769</b>
<b>Net increase (decrease) in cash, cash equivalents, and restricted cash</b>		<b>2,065</b>
<b>Cash and cash equivalents at the beginning of year</b>	12	<b>€ 6,544</b>
Effects of exchange rate changes on the balance of cash held in foreign currencies		(268)
<b>Cash and cash equivalents at end of the period</b>	12	<b>€ 8,341</b>
<b>Supplemental schedule of noncash investing and financing activities:</b>		
Purchases of property and equipment in accounts payable and accrued expenses		€ 117

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

# Lava Therapeutics B.V.

## Notes to unaudited interim consolidated financial statements

### For the six months ended June 30, 2020

(In thousands of euros, unless otherwise stated)

#### 1. Corporate information

Lava Therapeutics B.V., or the Company, which was founded in 2016, is a private limited company incorporated and domiciled in the Netherlands. The Company's registered office is Yalelaan 60, 3584CM in Utrecht. The Company is registered at the Chamber of Commerce under number 65335740.

The Company's subsidiary, Lava Therapeutics, Inc., which was founded in 2019, is incorporated in the United States.

The Company and its subsidiary, or the Group, are a clinical-stage biotechnology company focused on transforming cancer treatment by developing a platform of novel bispecific antibodies engineered to selectively induce gamma-delta T cell-mediated immunity against tumor cells. The Group's approach activates a specific and relatively abundant gamma-delta effector T cell subset called Vg9Vd2 T cells. These cells can naturally distinguish tumor cells from healthy cells through their ability to sense certain intracellular metabolites that are enriched in cancer cells. Vg9Vd2 T cell activation by the Group's gamma-delta bsTCEs occurs with very high potency and specificity thereby providing a significant opportunity to deliver effective and safe therapeutics to patients. The Group is currently advancing a pipeline of multiple gamma-delta bsTCEs for the potential treatment of both hematologic malignancies and solid tumors.

#### 2. Summary of significant accounting policies

The principal accounting policies applied in the preparation of these unaudited interim 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 unaudited interim consolidated financial statements of the Group have been prepared in accordance with IAS 34 Interim Financial Reporting with the exception that these consolidated financial statements do not include comparative figures. These unaudited interim consolidated financial statements have been prepared for the purpose of an initial confidential filing with the Securities and Exchange Commission. Given this specific circumstance, the comparative figures are not included for the reason that they will not be needed at the time the registration statement would become effective. These unaudited interim consolidated financial statements and should be read in conjunction with the Group's annual consolidated financial statements as at and for the year ended December 31, 2019, or the last annual financial statements. These unaudited interim consolidated financial statements do not include all the information required for a complete set financial statements prepared in accordance with IFRS as issued by the IASB. However, selected explanatory notes are included to explain events and transactions that are significant to an understanding of the changes in the Group's financial position and performance since the last annual financial statements.

The unaudited interim consolidated financial statements of the Group have been prepared on a historical cost basis.

The preparation of the unaudited interim 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 unaudited interim consolidated financial statements, are disclosed in note 3.

### **Going concern**

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

Through June 30, 2020, the Group funded its operations with proceeds from sales of equity financings, collaboration and licensing agreements, government grants and borrowings under various agreements. Since inception the Group has incurred recurring net losses of €7.1 million for six months ended June 30, 2020.

As of June 30, 2020, the Group had an accumulated deficit of €19.3 million. The group expects to continue to generate operating losses in the foreseeable future. The Group expects that its cash and cash equivalents of €8.3 million as of June 30, 2020 and committed equity financing of cumulative preference C shares, or the Series C Preferred, of €62.2 million, which will consist of net proceeds from the three tranches, will be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months following the issuance of these unaudited interim consolidated financial statements. The holders of Series C Preferred are entitled to a senior liquidation preference prior to holders of cumulative preference B shares, or the Series B Preferred, cumulative preference A shares, or the Series A Preferred, or common shares. Series C Preferred accrue an annual non-compounding dividend of 8% per subscription price per share. Series A Preferred, Series B Preferred and Series C Preferred hold conversion rights to convert into common shares.

Cash requirements and cash resource needs will vary significantly depending upon the amount and related timing of expenditures required to complete ongoing development and pre-clinical and clinical testing of products as well as regulatory efforts and collaborative arrangements necessary for the Group's products that are currently under development.

The Group will continue to seek financing to fund expansion of its operations, including but not limited to, further development of its products and services and efforts to meet regulatory requirements in the United States and other countries. The Group relies on capital raises to fund its future growth until which time it derives meaningful revenues through commercial product sales or strategic partnerships to provide the necessary cash flows to support its cost structure. The Group is actively exploring various options to secure financing and improve its financial position. The Group would consider exploring potential strategic partnerships, which could provide a capital infusion to the Group. There is no assurance, however, that the Group will complete any of these arrangements or obtain them on terms and conditions favorable to the Group.

The future viability of the Group beyond that point is dependent on its ability to generate revenue and positive cash flows by obtaining equity and/or borrowings financing to fund future operations.

The following matters have been considered by management in determining the appropriateness of the going concern basis of preparation in these unaudited interim consolidated financial statements:

### **Financing**

In September 2020, the Group closed an oversubscribed financing of the Series C Preferred that yielded gross proceeds of €71.0 million and net €62.2 million, to fund the advancement of our pipeline and platform. See Note 21 for further details.

### **Research and license revenue**

In May 2020, the Group entered into a research and license agreement with Janssen Biotech, Inc., or the Janssen Agreement. The Group's performance obligations under the terms of this agreement include discovery,



## [Table of Contents](#)

research and certain early pre-clinical development of bispecific antibodies. Payments to the Group include a non-refundable upfront payment, payments based upon the achievement of defined development and commercial milestones, and tiered-royalties on licensed product sales under the agreement.

The Group evaluates the Janssen Agreement in accordance with IFRS 15 "*Revenue from contracts with customers*". IFRS 15 requires a five-stage approach, including (i) identification of the contract; (ii) identification of performance obligations; (iii) determination of the transaction price; (iv) allocation of the transaction price; and (v) recognition of revenue.

### Upfront payment

The non-refundable upfront payment received by the Group under the Janssen Agreement was recorded as deferred revenue. Such amounts are recognized on a straight-line basis over 24 months, the term of the agreement.

### Development milestones

The Janssen Agreement includes milestone payments that are triggered by the achievement of predefined milestones. These milestone payments represent variable consideration that are not initially recognized within the transaction price. Revenue from milestones will be recognized at the time the specified milestone events have been achieved.

### Sales milestones and royalty payments

The Janssen Agreement also includes certain sales-based milestone and royalty payments upon successful commercialization of a licensed product. In accordance with IFRS 15, the Company recognizes revenues from sales-based milestone and royalty payments at the later of (i) the occurrence of the subsequent sale; or (ii) the performance obligation to which some or all of the sales-based milestone or royalty payments has been allocated has been satisfied. The Group anticipates recognizing these milestones and royalty payments if and when subsequent sales are generated from a licensed product under the Janssen Agreement.

## **COVID-19**

In March 2020, the COVID-19 virus caused a worldwide pandemic. Although the short- and long-term effects of this pandemic is unknown, management expects that the Group business operations can be directly or indirectly impacted by this situation. Currently there are no significant impacts on our operations, but we acknowledge there are risks and uncertainties with respect to:

- Availability of supplies and equipment for our laboratories
- Availability of staff
- Start dates of clinical trials due to risks of opening clinical sites and patient recruitment
- Fundraising and access to the capital market

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. However, the full impact of the COVID-19 outbreak continues to evolve as of the date of issuance of these unaudited interim consolidated financial statements. As such, it is uncertain as to the full magnitude that the pandemic will have on the Group's financial condition, liquidity, and future results of operations.

**(b) Basis of consolidation**

The unaudited interim consolidated financial statements comprise the financial statements of the Group as of June 30, 2020. Subsidiaries are all entities over which the Group has control. Control is achieved when the Group 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 Group 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 Group's accounting policies. All intragroup assets and liabilities, equity, income, expenses, and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

**(c) Foreign currency**

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates. The Group's unaudited interim consolidated financial statements are presented in Euro, or EUR, which is the Group's functional currency.

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year-end exchange rates are recognized in the consolidated statements of profit or loss or other within finance income or finance costs.

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

- Monetary assets and liabilities are translated at the closing rate at the reporting date;
- Income and expenses for each statement of profit or loss or other are translated at average exchange rates; and
- All resulting exchange differences are recognized in other comprehensive income/(loss).

**(d) Segment information**

In accordance with IFRS, the Group'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) Research and development expenses**

The Group expenses research and development expenses as incurred and does not capitalize them pursuant to IAS 38, *Intangible Assets*. The Group'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.

**(f) General and administrative expenses**

The Group's general and administrative expenses consist of personnel-related expenses for employees involved in general corporate functions, including accounting, finance, tax, legal and human relations, costs associated

## [Table of Contents](#)

with outside professional fees 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.

### **g) 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 Group issues equity-settled share-based awards and accounts for these awards in accordance with IFRS 2. For the Group's share option plans, management's judgement is that the Black-Scholes valuation formula is the most appropriate methods for determining the fair value of the Group's share options considering the terms and conditions attached to the grants made and to reflect exercise behavior. Since the Group is a private company, there is no published share price information available. Consequently, the Group needs to estimate the fair value of its shares and the expected volatility of that share value. These assumptions and estimates are further discussed in note 17 to the unaudited interim consolidated 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 Group's share options.

### **h) Employee benefits**

The Group provides defined contribution plans to its employees. Contributions to defined contribution plans are expensed when employees provide services. The Group has no further payment obligations once the contributions have been paid. The Group's post-employment schemes do not include any defined benefit plans.

### **i) 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.

## [Table of Contents](#)

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 group 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 Group expects, at the reporting date, to recover or settle the carrying amount of its assets and liabilities.

### **j) 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.

### **k) Property, plant, 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

## [Table of Contents](#)

Depreciation of property, plant and equipment used for Laboratory equipment and ICT equipment is included within Research and development expenses in the consolidated statement of profit or loss and other comprehensive income (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 statement of profit or loss and other comprehensive income (loss) when the asset is derecognized.

Management of the Group 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.

### **l) 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 profit or loss or other comprehensive income 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.

### **m) Provisions**

Provisions are recognized when the Group 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.

### **n) Value added tax**

Expenses and assets are recognized net of the amount of value added tax, or 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.

### **o) Financial instruments**

#### **(i) Financial assets**

The Group's financial assets are comprised of cash and cash equivalents, 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 Group receives or delivers the asset. The Group

## [Table of Contents](#)

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 Group 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 Group'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 profit or loss and other comprehensive income (loss).

Payables and borrowings are classified as current liabilities unless the Group 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 Group does not hold any financial assets and financial liabilities other than those measured at amortized cost. Management assessed that the carrying values of the Group's financial assets and financial liabilities measured at amortized cost are a reasonable approximation of their fair values.

## **p) Leases**

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

### (i) **Rights-of-use assets**

The Group 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 Group 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 Group 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 Group's unaudited interim 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 unaudited interim 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 Group's accounting policies, management has made the following judgments, which have the most significant effect on the amounts recognized in the unaudited interim consolidated financial statements:

##### ***Deferred tax assets***

Deferred tax assets have not been recognized in respect of tax losses, because the Group 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, instead of the general headline rate of 25%. Lava Therapeutics B.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, that 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 Group based its assumptions and estimates on parameters available when the unaudited interim 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 Group. Such changes are reflected in the assumptions when they occur.

#### **New standards, interpretations and amendments adopted by the Group**

The Group has not early adopted any standards, interpretations or amendments that have been issued, but are not yet effective. The Group intends to adopt these new and amended standards and interpretations, if applicable, when they become effective. The following amended standards and interpretations are not expected to have a significant impact on the Group's unaudited interim consolidated financial statements:

- Amendment to IFRS 3: Definition of a Business (effective date—January 1, 2020).
- Amendments to IAS 1 and IAS 8: Definition of Material (effective date—January 1, 2020).
- Amendments to References to Conceptual Framework in IFRS Standards (effective date—January 1, 2020).

## [Table of Contents](#)

- Amendments to IFRS 9, IAS 39 and IFRS 7: Interest Rate Benchmark Reform (effective January 1, 2020).
- Amendments to IFRS 17: Insurance Contracts (effective January 1, 2021).

### 4. Revenue

#### Research and license agreement

In May 2020, the Group entered into the Janssen Agreement. As part of the Janssen Agreement, the Group received a non-refundable upfront payment of €7.4 million. As of June 30, 2020, there was €6.8 million of unearned income related to this payment. The revenue has been recognized for two months beginning in May 2020. The unearned income is being recognized as revenue on a straight-line basis over the remaining 22-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. The Group is entitled to receive tiered royalties based on commercial sales levels from low to mid-single digit percentages of net sales of licensed products. Royalties are payable on a licensed product-by-licensed product and country-by-country basis beginning with the first commercial sale of such licensed product in such country of sale and expiring ten years after such sale, subject to specified and capped reductions for the market entry of biosimilar products, loss of patent coverage of licensed products, and for payments owed to third parties for additional rights necessary to commercialize licensed products in the territory.

The Group'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:

<b>(euros, in thousands)</b>	
<b>Balance at January 1, 2020</b>	<b>—</b>
Deferral of revenue	(7,397)
Recognized during the period	592
<b>Balance at June 30, 2020 (unaudited)</b>	<b>(6,805)</b>

### 5. Research and development expenses

Research and development expenses include the following categories:

	<b>June 30, 2020 (unaudited)</b>
Personnel-related expenses	695
Pre-clinical and clinical trial expenses	4,140
Research and development activities expenses	907
Share-based compensation expense	67
Facilities and other research and development expenses	201
	<b>6,010</b>



## 6. General and administrative expenses

General and administrative expenses include the following categories:

	<b>June 30, 2020</b>
	<b>(unaudited)</b>
Personnel-related expenses	604
Professional and consultant fees	402
Facilities, fees and other related costs	164
Share-based compensation expense	183
	<u>1,353</u>

## 7. Interest expense, net

<b>(euros in thousands)</b>	<b>June 30, 2020</b>
	<b>(unaudited)</b>
Interest expense on borrowings	80
Interest expense related to leases	28
	<u>108</u>

## 8. Taxation

The Group 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 Group is in a loss-making position and has a history of losses.

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 Group 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 the Group. Management concluded that there is not sufficient probability as per IAS 12 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

The activities of Lava Therapeutics, Inc. are limited and regarding only to the CEO and CMO for Lava Therapeutics B.V. who are both domiciled in the United States. The remuneration of Lava Therapeutics, Inc. is based on the costs incurred for the services rendered including a profit mark-up.

## 9. 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 June 30, 2020, 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:

(euros, in thousands)	June 30, 2020 (unaudited)
Loss attributable to the parent entity	€ (7,147)
<b>Loss attributable to common equity holders of the parent entity</b>	<b>€ (7,147)</b>
Weighted average number of common shares	2,025
<b>Basic and diluted loss per share (EUR)</b>	<b>€ (3,529.4)</b>

## 10. Property, plant and equipment

Movements in property, plant and equipment were as follows:

(euros, in thousands)	Building improvement	Laboratory equipment	Office equipment	ICT equipment	Total
<b>Cost</b>					
Balance at January 1, 2020	36	613	28	68	745
Additions	10	233	2	14	259
<b>Balance at June 30, 2020</b>	<b>46</b>	<b>846</b>	<b>30</b>	<b>82</b>	<b>1,004</b>
<b>Accumulated depreciation</b>					
Balance at January 1, 2020	1	79	3	8	91
Charge for the period	2	68	2	8	80
<b>Balance at June 30, 2020</b>	<b>3</b>	<b>147</b>	<b>5</b>	<b>16</b>	<b>171</b>
<b>Carrying amounts</b>					
<b>Balance at June 30, 2020</b>	<b>€ 43</b>	<b>€ 699</b>	<b>€ 25</b>	<b>€ 66</b>	<b>€ 833</b>

## 11. Leases

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

(euros, in thousands)	
Balance at January 1, 2020	370
Depreciation expense	(91)
<b>Balance at June 30, 2020 (unaudited)</b>	<b>279</b>

## [Table of Contents](#)

The following table provides information about the maturities of the Group's lease liabilities at June 30, 2020 (unaudited):

<b>(euros, in thousands)</b>	
<b>Year</b>	
2020	138
2021	243
<b>Total lease commitments</b>	<b>381</b>
Less: imputed lease interest	(34)
<b>Total lease liabilities</b>	<b>347</b>
<b>Current portion</b>	<b>212</b>
<b>Non-current portion</b>	<b>135</b>

The average incremental borrowing rate applied to the lease liabilities was 15.6%.

Interest expense related to leases during the six months ended June 30, 2020 (unaudited) was €28 thousand. Cash outflows related to leases during the six months ended June 30, 2020 was €121 thousand.

## 12. Cash and cash equivalents

<b>(euros, in thousands)</b>	<b>June 30, 2020 (unaudited)</b>
Current bank accounts	8,341
	<b>8,341</b>

Information about the credit risk over cash and cash equivalents is presented in note 19.

## 13. Share capital, share premium and other capital reserves

The following table provides information about the Group's share capital as of June 30, 2020 (unaudited):

	<b>Authorized</b>	<b>Issued and fully paid</b>
<b>Common shares of EUR 0.01 each</b>	<b>2,025</b>	<b>2,025</b>
Preference Series A shares of EUR 0.01 each	7,945	7,945
Preference Series B shares of EUR 0.01 each	17,646	17,646
<b>Preference shares of EUR 0.01 each</b>	<b>25,591</b>	<b>25,591</b>
	<b>27,616</b>	<b>27,616</b>

## Share capital and share premium

	<b>Preference Series A</b>		<b>Preference Series B</b>		<b>Total preference</b>			<b>Common</b>	
	<b>shares</b>	<b>premium</b>	<b>shares</b>	<b>premium</b>	<b>shares</b>	<b>premium</b>	<b>capital</b>	<b>shares</b>	<b>capital</b>
<b>At January 1, 2020</b>	7,945	€ 1,065	17,646	€ 16,001	25,591	€ 17,066	€ 0.26	2,025	€ 0.02
Issue of shares	—	—	—	—	—	—	—	—	—
<b>At June 30, 2020 (unaudited)</b>	7,945	€ 1,065	17,646	€ 16,001	25,591	€ 17,066	€ 0.26	2,025	€ 0.02

## [Table of Contents](#)

The following table provides information about the Group's major shareholders on a non-diluted basis as of June 30, 2020 (unaudited):

Vesuvius B.V.	33.3%
MRL Ventures	8.0%
Gilde Healthcare	28.0%
Versant Ventures	28.0%
Other shareholders	2.7%
	<u>100.0%</u>

## 14. Borrowings

(euros, in thousands)	Stated interest rate	Currency	Maturity	June 30, 2020 (unaudited) Amount, incl. accrued interest
Innovation Credit	10.0%	EUR	31.12.2023	1,996
<b>Total</b>				<u>1,996</u>
<b>Current</b>				—
<b>Non-current</b>				<u>1,996</u>

### Innovation credit

In 2019, the Group applied for, and received a €5.0 million Innovation Credit, or the Credit, from Rijksdienst voor Ondernemend Nederland, or RVO. The Credit contributes to the development of one of the Group's main projects, and certain assets of that project are pledged as a guarantee.

Borrowings under the Credit, which bear interest at 10%, 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 June 30, 2020, the Group had €2.0 million in borrowings under the Credit, all of which was classified as long-term.

The Credit contains customary limitations on the Group and its shareholders, including the shareholders of the Group 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 Group 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 Group has financed its own contribution in the project sufficiently

At June 30, 2020, the Group was in compliance with all of the terms of the Credit.

Interest expenses incurred during June 30, 2020 (unaudited) were €80 thousand.

## 15. Trade payables and other

(euros, in thousands)	June 30, 2020 (unaudited)
Trade payables and other	1,317
	<b>1,317</b>

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 Group's exposure to currency and liquidity risk in relation to its trade and other payables is included in note 19.

## 16. Accrued expenses and other current liabilities

(euros, in thousands)	June 30, 2020 (unaudited)
Personnel-related expenses	237
Research and development external project costs	653
Professional fees	109
Other provisions	10
	<b>1,009</b>

## 17. Share-based compensation

### 17.1 Description of Equity Incentive Plans

#### (i) Netherlands

The Group established a foundation "Stichting Administratiekantoor Lava Therapeutics", or the Foundation. The Foundation has an agreement with the Group to facilitate the administration of share-based compensation awards.

Options granted under the Group's share option programs entitle the eligible participant to purchase depository receipts for common shares in the Group, subject to meeting the vesting conditions. The ownership of such depository receipts is conditional to the terms and conditions of the foundation's Conditions of Administration. Under defined circumstances, the participants are obliged to offer the acquired depository receipts to the Foundation.

In 2018, the group established a share option plan that entitles employees, director, and consultants providing services to purchase depository receipts for common shares in the Group. Under this plan, holders of vested options are entitled to purchase depository receipts for common shares at the exercise price determined at the date of the grant.

Upon exercise of options, the Foundation issues to such individuals non-voting depository receipts representing the underlying common shares, against payment of the option exercise price. The voting rights associated with the common shares remain with the Foundation.

#### (ii) United States

In 2020, the Group established a U.S. share option plan that entitles employees, directors and consultants providing services to give the right to acquire a number of common shares. Under the U.S. plan, the holders of

## [Table of Contents](#)

vested options are entitled to purchase number of common shares at the exercise price determined at the date of the grant.

In both stock option plans, the options granted under the share option programs vest in installments over a four-year period from the grant date. 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 granted are exercisable once vested.

The following table provides information about share-based awards as at June 30, 2020 (unaudited):

	Number of options	Weighted average exercise price €
Outstanding at January 1 2020	1,548	0.01
Granted	1,335	849.27
Outstanding at June 30, 2020 (unaudited)	2,883	393.27
Exercisable at June 30, 2020 (unaudited)	728	388.84

### 17.2 Measurement of fair values

The fair value of the employee share options has been measured using the Black-Scholes model. 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 of the share options granted during the period ending on June 30, 2020 (unaudited):

	June 30, 2020 (unaudited)
Expected annual volatility	90.0%
Expected life, years—NL	3.92
Expected life, years—US	6.08
Dividend yield	—
Risk-free interest rate	(0.62%) - (0.91%)

Since the Group is a private company, 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 Group will continue to use this group for calculation of expected volatility data until sufficient historical market data is available for estimating the volatility of our common shares after the closing of this offering.

### Valuation of common shares

The fair value of the common shares is determined by the Group's management board and supervisory board, and takes into account our most recently available valuation of common shares performed by an independent

## Table of Contents

valuation firm and the assessment of additional objective and subjective factors the Group believes are relevant and which may have changed from the date of the most recent valuation through the date of the grant.

The Group's management board and supervisory board consider 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, or AICPA, *Audit and Accounting Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation* has been considered.

The "prior sale of company stock" method, a form of the market approach, has been applied to estimate the total enterprise value. The prior sale of company stock method considers any prior arm's length sales of the Group's equity securities. Considerations factored into the analysis include: 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 Group at the time of the sale. As such, the value per share has been benchmarked to the external transactions of Group stock and external financing rounds. For determining the value of the Group's shares, the prior sale of company stock method has been relied on to estimate the total value of the Group'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 is considered a strong indication of fair value.

Given that there are multiple classes of equity, the Option Pricing Method, or OPM, has 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, or DLOM, was applied, 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 were €250 thousand for the six months ended June 30, 2020 (unaudited), as referenced in notes 5 and 6.

## 18. Related parties

### Key management compensation

Key management includes members of the Group'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 six months ended June 30, 2020. The disclosure amounts are based on the expense recognized in the consolidated statements of profit or loss and other comprehensive income (loss).

<b>(euros, in thousands)</b>	<b>June 30, 2020</b>
	<b>(unaudited)</b>
<b>Key management compensation</b>	
Short term employee benefits	422
Share-based payments	203
Post-employment benefits	30
	<b>655</b>

### Director and shareholder compensation

A member of the Group's board of directors and existing shareholder receive consultancy fees. The compensation paid to this individual is presented below for the six months ended June 30, 2020. The disclosure amounts are based on the expense recognized in the consolidated statements of profit or loss and other comprehensive income (loss).

<b>(euros, in thousands)</b>	<b>June 30, 2020</b>
	<b>(unaudited)</b>
<b>Director and shareholder compensation</b>	
Consultancy fees	26
	<b>26</b>

## 19. Financial instruments, risk management and capital management

### 19.1 Financial assets and financial liabilities

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



## 19.2 Financial risk management

	June 30, 2020 (unaudited)
<b>(euros, in thousands)</b>	
<b>Financial assets measured at amortized cost</b>	
Cash and cash equivalents (note 12)	8,341
Trade receivables and other	114
Security deposits	27
<b>Total financial assets</b>	<b>8,482</b>
<b>Financial liabilities measured at amortized cost</b>	
Trade payables and other (note 15)	1,317
Lease liabilities (note 11)	347
Borrowings (note 14)	1,996
Accrued expenses and other current liabilities (note 16)	1,009
<b>Total financial liabilities</b>	<b>4,669</b>

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

### 19.2.1 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 Group, comprises two types of risk: interest rate risk and currency risk. Financial instruments affected by market risk include cash and cash equivalents, accounts receivable and trade and other payables.

The Group does not enter into any derivative financial instruments to manage its exposure to foreign currency risk and interest rate risk.

### 19.2.2 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 Group 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 Group held cash and cash equivalents of €8.3 million at June 30, 2020. Cash and cash equivalents are primarily held with banks, which are rated not less than BBB- to BBB, based on Standard & Poor's and Fitch ratings. As at June 30, 2020, the Group held 100% of its cash and cash equivalents with banks having external credit ratings of AA/A+.

## 19.3 Capital management

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

## [Table of Contents](#)

The capital structure of the Group consists of net debt (borrowings as detailed in note 14 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 Group'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 six months ended June 30, 2020.

## **20. Contingencies**

### **Legal proceedings**

From time to time, the Group 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 Group. In accordance with IFRS, the Group 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 Group 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.

On January 1, 2017, the Group entered into a license and assignment agreement with Stichting VUmc, or the VUmc Agreement, for the contingent transfer of patent rights, and non-severable improvements. Under the VUmc Agreement, the Group is obligated to pay royalties, as well as a milestone payment in the case of certain events, including the listing of the majority of the shares of the Group on a recognized stock exchange, or ten years after the agreement's effective date. In accordance with IFRS, these obligations are not reflected in the accompanying consolidated statements of financial position.

## **21. Events after the reporting date**

### **Series C preferred financing**

In September 2020, the Group closed an oversubscribed financing of Series C Preferred that resulted in tranche-based commitments of €71.0 million gross and €62.2 million net, to fund the advancement of our pipeline and platform. In connection with the Series C Preferred financing, the Group agreed to sell the Series C Preferred in three tranches. On September 15, 2020, the first tranche of gross €19.1 million and 18,705 preferential shares, was funded and €4.1 million of Series A Preferred were repurchased, resulting in net proceeds of €15.0 million. Funding of the remaining two tranches is subject to satisfaction of certain milestones. If funded, the two remaining tranches would yield net proceeds of €47.2 million in the aggregate, after repurchasing the 3,250 shares of Series A Preferred and 750 common shares from one investor. Series C Preferred accrue an annual non-compounding dividend of 8% per subscription price per share.

### **Janssen agreement**

In December 2020, the Group achieved the first Research Milestone, as defined in the Janssen Agreement, triggering a milestone payment of €0.8 million.

# Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Lava Therapeutics B.V.

## ***Qualified Opinion on the Financial Statements***

We have audited the accompanying consolidated statement of financial position of Lava Therapeutics B.V. and its subsidiaries (the “Company”) as of December 31, 2019, and the related consolidated statements of profit or loss and other comprehensive income (loss), changes in equity and cash flows for the year then ended, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, except for the effects of the matter discussed in the following paragraph, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019, and the results of its operations and its cash flows for the year then ended in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

As discussed in Note 2 to the consolidated financial statements, the consolidated financial statements do not include comparative figures or required transition disclosures as required by IFRS 1, “First-time adoption of International Financial Reporting Standards,” which constitutes a departure from International Financial Reporting Standards as issued by the International Accounting Standards Board.

## ***Basis for Qualified 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 audit. 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 audit of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ R.M.N. Admiraal RA  
PricewaterhouseCoopers Accountants N.V.  
Eindhoven, the Netherlands  
January 22, 2021

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

# Lava Therapeutics B.V.

## Consolidated statements of profit or loss and other comprehensive income (loss)

(In thousands of euros, except share and per share amounts)

	Notes	Year ended December 31, 2019
<b>Operating expenses:</b>		
Research and development	4	€ (7,470)
General and administrative	5	(1,111)
<b>Total operating expenses</b>		<b>(8,581)</b>
<b>Operating loss</b>		<b>(8,581)</b>
Interest expense, net	6	(78)
Foreign currency exchange loss, net		(16)
<b>Total non-operating expenses</b>		<b>(94)</b>
<b>Loss before income tax</b>		<b>(8,675)</b>
Income tax benefit (expense)	7	—
<b>Loss for the period</b>		<b>€ (8,675)</b>
Total comprehensive loss for the period		€ (8,675)
<b>Loss per share, in Euros</b>		
Basic and diluted loss per share attributable to common equity holders	8	€ (4,284.1)
Basic and diluted weighted average number of common shares		2,025

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

# Lava Therapeutics B.V.

## Consolidated statements of financial position

(In thousands of euros)

	Notes	December 31, 2019
<b>Assets</b>		
<b>Non-current assets:</b>		
Property and equipment, net	9	€ 654
Right-of-use assets	10	370
Non-current assets and security deposits		26
<b>Total non-current assets</b>		<b>1,050</b>
<b>Current assets:</b>		
Trade receivables and other		61
Prepaid expenses and other current assets		55
VAT receivable		134
Cash and cash equivalents	11	6,544
<b>Total current assets:</b>		<b>6,794</b>
<b>Total assets</b>		<b>€ 7,844</b>
<b>Equity and Liabilities</b>		
<b>Equity</b>		
Share capital		—
Share premium	12	€ 17,066
Equity-settled employee benefits reserve		324
Accumulated deficit		(12,179)
<b>Total equity</b>		<b>5,211</b>
<b>Non-current liabilities</b>		
Lease liabilities	10	211
Borrowings	13	1,134
<b>Total non-current liabilities</b>		<b>1,345</b>
<b>Current liabilities</b>		
Trade payables and other	14	376
Lease liabilities	10	229
Accrued expenses and other current liabilities	15	683
<b>Total current liabilities</b>		<b>1,288</b>
<b>Total liabilities</b>		<b>2,633</b>
<b>Total equity and liabilities</b>		<b>€ 7,844</b>

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

# Lava Therapeutics B.V.

## Consolidated statements of changes in equity

(In thousands of euros, except for per share amounts)

	Note	Preference				Common share shares	Share capital	Equity- settled employee benefits reserves	Accumulated losses	Total
		Series A shares	Series A Share premium	Series B shares	Series B Share premium					
<b>Balance at January 1, 2019</b>		<b>7,945</b>	<b>€ 1,065</b>	<b>17,646</b>	<b>€ 16,001</b>	<b>2,025</b>	<b>—</b>	<b>€ 151</b>	<b>€ (3,504)</b>	<b>€13,713</b>
Loss for the period		—	—	—	—	—	—	—	(8,675)	(8,675)
Share-based compensation expense	16	—	—	—	—	—	—	173	—	173
<b>Balance at December 31, 2019</b>		<b>7,945</b>	<b>€ 1,065</b>	<b>17,646</b>	<b>€ 16,001</b>	<b>2,025</b>	<b>—</b>	<b>€ 324</b>	<b>€ (12,179)</b>	<b>€ 5,211</b>

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

# Lava Therapeutics B.V.

## Consolidated statements of cash flows

(In thousands of euros)

	Notes	Year ended December 31, 2019
<b>Cash flows from operating Activities</b>		
Loss before income tax		(€8,675)
Adjusted for:		
Depreciation and amortization of non-current assets		90
Foreign currency exchange loss, net		—
Depreciation and amortization of right of use assets	10	143
Share-based compensation expense	16	173
Changes in working capital:		
Trade receivables and other		33
VAT receivable		39
Other assets		73
Trade accounts payable and other	14	(169)
Operating lease liabilities	10	368
Other liabilities	15	578
<b>Net cash provided by (used in) operating activities</b>		<b>7,715</b>
<b>Cash flows from investing activities</b>		
Purchase of property and equipment	9	(724)
Change in restricted cash		(26)
<b>Net cash used in investing activities</b>		<b>(750)</b>
<b>Cash flows from financing activities</b>		
Proceeds from borrowings	13	1,048
Payment of principal portion of lease liabilities		(86)
<b>Net cash provided by financing activities</b>		<b>1,048</b>
<b>Net increase (decrease) in cash, cash equivalents, and restricted cash</b>		<b>(7,417)</b>
<b>Cash and cash equivalents at the beginning of year</b>	11	<b>€ 13,961</b>
Effects of exchange rate changes on the balance of cash held in foreign currencies		—
<b>Cash and cash equivalents at end of the period</b>	11	<b>€ 6,544</b>
<b>Supplemental schedule of noncash investing and financing activities:</b>		
Purchases of property and equipment in accounts payable and accrued expenses		—

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

# Lava therapeutics B.V.

## Notes to consolidated financial statements

### For the year ended December 31, 2019

(In thousands of euros, unless otherwise stated)

#### 1. Corporate information

Lava Therapeutics B.V., or the Company, which was founded in 2016, is a private limited company incorporated and domiciled in the Netherlands. The Company's registered office is Yalelaan 60, 3584CM in Utrecht. The Company is registered at the Chamber of Commerce under number 65335740.

The Company's subsidiary, Lava Therapeutics, Inc., which was founded in 2019, is incorporated in the United States.

The Company and its subsidiary, or the Group, are a clinical-stage biotechnology company focused on transforming cancer treatment by developing a platform of novel bispecific antibodies engineered to selectively induce gamma-delta T cell-mediated immunity against tumor cells. The Group's approach activates a specific and relatively abundant gamma-delta effector T cell subset called Vg9Vd2 T cells. These cells can naturally distinguish tumor cells from healthy cells through their ability to sense certain intracellular metabolites that are enriched in cancer cells. Vg9Vd2 T cell activation by the Group's gamma-delta bsTCEs occurs with very high potency and specificity thereby providing a significant opportunity to deliver effective and safe therapeutics to patients. The Group is currently advancing a pipeline of multiple gamma-delta bsTCEs for the potential treatment of both hematologic malignancies and solid tumors.

#### 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 Group have been prepared in accordance with and comply with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, with the exception that these consolidated financial statements do not include figures or required transition disclosures, as required by IFRS 1, "First-time adoption of International Financial Reporting Standards", which constitute departures from IFRS as issued by the IASB. These consolidated financial statements have been prepared for the purpose of an initial confidential filing with the Securities and Exchange Commission. Given this specific circumstance, the comparative figures are not included for the reason that they will not be needed at the time the registration statement would become effective.

The consolidated financial statements of the Group 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 Group will be able to continue as a going concern, which presumes that the Group will, for the foreseeable future, be able to realize its assets and discharge its liabilities in the normal course of business.

Through December 31, 2019, the Group funded its operations with proceeds from sales of equity financings, collaboration and licensing agreements, government grants and borrowings under various agreements. Since inception the Group has incurred recurring net losses of €8.7 million for year ended December 31, 2019.

As of December 31, 2019, the Group had an accumulated deficit of €12.2 million. The group expects to continue to generate operating losses in the foreseeable future. The Group expects that its cash and cash equivalents of €6.5 million as of December 31, 2019 and committed equity financing of cumulative preference C shares or, the Series C Preferred, of €62.2 million, which will consist of net proceeds from the three tranches, will be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months following the issuance of these financial statements. The holders of Series C Preferred are entitled to a senior liquidation preference prior to holders of cumulative preference B shares, (or Series B Preferred), cumulative preference A shares, (or Series A Preferred), or common shares. Series C Preferred accrue an annual non-compounding dividend of 8% per subscription price per share. Series A Preferred, Series B Preferred and Series C Preferred hold conversion rights to convert into common shares.

Cash requirements and cash resource needs will vary significantly depending upon the amount and related timing of expenditures required to complete ongoing development and pre-clinical and clinical testing of products as well as regulatory efforts and collaborative arrangements necessary for the Group's products that are currently under development.

The Group will continue to seek financing to fund expansion of its operations, including but not limited to, further development of its products and services and efforts to meet regulatory requirements in the United States and other countries. The Group relies on capital raises to fund its future growth until which time it derives meaningful revenues through commercial product sales or strategic partnerships to provide the necessary cash flows to support its cost structure. The Group is actively exploring various options to secure financing and improve its financial position. The Group would consider exploring potential strategic partnerships, which could provide a capital infusion to the Group. There is no assurance, however, that the Group will complete any of these arrangements or obtain them on terms and conditions favorable to the Group.

The future viability of the Group beyond that point is dependent on its ability to generate revenue and positive cash flows by obtaining equity and/or borrowings financing to fund future operations.

The following matters have been considered by management in determining the appropriateness of the going concern basis of preparation in these consolidated financial statements:

### **Financing**

In September 2020, the Group closed an oversubscribed financing of preference C shares (or, the Series C Preferred) that yielded gross proceeds of €71.0 million and net €62.2 million, to fund the advancement of our pipeline and platform. See Note 20 for further details.

### **COVID-19**

In March 2020, the COVID-19 virus caused a worldwide pandemic. Although the short- and long-term effects of this pandemic is unknown, management expects that the Group business operations can be directly or

## [Table of Contents](#)

indirectly impacted by this situation. Currently there are no significant impacts on our operations, but we acknowledge there are risks and uncertainties with respect to:

- Availability of supplies and equipment for our laboratories
- Availability of staff
- Start dates of clinical trials due to risks of opening clinical sites and patient recruitment
- Fundraising and access to the capital market

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. However, the full impact of the COVID-19 outbreak continues to evolve as of the date of issuance of these financial statements. As such, it is uncertain as to the full magnitude that the pandemic will have on the Group's financial condition, liquidity, and future results of operations.

### **(b) Basis of consolidation**

The consolidated financial statements comprise the financial statements of the Group as December 31, 2019. Subsidiaries are all entities over which the Group has control. Control is achieved when the Group 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 Group 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 Group's accounting policies. All intragroup assets and liabilities, equity, income, expenses, and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

### **(c) Foreign currency**

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates. The Group's consolidated financial statements are presented in Euro, or EUR, which is the Group's functional currency.

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year-end exchange rates are recognized in the consolidated statements of profit or loss or other within finance income or finance costs.

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

- Monetary assets and liabilities are translated at the closing rate at the reporting date;
- Income and expenses for each statement of profit or loss or other are translated at average exchange rates; and
- All resulting exchange differences are recognized in other comprehensive income/(loss).

### **(d) Segment information**

In accordance with IFRS, the Group'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) Research and development expenses**

The Group expenses research and development expenses as incurred and does not capitalize them pursuant to IAS 38, *Intangible Assets*. The Group'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.

**f) General and administrative expenses**

The Group's general and administrative expenses consist of personnel-related expenses for employees involved in general corporate functions, including accounting, finance, tax, legal and human relations, costs associated with outside professional fees 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.

**g) 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 Group issues equity-settled share-based awards and accounts for these awards in accordance with IFRS 2. For the Group's share option plans, management's judgement is that the Black-Scholes valuation formula is the most appropriate methods for determining the fair value of the Group's share options considering the terms and conditions attached to the grants made and to reflect exercise behavior. Since the Group is a private company, there is no published share price information available. Consequently, the Group needs to estimate the fair value of its shares and the expected volatility of that share value. These assumptions and estimates are further discussed in note 16 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 Group's share options.

**h) Employee benefits**

The Group provides defined contribution plans to its employees. Contributions to defined contribution plans are expensed when employees provide services. The Group has no further payment obligations once the contributions have been paid. The Group's post-employment schemes do not include any defined benefit plans.

**i) 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 group 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 Group expects, at the reporting date, to recover or settle the carrying amount of its assets and liabilities.

**j) 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.

**k) Property, plant, 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.

## Table of Contents

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

Depreciation of property, plant and equipment used for Laboratory equipment and ICT equipment is included within Research and development expenses in the consolidated statement of profit or loss and other comprehensive income (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 statement of profit or loss and other comprehensive income (loss) when the asset is derecognized.

Management of the Group 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.

### **l) 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 profit or loss or other comprehensive income 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.

### **m) Provisions**

Provisions are recognized when the Group 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.

### **n) Value added tax**

Expenses and assets are recognized net of the amount of value added tax, or 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.

## [Table of Contents](#)

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.

### **o) Financial instruments**

#### **(i) Financial assets**

The Group's financial assets are comprised of cash and cash equivalents, 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 Group receives or delivers the asset. The Group 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 Group 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 Group'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 profit or loss and other comprehensive income (loss).

Payables and borrowings are classified as current liabilities unless the Group 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 Group does not hold any financial assets and financial liabilities other than those measured at amortized cost. Management assessed that the carrying values of the Group's financial assets and financial liabilities measured at amortized cost are a reasonable approximation of their fair values.

### **p) Leases**

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

#### **(i) Rights-of-use assets**

The Group 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 Group 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 Group 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 Group'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 Group's accounting policies, management has made the following judgments, which have the most significant effect on the amounts recognized in the consolidated financial statements:

***Deferred tax assets***

Deferred tax assets have not been recognized in respect of tax losses, because the Group 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 (2020 figure), instead of the general headline rate of 25%. Lava Therapeutics B.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, that 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 Group 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 Group. Such changes are reflected in the assumptions when they occur.

## New standards, interpretations and amendments adopted by the Group

The Group has not early adopted any standards, interpretations or amendments that have been issued, but are not yet effective. The Group intends to adopt these new and amended standards and interpretations, if applicable, when they become effective. The following amended standards and interpretations are not expected to have a significant impact on the Group's financial statements:

- Amendment to IFRS 3: Definition of a Business (effective date—January 1, 2020).
- Amendments to IAS 1 and IAS 8: Definition of Material (effective date—January 1, 2020).
- Amendments to References to Conceptual Framework in IFRS Standards (effective date—January 1, 2020).
- Amendments to IFRS 9, IAS 39 and IFRS 7: Interest Rate Benchmark Reform (effective January 1, 2020).
- Amendments to IFRS 17: Insurance Contracts (effective January 1, 2021).

## 4. Research and development expenses

Research and development expenses include the following categories:

<b>(euros, in thousands)</b>	<b>December 31, 2019</b>
Personnel-related expenses	1,305
Pre-clinical and clinical trial expenses	4,594
Research and development activities expenses	1,351
Share-based compensation expense	163
Facilities and other research and development expenses	57
	<u>7,470</u>

## 5. General and administrative expenses

General and administrative expenses include the following categories:

<b>(euros in thousands)</b>	<b>December 31, 2019</b>
Personnel-related expenses	393
Professional and consultant fees	608
Facilities, fees, and other related costs	100
Share-based compensation expense	10
	<u>1,111</u>

## 6. Interest income / (expense), net

<b>(euros in thousands)</b>	<b>December 31, 2019</b>
Interest expense on borrowings	12
Interest expense related to leases	66
	<u>78</u>

## 7. Taxation

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



## Table of Contents

### Netherlands

No tax charge or income was recognized during the reporting periods since the Group is in a loss-making position and has a history of losses. As at December 31, 2019 the Group has Dutch tax loss carry-forwards of €11.8 million. The 2019 taxable amount is not final as the 2019 Dutch corporate income tax return is still in draft.

As a result of the Dutch corporate income tax law, tax loss carryforwards are subject to a time limitation of six years. However, tax-losses incurred up to and including the 2018 tax year, can be set-off against any profit in the nine following years:

<b>(euros in millions)</b>		
<b>Year</b>	<b>Loss per year</b>	<b>Evaporation per year</b>
2016	€ 0.1	2025
2017	0.8	2026
2018	2.5	2027
2019	8.4	2025
	<u>€ 11.8</u>	

On the basis of the 2019 annual accounts according to IFRS, there are accounting-to-tax differences of €0.3 million. These differences relate to the IFRS 16 lease amounts and expenses which were treated as non-deductible for Dutch corporate income tax purposes of €0.1 million and non-deductible share-based payments and other non-deductible mixed expenses of €0.2 million.

Up to and including 2019, 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 Group 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 the Group. Management concluded that there is not sufficient probability as per IAS 12 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

The activities of Lava Therapeutics, Inc. are limited and regarding only to the CEO and CMO for Lava Therapeutics B.V. who are both domiciled in the United States. The remuneration of Lava Therapeutics, Inc. is based on the costs incurred for the services rendered including a profit mark-up.

## **8. 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.

## [Table of Contents](#)

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, 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:

(euros, in thousands)	<b>December 31, 2019</b>
Loss attributable to the parent entity	€ (8,675)
<b>Loss attributable to common equity holders of the parent entity</b>	<b>€ (8,675)</b>
Weighted average number of common shares	2,025
<b>Basic and diluted loss per share (EUR)</b>	<b>€ (4,284.1)</b>

## 9. Property, plant and equipment

Movements in property, plant and equipment were as follows:

(euros, in thousands)	Building improvement	Laboratory equipment	Office equipment	ICT equipment	Total
<b>Cost</b>					
Balance at January 1, 2019	—	—	—	21	21
Additions	36	613	28	47	724
<b>Balance at December 31, 2019</b>	<b>36</b>	<b>613</b>	<b>28</b>	<b>68</b>	<b>745</b>
<b>Accumulated depreciation</b>					
Balance at January 1, 2019	—	—	—	1	1
Charge for the year	1	79	3	7	90
<b>Balance at December 31, 2019</b>	<b>1</b>	<b>79</b>	<b>3</b>	<b>8</b>	<b>91</b>
<b>Carrying amounts</b>					
<b>Balance at December 31, 2019</b>	<b>€ 35</b>	<b>€ 534</b>	<b>€ 25</b>	<b>€ 60</b>	<b>€ 654</b>

## 10. Leases

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

(euros, in thousands)	
<b>Balance at January 1, 2019</b>	<b>58</b>
Additions	455
Depreciation charges	(143)
<b>Balance at December 31, 2019</b>	<b>370</b>

## [Table of Contents](#)

The following table provides information about the maturities of the Group's lease liabilities at December 31, 2019:

<b>(euros, in thousands)</b>	
<b>Year</b>	
2020	259
2021	243
<b>Total lease commitments</b>	<b>502</b>
Less: imputed lease interest	(62)
<b>Total lease liabilities</b>	<b>440</b>
<b>Current portion</b>	<b>229</b>
<b>Non-current portion</b>	<b>211</b>

The average incremental borrowing rate applied to the lease liabilities was 15.6%.

Interest expense related to leases during the year ended December 31, 2019 was €66 thousand. Cash outflows related to leases during the year ended December 31, 2019 was €151 thousand.

## 11. Cash and cash equivalents

<b>(euros, in thousands)</b>	<b>December 31, 2019</b>
Short-term deposits	100
Current bank accounts	6,444
	<b>6,544</b>

Short-term deposits are made for varying periods of between one day and three months, depending on the immediate cash requirements of the Group, and earn interest at the respective short-term deposit rates. Information about the credit risk over cash and cash equivalents is presented in note 18.

## 12. Share capital, share premium and other capital reserves

The following table provides information about the Group's share capital as of December 31, 2019:

	<b>Authorized</b>	<b>Issued and fully paid</b>
<b>Common shares of EUR 0.01 each</b>	<b>2,025</b>	<b>2,025</b>
Preference Series A shares of EUR 0.01 each	7,945	7,945
Preference Series B shares of EUR 0.01 each	17,646	17,646
<b>Preference shares of EUR 0.01 each</b>	<b>25,591</b>	<b>25,591</b>
	<b>27,616</b>	<b>27,616</b>

## Share capital and share premium

	<b>Preference series A</b>		<b>Preference series B</b>		<b>Total preference</b>			<b>Common</b>	
	<b>shares</b>	<b>premium</b>	<b>shares</b>	<b>premium</b>	<b>shares</b>	<b>premium</b>	<b>capital</b>	<b>shares</b>	<b>capital</b>
<b>At January 1, 2019</b>	7,945	€ 1,065	17,646	€ 16,001	25,591	€ 17,066	€ 0.26	2,025	€ 0.02
Issue of shares	—	—	—	—	—	—	—	—	—
<b>At December 31, 2019</b>	7,945	€ 1,065	17,646	€ 16,001	25,591	€ 17,066	€ 0.26	2,025	€ 0.02

## [Table of Contents](#)

The following table provides information about the Group's major shareholders on a non-diluted basis as of December 31, 2019:

Vesuvius B.V.	33.3%
MRL Ventures	8.0%
Gilde Healthcare	28.0%
Versant Ventures	28.0%
Other shareholders	2.7%
	<u>100.0%</u>

## 13. BORROWINGS

(euros, in thousands)	Stated interest rate	Currency	Maturity	December 31, 2019
				Amount, incl. accrued interest
Innovation Credit	10.0%	EUR	31.12.2023	1,134
<b>Total</b>				<b>1,134</b>
<b>Current</b>				<b>—</b>
<b>Non-current</b>				<b>1,134</b>

### Innovation credit

In 2019, the Group applied for, and received a €5.0 million Innovation Credit (the "Credit") from Rijksdienst voor Ondernemend Nederland, or RVO. The Credit contributes to the development of one of the Group's main projects, and certain assets of that project are pledged as a guarantee.

Borrowings under the Credit, which bear interest at 10%, 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, 2019, the Group had €1.1 million in borrowings under the Credit, all of which was classified as long-term.

The Credit contains customary limitations on the Group and its shareholders, including the shareholders of the Group 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 Group 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 Group has financed its own contribution in the project sufficiently

At December 31, 2019, the Group was in compliance with all of the terms of the Credit.

Interest expenses incurred during December 31, 2019 were €12 thousand.

## 14. Trade payables and other

(euros, in thousands)	December 31, 2019
Trade payables and other	376
	<b>376</b>

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 Group's exposure to currency and liquidity risk in relation to its trade and other payables is included in note 17.

## 15. Accrued expenses and other current liabilities

(euros, in thousands)	December 31, 2019
Personnel-related expenses	114
Research and development external project costs	369
Professional fees	187
Other provisions	13
	<b>683</b>

## 16. Share-based compensation

### 16.1 Description of equity incentive plans

#### (i) Netherlands

The Group established a foundation "Stichting Administratiekantoor Lava Therapeutics," or the Foundation. The Foundation has an agreement with the Group to facilitate the administration of share-based compensation awards.

Options granted under the Group's share option programs entitle the eligible participant to purchase depositary receipts for common shares in the Group, subject to meeting the vesting conditions. The ownership of such depositary receipts is conditional to the terms and conditions of the foundation's Conditions of Administration. Under defined circumstances, the participants are obliged to offer the acquired depositary receipts to the Foundation.

In 2018, the group established a share option plan that entitles employees, director, and consultants providing services to purchase depositary receipts for common shares in the Group. Under this plan, holders of vested options are entitled to purchase depositary receipts for common shares at the exercise price determined at the date of the grant.

Upon exercise of options, the Foundation issues to such individuals non-voting depositary receipts representing the underlying common shares, against payment of the option exercise price. The voting rights associated with the common shares remain with the Foundation.

## [Table of Contents](#)

### (ii) United States

The following table provides information about share-based awards as at December 31, 2019:

	Number of options	Weighted average exercise price €
Outstanding at January 1, 2019	1,185	0.01
Granted	393	0.01
Exercised	—	—
Forfeited	(30)	0.01
Outstanding at December 31, 2019	1,548	0.01
Exercisable at December 31, 2019	279	0.01

### 16.2 Measurement of fair values

The fair value of the employee share options has been measured using the Black-Scholes model. 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 of the share options granted during the period ending on December 31, 2019:

	December 31, 2019
Expected annual volatility	90.0%
Expected life, years—NL	3.92
Dividend yield	—
Risk-free interest rate	(0.44%) - (0.76%)

Since the Group is a private company, 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 Group will continue to use this group for calculation of expected volatility data until sufficient historical market data is available for estimating the volatility of our common shares after the closing of this offering.

### **Valuation of common shares**

The fair value of the common shares is determined by the Group's management board and supervisory board, and takes into account our most recently available valuation of common shares performed by an independent valuation firm and the assessment of additional objective and subjective factors the Group believes are relevant and which may have changed from the date of the most recent valuation through the date of the grant.

The Group's management board and supervisory board consider 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;

## [Table of Contents](#)

- 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, or AICPA, *Audit and Accounting Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation* has been considered.

The “prior sale of company stock” method, a form of the market approach, has been applied to estimate the total enterprise value. The prior sale of company stock method considers any prior arm’s length sales of the Group’s equity securities. Considerations factored into the analysis include: 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 Group at the time of the sale. As such, the value per share has been benchmarked to the external transactions of Group stock and external financing rounds. For determining the value of the Group’s shares, the prior sale of company stock method has been relied on to estimate the total value of the Group’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 is considered a strong indication of fair value.

Given that there are multiple classes of equity, the Option Pricing Method, or OPM, has 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, or DLOM, was applied, 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 were €173 thousand for the year ended December 31, 2019, as referenced in notes 4 and 5.

## 17. Related parties

### Key management compensation

Key management includes members of the Group'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 year ended December 31, 2019. The disclosure amounts are based on the expense recognized in the consolidated statements of profit or loss and other comprehensive income (loss).

<b>(euros, in thousands)</b>	<b>December 31, 2019</b>
<b>Key management compensation</b>	
Short term employee benefits	829
Share-based payments	137
Post-employment benefits	34
	<u>1,000</u>

### Director and shareholder compensation

A member of the Group's board of directors and existing shareholder receive consultancy fees. The compensation paid to this individual is presented below for the year ended December 31, 2019. In our trade payables position at December 31, 2019 is a €17.0 thousand related party expenses. The disclosure amounts are based on the expense recognized in the consolidated statements of profit or loss and other comprehensive income (loss).

<b>(euros, in thousands)</b>	<b>December 31, 2019</b>
<b>Director and shareholder compensation</b>	
Consultancy fees	79
	<u>79</u>

## 18. Financial instruments, risk management and capital management

### 18.1 Financial assets and financial liabilities

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



## 18.2 Financial risk management

<b>(euros, in thousands)</b>	<b>December 31, 2019</b>
<b>Financial assets measured at amortized cost</b>	
Cash and cash equivalents (note 11)	6,544
Trade receivables and other	61
Security deposits	26
<b>Total financial assets</b>	<b>6,631</b>
<b>Financial liabilities measured at amortized cost</b>	
Trade payables and other (note 14)	376
Lease liabilities (note 10)	440
Borrowings (note 13)	1,134
Accrued expenses and other current liabilities (note 15)	683
<b>Total financial liabilities</b>	<b>2,633</b>

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

### 18.2.1 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 Group, comprises two types of risk: interest rate risk and currency risk. Financial instruments affected by market risk include cash and cash equivalents, accounts receivable and trade and other payables.

The Group does not enter into any derivative financial instruments to manage its exposure to foreign currency risk and interest rate risk.

### 18.2.2 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 Group 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 Group held cash and cash equivalents of €6.5 million at December 31, 2019. Cash and cash equivalents are primarily held with banks, which are rated not less than BBB- to BBB, based on Standard & Poor's and Fitch ratings. As at December 31, 2019, the Group held 100% of its cash and cash equivalents with banks having external credit ratings of AA/A+.

## 18.3 Capital management

The Group manages its capital to ensure that companies in the Group 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 Group consists of net debt (borrowings as detailed in note 13 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 Group'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, 2019.

## **19. Contingencies**

### **Legal proceedings**

From time to time, the Group 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 Group. In accordance with IFRS, the Group 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 Group 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.

On January 1, 2017, the Group entered into a license and assignment agreement with Stichting VUmc, or the VUmc Agreement, for the contingent transfer of patent rights, and non-severable improvements. Under the VUmc Agreement, the Group is obligated to pay royalties, as well as a milestone payment in the case of certain events, including the listing of the majority of the shares of the Group on a recognized stock exchange, or ten years after the agreement's effective date. In accordance with IFRS, these obligations are not reflected in the accompanying consolidated statements of financial position.

## **20. Events after the reporting date**

### **Share-based Awards**

In January and February 2020, the Group granted to employees and consultants 1,335 share-based awards. The options granted under the share option programs vest in installments over a four-year period from the grant date. 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 granted are exercisable once vested.

### **Janssen agreement**

In May 2020, the Group entered into the Janssen Agreement. As part of the Janssen Agreement, the Group received a non-refundable upfront payment of €7.4 million. As of June 30, 2020, there was €6.8 million of unearned income related to this payment. The revenue has been recognized for two months beginning in May 2020. The unearned income is being recognized as revenue on a straight-line basis over the remaining 22-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. The Group 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 Group is eligible to receive a research milestone and further payments upon the achievement of certain development and commercial milestones. In December 2020, the Group achieved the first Research Milestone, as defined in the Janssen Agreement, triggering a milestone payment of €0.8 million.

### **Series C preferred financing**

In September 2020, the Group closed an oversubscribed financing of Series C Preferred that resulted in tranche-based commitments of €71.0 million gross and €62.2 million net, to fund the advancement of our pipeline and platform. In connection with the Series C Preferred financing, the Group agreed to sell the Series C Preferred in three tranches. On September 15, 2020, the first tranche of gross €19.1 million and 18,705 preferential shares, was funded and €4.1 million of Series A Preferred were repurchased, resulting in net proceeds of €15.0 million. Funding of the remaining two tranches is subject to satisfaction of certain milestones. If funded, the two remaining tranches would yield net proceeds of €47.2 million in the aggregate, after repurchasing the 3,250 shares of Series A Preferred and 750 common shares from one investor. Series C Preferred accrue an annual non-compounding dividend of 8% per subscription price per share.

## **Shares**



# **LAVA Therapeutics B.V.**

*Common shares*

## **Preliminary prospectus**

*Joint Book-running managers*

**J.P. Morgan**

**Jefferies**

**SVB Leerink**

*Lead manager*

**Wedbush PacGrow**

## Part II—Information not required in the prospectus

### Item 6. Indemnification of directors and officers

Under Dutch law, our directors may be held liable for damages in the event of improper or negligent performance of their duties. They may be held jointly and severally liable for damages to our company and to third parties for infringement of our articles of association or of certain provisions of Dutch law. In certain circumstances, they may also incur additional specific civil and criminal liabilities. Subject to certain exceptions, our articles of association provide for indemnification of our current and former directors and other current and former officers and employees as designated by our board of directors. No indemnification under our articles of association shall be given to an indemnified person:

- if a competent court or arbitral tribunal has established, without having (or no longer having) the possibility for appeal, that the acts or omissions of such indemnified person that led to the financial losses, damages, expenses, suit, claim, action or legal proceedings as described above are of an unlawful nature (including acts or omissions which are considered to constitute malice, gross negligence, intentional recklessness and/or serious culpability attributable to such indemnified person);
- to the extent that his or her financial losses, damages and expenses are covered under insurance and the relevant insurer has settled, or has provided reimbursement for, these financial losses, damages and expenses (or has irrevocably undertaken to do so);
- in relation to proceedings brought by such indemnified person against our company, except for proceedings brought to enforce indemnification to which he is entitled pursuant to our articles of association, pursuant to an agreement between such indemnified person and our company which has been approved by our board of directors or pursuant to insurance taken out by our company for the benefit of such indemnified person; and
- for any financial losses, damages or expenses incurred in connection with a settlement of any proceedings effected without our prior consent.

Under our articles of association, our board of directors may stipulate additional terms, conditions and restrictions in relation to the indemnification described above.

We have entered into or will enter into indemnification agreements with each of our current directors and executive officers.

### Item 7. Recent sales of unregistered securities.

Set forth below is information regarding share capital issued and options and warrants granted by us since January 1, 2018. None of the below described transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Some of the transactions described below involved directors, officers and 5% shareholders and are more fully described under the section of the prospectus titled "Related Party Transactions."

Since January 1, 2018, we have sold common shares in the following transactions that were not registered under the Securities Act:

The offers, sales and issuances of the securities described in the preceding paragraphs were exempt from registration either (a) under Section 4(a)(2) of the Securities Act in that the transactions were between an issuer and sophisticated investors or members of its senior executive management and did not involve any public offering within the meaning of Section 4(a)(2), (b) under Regulation S promulgated under the Securities

Act in that offers, sales and issuances were not made to persons in the United States and no directed selling efforts were made in the United States or (c) under Rule 701 promulgated under the Securities Act in that the transactions were under compensatory benefit plans and contracts relating to compensation.

## Item 8. Exhibits and financial statement schedules.

(a) The following exhibits are filed as part of this registration statement:

Exhibit number	Description of exhibit
1.1*	Form of Underwriting Agreement.
3.1**	English translation of Articles of Association of LAVA Therapeutics B.V. as they are in effect prior to completion of our corporate reorganization.
3.2*	English translation of Articles of Association of LAVA Therapeutics N.V. as they will be in effect immediately following the completion of our corporate reorganization.
3.3*	Form of internal rules of the board of directors of LAVA Therapeutics N.V., as they will be in effect immediately following the completion of our corporate reorganization.
3.4**	Form of Share Issue Deed.
5.1*	Opinion of NautaDutilh N.V., Dutch Counsel of the Registrant, as to validity of the common shares.
8.1*	Opinion of NautaDutilh N.V., Dutch counsel of the Registrant as to Dutch tax matters.
10.1*[†]	License and Assignment Agreement, dated as of January 1, 2017, by and among Lava Therapeutics, B.V., and Stichting Vumc.
10.2*[†]	Research Collaboration and Licence Agreement, dated as of May 13, 2020, by and among Lava Therapeutics, B.V., and Janssen Biotech, Inc.
10.3*	Form of Indemnification Agreement for directors and executive officers.
14.1*	Form of Code of Business Conduct and Ethics of the Registrant
21.1**	Subsidiaries of the Registrant.
23.1*	Consent of PricewaterhouseCoopers Accountants N.V.
23.2*	Consent of NautaDutilh N.V., counsel of the Registrant (included in Exhibit 5.1 and 8.1).
24.1*	Powers of attorney (included on signature page to the registration statement).

\* To be filed by amendment.

\*\* Filed herein.

† Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the Securities and Exchange Commission, certain portions of this exhibit have been redacted because they are not material.

### **(b) Financial statement schedules**

All schedules have been omitted because the information required to be set forth therein is not applicable or has been included in the consolidated financial statements and notes thereto.

## Item 9. Undertakings.

The undersigned registrant hereby undertakes:

- (a) The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.
- (b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions referenced in Item 14 of this registration statement, or otherwise, the registrant has been advised that in the opinion of the

## Table of Contents

Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered hereunder, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

## Signatures

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in \_\_\_\_\_ on \_\_\_\_\_, 2021.

**LAVA THERAPEUTICS B.V.**

By: \_\_\_\_\_  
Name: Stephen Hurly  
Title: Chief Executive Officer



## Power of attorney

We, the undersigned members of the board of directors, officers and authorized representative of LAVA Therapeutics B.V. hereby severally constitute and appoint Stephen Hurly and \_\_\_\_\_, and each of them singly, his or her true and lawful agent, proxy and attorney-in-fact, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to (i) act on, sign and file with the Securities and Exchange Commission any and all amendments (including post-effective amendments) to this Registration Statement together with all schedules and exhibits thereto and any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (iii) act on and file any supplement to any prospectus included in this Registration Statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and (iv) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
_____ Stephen Hurly	Chief Executive Officer (Principal Executive Officer)	, 2021
_____ Erik J. van den Berg	Chief Financial Officer (Principal Financial and Accounting Officer)	, 2021
_____ Joël J.P. Jean-Mairet, Ph.D.	Director and Chairperson of the Board	, 2021
_____ Nanna Lüneborg, Ph.D.	Director	, 2021
_____ Stefan Luzi, Ph.D.	Director	, 2021
_____ Guido Magni, M.D., Ph.D.	Director	, 2021

Authorized Representative in the United States

By: \_\_\_\_\_, 2021

Name:

Title:

*In this translation an attempt has been made to be as literal as possible without jeopardizing the overall continuity. Inevitably, differences may occur in translation, and if so the Dutch text shall prevail.*

## AMENDMENT OF ARTICLES OF ASSOCIATION LAVA THERAPEUTICS B.V.

This day, the fifteenth of September two thousand twenty, the following person appears before me, Cornelis Johannes Jozefus Maria van Gool, civil-law notary in Amsterdam:

Arlette Gerda Margaretha Vrolijk, employed at my office at the Jachthavenweg 130 in Amsterdam, the Netherlands, born in Amsterdam on the fifth day of October nineteen hundred ninety.

The person appearing before me hereby declares:

- (A) The articles of association of **LAVA Therapeutics B.V.**, a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*), having its seat in 's-Hertogenbosch and its address at Yalelaan 60, 3584 CM Utrecht, registered with the Trade Register under number 65335740 (the **company**) were most recently amended by deed executed on the thirty-first day of January two thousand eighteen before M.W. van der Zanden, civil-law notary in Amsterdam.
- (B) The general meeting (*algemene vergadering*) of the company has resolved to integrally amend the articles of association of the company.  
By virtue of this resolution the person appearing before me was authorised to have the deed of amendment of the articles of association executed.
- (C) This resolution and this authorisation appear from a shareholders' resolution which has been attached to this deed.

Subsequently, the person appearing before me declared, in pursuance of the referred resolutions, to integrally amend the articles of association of the company, so they will read as follows:

### CHAPTER I.

#### 1. Definitions

1.1 In these articles of association the following expressions shall have the following meanings:

- (a) **Shareholders:** the holders of shares in the capital of the Company;
- (b) **Accountant:** a registered accountant or other accountant as referred to in Section 2:393 DCC or as the case may be an organisation in which such accountants work together;
- (c) **General Meeting:** (i) the body of the Company formed by the Authorised Persons and (ii) the meeting of Authorised Persons;
- (d) **Management Board:** the management board of the Company, consisting of one or more managing directors;
- (e) **DCC:** Dutch Civil Code;
- (f) **ESOP:** the employee stock option plan adopted by the Company on the twentieth day of July two thousand seventeen and amended as of the date hereof, pursuant to which employees, directors and supervisory directors of the Company may receive an option right to purchase depositary receipts (*cetificaten van aandelen*) which are to be issued by Stichting Administratiekantoor LAVA Therapeutics as amended, supplemented, novated, restated or replaced from time to time;

- (g) **IPO:** an underwritten initial public offering (including a Qualified IPO) of all or any portion of the shares of any kind of the Company on (a) NASDAQ (National Association of Securities Dealers Automated Quotation), NYSE (New York Stock Exchange) or (b) another stock exchange qualifying as a market in financial instruments or, as the case may be, as a regulated market within the meaning of Directive 2004/39/EC of the European Parliament and of the Council of 21 April 2004 on markets in financial instruments;
- (h) **Annual Accounts:** the individual financial statements consisting of the balance sheet and profit and loss account with the explanatory notes and the consolidated financial statements if the Company draws up consolidated financial statements;
- (i) **Agreement:** the shareholders agreement relating to the Company, dated the fifteenth day of September two thousand twenty, as amended, supplemented, novated, restated or replaced from time to time;
- (j) **Qualified Board Majority:** the majority vote of four (4) Supervisory Directors C consisting of at least (i) two (2) votes from either the Supervisory Director C1, the Supervisory Director C2 or the Supervisory Director C3 as well as (ii) two (2) votes from either the Supervisory Director C4, the Supervisory Director C5 or the Supervisory Director C6;
- (k) **Qualified IPO:** an underwritten public offering of ordinary shares in relation to the Company on a United States stock exchange at a price per ordinary share no less than one point eight (1.8) times the subscription price of a cumulative preference C share as agreed between the Shareholders of the Company in the Agreement (the **First Tranche Series C Subscription Price**) and for a total offering of not less than sixty million United States Dollar (USO 60,000,000.-) (before deduction of underwriters commissions and expenses and adjusted for stock splits stock splits, combinations, recapitalizations or any other similar actions that have led to a different capitalization of the Company as if no such stock split, combination, recapitalization or any such other action had taken place);
- (l) **Qualified Preferred Majority:** the majority vote of (i) at least seventy per cent (70%) of the votes cast on the cumulative preference shares A, the cumulative preference shares B and the cumulative preference shares C and (ii) two/third (2/3) of the votes cast on the cumulative preference shares C;
- (m) **Supervisory Board:** the supervisory board of the Company, consisting of supervisory directors;
- (n) **in writing:** any communication sent by post, telefax, e-mail or by any other regular electronic device which can transmit text, unless expressly provided otherwise;
- (o) **Articles:** the articles of association of the Company;
- (p) **Company:** the private company with limited liability LAVA Therapeutics B.V. of which the Articles are included in this deed;
- (q) **Authorised Persons:** (i) Shareholders and (ii) pledgees who are entitled to vote in accordance with article 12 paragraph 3 of the Articles;
- (r) **Business Day:** a day other than a Saturday, a Sunday or any other day on which commercial banks in the Netherlands are authorized or required by law to be closed.

1.2 Unless the contrary is shown or it is manifestly intended otherwise, a reference to a concept or word in the singular includes a reference to the plural form of this concept or word and vice versa.

- 1.3 Unless the contrary is shown or it is manifestly intended otherwise, a reference to a male concept or word includes a reference to the female form of this concept or word and vice versa.

## **CHAPTER II.**

### **Name, seat, objects**

#### **2. Name and seat**

- 2.1 The name of the Company is:

**LAVA Therapeutics B.V.**

- 2.2 The registered seat of the Company is in Utrecht (the Netherlands).

- 2.3 The Company may have business offices, both in and outside of the Netherlands.

#### **3. Objects**

- 3.1 The objects of the Company are:

- (a) to, either individually or jointly or with other entities, engage in cellular therapy, immunotherapy and other oncological therapies and the fight against cancer (cells), as well as the development of products, intellectual property, the acquiring thereof and to register patentable findings and the performing of medical, commercial and industrial activities in the widest sense of the word;
- (b) to cooperate with, to participate in, to take over and to manage companies and other legal entities;
- (c) to finance companies and other legal entities, also by providing securities;
- (d) to acquire, manage and alienate registered property and items of property in general, securities and other valuable papers, to borrow and to lend funds and to grant guarantees on behalf of third parties;
- (e) to make periodic payments, to administer pension schemes and to arrange for annuity contracts, as well as everything pertaining to the foregoing, relating thereto or conducive thereto. The objects of the Company include to enhance and promote the interest of the group of companies of which the Company forms part.

## **CHAPTER III.**

### **Capital. Register.**

#### **4. Capital. Conversion**

- 4.1 The capital of the Company is divided into:

- (a) one or more ordinary shares, and/or
- (b) one or more (in ordinary shares convertible) cumulative preference shares A; and/or
- (c) one or more (in ordinary shares convertible) cumulative preference shares B; and/or
- (d) one or more (in ordinary shares convertible) cumulative preference shares C, of one cent (EUR 0.01) each.

4.2 All shares are registered shares.

The ordinary shares are continuously numbered from 1, the cumulative preference shares A are continuously numbered from CPA 1, the cumulative preference shares B are continuously numbered from CPB1 and the cumulative preference shares C are continuously numbered from CPC1.

No share certificates shall be issued.

4.3 If in the Articles **shares** are mentioned, this expression shall refer to ordinary shares, cumulative preference shares A, cumulative preference shares B and cumulative preference shares C, save as otherwise expressed.

4.4 At all times at least one share with voting right is or should be held by and for the account of a person other than the Company or any of its subsidiaries.

4.5 For each of the classes of shares a separate share premium reserve shall be maintained on behalf of the Shareholders of the relevant class.

4.6 Upon the written request of the holder of a specific class of shares to the Company, one or more cumulative preference shares A and/or one or more cumulative preference shares B and/or one or more cumulative preference shares C as the case may be shall be converted into ordinary shares, on a one for one basis.

The conversion as referred to in the previous sentence shall be effective per the date of receipt by the Company of the request as referred to in the previous sentence, which shall be evidenced by a corresponding entry by the Management Board in the shareholders register as referred to in paragraph 8 hereunder.

The Agreement contains certain provisions with respect to the optional conversion of shares.

4.7 Notwithstanding the previous paragraph, all issued cumulative preference shares A and all issued cumulative preference shares B and all issued cumulative preference shares C shall automatically convert into ordinary shares, on a one for one basis, upon the earlier to occur of:

- (a) a resolution of the General Meeting including the Qualified Preferred Majority to consent to a conversion of all cumulative preference shares A, cumulative preference shares B and cumulative preference shares C into ordinary shares; or
- (b) the closing of a Qualified IPO.

All holders of cumulative preference shares A, cumulative preference shares B and cumulative preference shares C shall be sent a written notice of the time and the place designated for the automatic conversion as referred to under (a) of this paragraph.

The Agreement contains certain provisions with respect to the automatic conversion of shares.

4.8 The Management Board shall, in case of a conversion as referred to in paragraph 6 or paragraph 7 of this article, register the change in the capital of the Company within eight (8) days with the Dutch Chamber of Commerce, if necessary, and enter such change in the shareholders register of the Company, the ordinary shares that come into existence as a result of the conversion shall be numbered in sequence to the last number of ordinary shares as issued before such conversion.

4.9 In the event one or more cumulative preference shares A and/or one or more cumulative preference shares B and/or one or more cumulative preference shares C are converted in ordinary shares in accordance with paragraph 6 or paragraph 7 of this article, the share premium reserve relating to such shares before the conversion will decrease in proportion to the total number of cumulative preference shares A or cumulative preference shares B or cumulative preference shares C respectively and this amount will be added to the share premium reserve relating to the ordinary shares.

## 5. Register of shareholders. Quality requirement

- 5.1 Each Shareholder, each usufructuary and each pledgee is required to give notice to the Company of their (email) address.
- 5.2 The Management Board shall keep a register in which the names and (email) addresses of all Shareholders are recorded, showing the date on which they acquired the shares, the date of the acknowledgement or notification, the class of shares that they hold and the amount paid on each share.
- The names and (email) addresses of usufructuaries and pledgees, showing the date on which they acquired such rights, specifying the rights attached to the shares and the date of the acknowledgement or notification, are also recorded in the register.
- 5.3 The register shall be kept accurate and up to date.
- All entries and notes in the register shall be signed by a managing director.
- 5.4 On application by a Shareholder, a usufructuary or a pledgee, the Management Board shall furnish an extract from the register, free of charge, insofar as it relates to his rights in a share.
- If a right of usufruct is vested on a share or if a share is pledged, the extract also sets forth who is entitled to exercise the voting rights attached to the share and/or who is entitled to attend the General Meeting.
- 5.5 The Management Board shall make the register available at the Company's office for inspection by the Authorised Persons.
- 5.6 If and insofar there are two (2) or more Shareholders, only parties that entered into or have adhered to the Agreement and in respect of whom the Agreement has not been terminated (the **Quality Requirement**), can be or become Shareholder.
- 5.7 As per the moment a Shareholder does not meet the Quality Requirement:
- (a) that Shareholder can no longer exercise the voting rights and the meeting rights in a General Meeting attached to the shares held by him and any rights on dividend or other distributions of that Shareholder will be suspended and that Shareholder is obliged to inform the Management Board and the other Shareholders thereof at the latest ten (10) days after such occurrence; and
  - (b) the shares concerned or all of the shares belonging to the Shareholder concerned (the **Offerer**) must be offered for sale to the other Shareholders.
- 5.8 For the application of this article **shares** shall be deemed to include **the right to subscribe for shares**.
- 5.9 The price to be paid for the shares offered for sale shall be determined by mutual agreement of the parties.
- If the parties should fail to reach such agreement, the price shall be determined by one (1) independent expert to be appointed by the Offeror and the prospective purchaser(s) by mutual consent.
- If no agreement is reached on the designation of the independent expert as referred to in the previous sentence, the price shall be determined by three (3) independent experts, all to be appointed by the chairman of the Dutch Institute for Register Valuers (*Vereniging Nederlands Instituut voor Register Valuers (NIRV)*).
- 5.10 The Offeror shall not be authorized to withdraw his offer.

- 5.11 If there should be no prospective purchasers or insufficient prospective purchasers among the other Shareholders to purchase for cash all the shares being offered for sale, the Offeror shall be entitled to retain the shares concerned.
- 5.12 If a Shareholder does not comply with the obligation to offer his shares within a reasonable period of time, the Company is irrevocably authorised to offer and transfer the shares.
- 5.13 When there are no prospective purchasers to whom the Shareholder can transfer his offered shares pursuant to this article, the authorisation is withdrawn and the Shareholder is irrevocably exempt from the obligation to offer and transfer the shares and his rights are no longer suspended.

#### **CHAPTER IV.**

##### **Issue of shares. Own shares.**

##### **6. Issue of shares. Body of the Company competent to issue shares. Conditions of issue**

- 6.1 The issue of shares may only be effected pursuant to a resolution of the General Meeting.  
The General Meeting may transfer its authority to resolve to issue shares.
- 6.2 A resolution for the issue of shares shall stipulate the price and further conditions of issue.

##### **7. Rights of pre-emption**

- 7.1 Upon an issue of shares, each Shareholder shall have a right of pre-emption in proportion to the number of shares held by such Shareholder, subject to the limitations set by law.
- 7.2 Prior to each single issue the right of pre-emption may be limited or excluded by the body of the Company authorised to issue.
- 7.3 The provisions in this article apply mutatis mutandis if options are granted to subscribe for shares, but do not apply to the issue of shares to someone who exercises a granted right to subscribe for shares.

##### **8. Payment for shares**

- 8.1 At the subscription of shares, the nominal amount of such shares must be paid.  
The subscriber for shares and the Company may agree, subject to the prior approval of the General Meeting, that only part of the nominal value of such shares must be paid up at the time of issue, or alternatively payment on such shares must be made in instalments, each after the expiration of a certain period of time or at the moment the Company claims the payment on the shares.
- 8.2 Unless another manner of payment has been agreed on, payment on a share must be made in cash.  
Payment in a currency other than the denominated nominal value of the shares can be made only after approval by the Company.  
When payment is made in a currency other than the denominated nominal value of the shares, the selling rate established by the European Central Bank on the date of the payment shall apply.
- 8.3 Payment in kind on a share requires the prior approval of the General Meeting.

##### **9. Own shares**

- 9.1 The Management Board decides whether or not the Company acquires shares in its own capital.

9.2 The Company may, subject to article 4 paragraph 4 of the Articles and the relevant provisions of the law, acquire fully paid up shares in its own capital or depository receipts thereof.

9.3 No voting rights may be exercised in the General Meeting for any share held by the Company or any of its subsidiaries.

9.4 In determining the number of votes cast by the Shareholders and to what extent the share capital is present or represented, or to what extent the share capital of the Company is provided or represented, no account is taken of shares in respect of which no vote can be cast.

#### **10. Issue or transfer of shares. Formalities**

10.1 The issue or transfer of shares or the transfer of a right *in rem* thereon shall require a deed drawn up for that purpose, executed before a civil-law notary registered in the Netherlands.

10.2 The transfer of shares or the transfer of a right *in rem* thereon also binds the Company by operation of law.

Unless the Company itself is party to the legal act, the rights attached to the shares can only be exercised after the Company has acknowledged said legal act or said deed has been served on the Company in accordance with the relevant provisions of the law.

### **CHAPTER V.**

#### **Capital reduction. Limited rights.**

##### **11. Capital reduction**

11.1 The General Meeting may resolve to reduce the issued capital of the Company by a cancellation of shares or by reduction of the nominal value of the shares by amendment of the Articles, with due observance of article 4 paragraph 4 of the Articles and the relevant provisions of the law.

11.2 A resolution to cancel shares held by the Company itself or of which the Company holds the depository receipts, may be effected without the Company's consent. In all other cases the cancellation of shares requires the consent of the Shareholders involved.

11.3 Reduction of capital may also be effected with respect to either the ordinary shares or the cumulative preference shares.

The capital reduction shall be effected in proportion to the shares included therein, unless all of the Shareholders concerned consent to deviate from this principle.

11.4 Any reduction of the nominal value of the shares without repayment and without a release of the obligation to pay up the shares must be made pro rata to all shares of the same class.

Such pro rata requirement may be waived with the consent of all Shareholders concerned.

11.5 Section 2:216 paragraph 2 through 4 DCC applies mutatis mutandis to a resolution to reduce the issued capital with repayment on the shares.

Repayment or a release of the obligation to pay up the shares within the meaning of Section 2:208 paragraph 4 DCC, is only allowed to the extent the net assets of the Company exceed the reserves which must be maintained under the law or the Articles.

##### **12. Usufruct, pledge on shares and depository receipts**

12.1 A right of usufruct or a right of pledge can be vested on the shares.



- 12.2 If a share is pledged or the Shareholder creates a right of usufruct on a share, the Shareholder remains entitled to exercise the voting rights.
- 12.3 Notwithstanding the provisions of paragraph 2 of this article, the pledgee shall have the voting rights on the shares if so provided—either under a condition precedent or otherwise—upon the establishment of the right of pledge or later in time agreed in writing between the Shareholder and the pledgee, provided the General Meeting has granted its prior approval to such transfer of voting rights.
- 12.4 Notwithstanding the provision of article 1 paragraph 1 under (n) the expression ‘in writing’ in paragraph 3 of this article means: by agreement or deed.
- 12.5 Section 2: 196a DCC and 2: 196b DCC apply *mutatis mutandis* to the written agreement or deed as referred to in paragraphs 3 and 4 of this article.
- 12.6 Holders of depository receipts do not have meeting rights as referred to in Section 2:227 paragraph 1 DCC.

## **CHAPTER VI.**

### **13. Blocking clause**

- 13.1 If the Quality Requirement as described in article 5 paragraph 6 of the Articles is no longer effective or if the Agreement is terminated, the statutory restrictions as referred to in Section 2:195 DCC apply to any transfer of shares in the capital of the Company.
- 13.2 In all other circumstances, a transfer of one or more shares by a Shareholder who meets the Quality Requirement may only be effected in accordance with the Agreement and provided that the civil-law notary (*notaris*) who is to execute the deed referred to in article 10 may request each Shareholder that meets the Quality Requirement to confirm compliance of such transfer or transmission with the Agreement.

## **CHAPTER VII.**

### **The Management Board.**

#### **14. Management Board**

- 14.1 The Management Board of the Company shall consist of one or more managing directors.
- 14.2 The General Meeting shall fix the number of managing directors.

#### **15. Appointment. Suspension and dismissal**

- 15.1 The General Meeting shall appoint the managing directors.
- 15.2 The General Meeting may suspend or dismiss the managing director at any time.

The managing directors can also be suspended by the Supervisory Board.

- 15.3 Every suspension may be extended one or more times, but the total term of suspension cannot exceed three (3) months.  
If the General Meeting does not terminate the suspension or resolve to dismiss the respective managing director within this period, the suspension ends.
- 15.4 The General Meeting shall determine the remuneration and further conditions of employment of the managing directors.

## **16. Duties of the Management Board**

- 16.1 Subject to the restrictions imposed by the Articles, the Management Board shall be entrusted with the management of the Company.
- 16.2 In fulfilling their duties the managing directors shall act in accordance with the corporate interests of the Company and its business.
- 16.3 The Management Board may, in consultation with the Supervisory Board, determine—in regulations or otherwise—the specific duties each managing director will be charged with.
- 16.4 The Management Board must follow the instructions of the General Meeting in respect of general lines of financial, social, economic and employment policies, unless it is in conflict with the interest of the Company or its business.

## **17. Decision-making process**

- 17.1 Meetings of the Management Board shall be held as often as a managing director deems such necessary.
- 17.2 The convocation shall take place not less than four (4) Business Days prior to the Management Board meeting unless all managing directors approve a shorter notice period.
- The notice for Managing Board meetings shall set out the place, date and time of the meeting and shall include an agenda identifying the matters to be discussed at the meeting.
- 17.3 Each managing director has the right to cast one (1) vote in Management Board meetings.
- 17.4 All resolutions shall be adopted by an absolute majority of the votes cast. If there is a tie of votes the proposal is rejected.
- 17.5 In case a managing director has a direct or indirect personal interest which conflicts with the interests of the Company and its business, such managing director will not participate in the deliberation and decision-making of the Management Board. If as a result hereof no resolution can be adopted by the Management Board, the resolution will be adopted by the Supervisory Board.
- 17.6 The Management Board may lay down regulations regarding its own decision-making process.
- 17.7 A managing director may be represented by another managing director authorised in writing.
- A managing director may not act as representative for more than one other managing director.
- 17.8 Meetings of the Management Board can be held by telephone conference, videoconference or any other electronic means of communication, provided that all managing directors can communicate with each other.
- 17.9 A managing director can attend a meeting of the Management Board by telephone conference, videoconference or any other electronic means of communication, provided this managing director can communicate with the other attending managing directors at all times and vice versa.
- 17.10 Resolutions of the Management Board may also be adopted in writing without recourse to a Management Board meeting, provided that all managing directors have been consulted and none of the managing directors has objected to this this form of decision-making.

## **18. Representation. Proxy holders**

- 18.1 The Management Board shall be authorised to represent the Company.
- In addition, each managing director is solely authorised to represent the Company.

18.2 The Management Board may appoint persons with general or limited power to represent the Company.

Each of those persons shall be authorised to represent the Company with due regard to any restrictions imposed on him.

18.3 The Management Board can determine to grant a specific title to the persons as referred to in paragraph 2 of this article.

#### **19. Approval of decisions of the Management Board**

19.1 The General Meeting as well as the Supervisory Board is entitled to require resolutions of the Management Board to be subject to its approval.

These resolutions shall be clearly specified and notified to the Management Board in writing.

19.2 Without prejudice to any other appropriate provision of these Articles, the Management Board shall obtain the approval of Supervisory Board for managerial decisions with respect to any one or more of the following matters:

- (a) any transaction with any related party or parties that, in the aggregate, exceeds ten per cent (10%) of the approved budget;
- (b) entering into a clinical trial application (CT A) or investigational new drug Applications (IND) application procedure;
- (c) any transaction or series of transactions that in the aggregate would result in the incurrence by the Company of indebtedness for borrowed money, including guarantees of the obligations of others and capitalized leases and similar financing arrangements in excess of one hundred thousand euro (EUR 100,000.-);
- (d) guarantee any indebtedness;
- (e) modification of the strategy of the Company's activities, including without limitation, the determination and modification of the budget, including the business plan;
- (f) the appointment, suspension and dismissal of any key executive and any managing director), any decision concerning the contractual relationship between the Company on the one hand and any key executive on the other, and the grant of any debt owed by or to a key executive;
- (g) initiate any litigation;
- (h) the appointment of agents or any financial or legal advisors in connection to the listing of the Company's shares on a stock exchange market;
- (i) any transaction relating to intellectual property rights owned or controlled by the Company or a third party;
- (j) disposing of any material asset of the Company or terminating the business of the Company or a substantial part thereof involving an amount exceeding one hundred thousand euro (EUR 100,000.-);
- (k) establishment of pension plans and granting pension rights in excess of those arising from existing arrangements;

- (l) the application to have shares in the capital of the Company listed at a stock exchange as well as any action to prepare for such listing;
- (m) undertaking any such legal acts as will be determined and clearly defined by the Supervisory Board and notified to the Management Board in writing;
- (n) direct or indirect participation in the capital of another company and changing the size of such participation;
- (o) long term direct or indirect cooperation with another company, entity or person involving an amount exceeding one hundred thousand euro (EUR 100,000.-), including termination of such cooperation;
- (p) any (voluntary) dissolution and liquidation of the Company (including the appointment and remuneration of the liquidator(s));
- (q) the incorporation, relocation or liquidation of subsidiaries, branches or enterprises, purchase or sale of shareholdings in other companies as well as the purchase of other businesses in whole or in essential parts;
- (r) any acquisition, investment, capital expenditure, sale or lease of assets, major licensing or distribution agreement, or creation of a contract to the extent that (i) such transaction or series of related transactions has a cost or value to the Company exceeding one hundred thousand euro (EUR 100,000.-) in the aggregate over a twelve (12) month period and (ii) was not budgeted for in the annual budget (excluding ordinary business);
- (s) disposal of intellectual property rights and the conclusion or termination of patent, license, know-how and cooperation agreements in relation to intellectual property, if and insofar such disposal, conclusion or termination exceeds the ordinary course of business of the Company or the disposal or series of related disposals of any other essential assets of the Company outside the ordinary course of business for a value exceeding one hundred thousand euro (EUR 100,000.-) in the aggregate;
- (t) the granting of security interests over the Company's assets, provision of personal securities, guarantees and joint liabilities as well as acceptance of liabilities, except for such measures that are within the ordinary course of business of the Company;
- (u) conclusion, modification or termination of any contract, financial arrangement or other transaction between, on the one hand, the Company or one of its affiliates (if any) and, on the other hand: (i) a Shareholder or (ii) a manager of the Company or (iii) a related person of a shareholder or a manager of the Company;
- (v) the amendment of the ESOP, grant of options under the ESOP or depositary receipts under Stichting Administratiekantoor LAVA Therapeutics, or adopting a new plan to incentivise key employees;
- (w) determination of remuneration and bonuses of key employees;
- (x) proposal to dissolve and liquidate the Company or entering into bankruptcy proceedings or filing for a suspension of payments on behalf of the Company;
- (y) borrow or lend money or enter into any other financing transactions, excluding ordinary business;
- (z) initiate a sales process in relation to the fifty per cent (50%) or more of the shares of the Company or a substantial part of its assets;

- (aa) enter into settlement agreements or conduct any litigation, except for legal actions that cannot be postponed or the purpose of which is solely to reserve rights and also except for measures taken to collect money claims on account of goods delivered or services rendered by the Company.
  - (bb) increase or decrease the minimum coverage of the Company's (managing) directors' and officers' liability insurance.
  - (cc) repurchase (*inkoop*) of shares in the Company's own capital, shares in the capital of a subsidiary or depositary receipts representing any such shares or the delegation of powers with respect to the approval of the purchase of the Company's own shares.
- 19.3 Without prejudice to any other appropriate provision of these Articles, the Management Board shall obtain the prior approval of the General Meeting with a Qualified Preferred Majority for the resolutions set out in article 28 paragraph 9 of the Articles taken by the Company in its capacity as shareholder.
- 19.4 The lack of approval referred to in paragraphs 1 and 2 of this article does not affect the authority of the Management Board or the directors to represent the Company.

## **20. Absence or prevention**

- 20.1 If a managing director is absent or prevented from performing his duties, the remaining managing directors or managing director shall be entrusted with the entire management of the Company.
- 20.2 If all managing directors, or the sole managing director, are or is absent or prevented from performing their/its duties, the management of the Company shall be temporarily entrusted to the person designated for this purpose by the General Meeting.
- This person takes all necessary steps to provide for a final measure as soon as possible.
- 20.3 In the Articles the expression 'absent' includes the situation in which a managing director is (temporarily) not able to perform his duties due to suspension, missing or long-term illness.

## **CHAPTER VIII.**

### **Supervisory Board.**

#### **21. Supervisory Board. Appointment. Suspension and dismissal. Remuneration.**

- 21.1 The Company shall have a Supervisory Board, consisting of a maximum of eight (8) supervisory directors.
- With due observance of the provisions of the previous sentence, the General Meeting shall determine the number of supervisory directors.
- Only natural persons can be supervisory directors.
- 21.2 The supervisory directors shall be appointed as follows:
- (a) one (1) supervisory director shall be appointed by the General Meeting upon the binding nomination of the holder of cumulative preference share with number CPC1 (the **Supervisory Director C1**);
  - (b) one (1) supervisory director shall be appointed by the General Meeting upon the binding nomination of the holder of cumulative preference share with number CPC3, 165 (the **Supervisory Director C2**);

- (c) one (1) supervisory director shall be appointed by the General Meeting upon the binding nomination of the holder of cumulative preference share with number CPC6,329 (the **Supervisory Director C3**);
- (d) one (1) supervisory director shall be appointed by the General Meeting upon the binding nomination of the holder of cumulative preference share with number CPC7,383 (the **Supervisory Director C4**);
- (e) one (1) supervisory director shall be appointed by the General Meeting upon the binding nomination of the holder of cumulative preference share with number CPC11,339 (the **Supervisory Director C5**);
- (f) one (1) supervisory director shall be appointed by the General Meeting upon the binding nomination of the holder of cumulative preference share with number CPC13,712 (the **Supervisory Director C6** and the Supervisory Director C1, the Supervisory Director C2, the Supervisory Director C3, the Supervisory Director C4, the Supervisory Director C5 and the Supervisory Director C6 jointly the **Supervisory Directors C**); and
- (g) two (2) supervisory directors shall be appointed by the General Meeting (each an **Independent Supervisory Director**) upon the binding nomination of the Supervisory Board, adopted in a meeting of the Supervisory Board with a Qualified Board Majority.

If the nomination contains only one candidate for one vacancy, then the resolution regarding the nomination has the effect that the candidate is appointed, unless the nomination is deprived of its binding character.

The General Meeting may by a resolution passed with a two-thirds majority of the votes cast representing more than one half of the issued capital, resolve that the nomination shall not be binding.

21.3 Every supervisory director may be suspended or dismissed by the General Meeting at any time.

21.4 The General Meeting shall grant the title Chairman to an Independent Supervisory Director.

21.5 Unless the General Meeting has resolved otherwise, supervisory directors shall not receive any remuneration.

## **22. Duties and powers. Proceedings and decision making process**

22.1 It shall be the duty of the Supervisory Board to supervise the management of the Management Board and the general course of affairs in the Company and in the business connected with it.

The Supervisory Board shall assist the Management Board with advice.

In performing their duties the supervisory directors shall act in accordance with the corporate interests of the Company and of the business connected with it.

22.2 The Supervisory Board shall meet at least five (5) times a year and whenever a supervisory director deems such necessary.

22.3 The convocation shall take place not less than ten (10) Business Days prior to the Supervisory Board meeting unless all supervisory directors approve a shorter notice period.

The notice for Supervisory Board meetings shall set out the place, date and time of the meeting and shall include an agenda identifying the matters to be discussed at the meeting.

22.4 Each supervisory director has the right to cast one (1) vote in Supervisory Board meetings.

Resolutions of the Supervisory Board:

- (a) other than as listed in article 19 paragraph 2 of the Articles, shall be adopted by a simple majority of the votes cast;
- (b) listed in article 19 paragraph 2 of the Articles, shall be adopted with a simple majority of the votes cast, including a Qualified Board Majority, in a meeting where at least four (4) Supervisory Directors C are present, either in person or in accordance with paragraph 8 of this article, or represented.

If in such meeting this quorum is not present or represented, the meeting shall be adjourned upon notice to the supervisory directors, stating that the meeting has been adjourned due to lack of quorum and by setting a new date and time, in accordance with paragraph 3 of this article.

No quorum requirements shall apply to any such second meeting.

The Agreement contains certain provisions with respect to resolutions of the Supervisory Board.

In the event of a tie of votes, the proposal is rejected, provided that if there is a tie of votes and the Supervisory Board is composed of eight (8) supervisory directors the resolution shall be adopted by the General Meeting, with the approval of two-third (2/3) of the votes cast on the cumulative preference shares C.

- 22.5 In case a supervisory director has a direct or indirect personal interest which conflicts with the interests of the Company and its business, such supervisory director will not participate in the deliberation and decision-making of the Supervisory Board.

If as a result hereof no resolution can be adopted by the Supervisory Board, the resolution will be adopted by the General Meeting.

- 22.6 A supervisory director may be represented by another supervisory director authorised in writing.

A supervisory director may not act as representative for more than one other supervisory director.

- 22.7 Meetings of the Supervisory Board can be held by telephone conference, videoconference or any other electronic means of communication, provided that all supervisory directors can communicate with each other.

- 22.8 A supervisory director can attend a meeting of the Supervisory Board by telephone conference, videoconference or any other electronic means of communication, provided this supervisory director can communicate with the other attending supervisory directors at all times and vice versa.

- 22.9 Resolutions of the Supervisory Board may also be adopted in writing without recourse to a Supervisory Board meeting, provided that all supervisory directors have been consulted and none of the supervisory directors has objected to this form of decision-making

- 22.10 The Supervisory Board shall meet together with the Management Board as often as the Supervisory Board or the Management Board deems such necessary.

- 22.11 In the event that a supervisory director is absent or prevented from performing his duties, the person designated thereto by the holder of the cumulative preference share that is authorised to nominate such supervisory director (i) shall be entrusted with the tasks (including, but not limited to, the right to vote in supervisory board meetings) of such supervisory director and (ii) will have the same rights as such supervisory director.

- 22.12 In the Articles the expression ‘absent’ shall include the situation in which a supervisory director is (temporarily) not able to perform his duties due to suspension, a conflict of interest as referred to in article 22 paragraph 5, missing or long-term illness.

## **CHAPTER IX.**

### **Annual accounts. Profits.**

- 23. Financial year. Drawing up of the annual accounts. Accountant**

23.1 The financial year shall be the calendar year.

23.2 Annually, not later than five (5) months after the end of the financial year, unless by reason of special circumstances this term is extended by the General Meeting for a period not exceeding five (5) months, the Management Board shall draw up the Annual Accounts and make these available for inspection by the Authorised Persons and the Supervisory Board at the Company’s office.

Within this period the Management Board also makes the management report available for inspection by the Authorised Persons and the Supervisory Board, unless the provisions of Section 2:396 paragraph 7 or Section 2:403 DCC apply.

23.3 The Annual Accounts shall be signed by all managing directors and all supervisory directors.

If the signature of one or more of them is lacking, this shall be expressly stated and explained.

23.4 If the Annual Accounts provide for a dividend payment proposed by the Management Board, this proposal should be considered as approval as mentioned in article 25 paragraph 8.

23.5 The Company may, and if the law so requires shall, appoint an Accountant to audit the Annual Accounts.

- 24. Adoption of the annual accounts. Discharge. Publication.**

24.1 The General Meeting shall adopt the Annual Accounts.

Adoption of the Annual Accounts shall not automatically discharge a managing director or supervisory director.

The General Meeting may discharge a managing director or a supervisory director by a separate resolution.

24.2 The Company shall make the Annual Accounts publicly available within eight (8) days following the adoption thereof, unless a statutory exemption is applicable.

- 25. Profit. Reserves**

25.1 The General Meeting is authorised to resolve to allocate the profits as determined by virtue of the adoption of the Annual Accounts.

The Agreement contains certain provisions with respect to the (distribution of) profits.

25.2 The General Meeting is authorised to determine a distribution of the profits, to the extent that its net assets exceed the reserves which must be maintained under the law or the articles of association.

25.3 The General Meeting may resolve to distribute the reserves in whole or in part, taking into account the relevant statutory provisions.



- The Agreement contains certain provisions with respect to the (distribution of) reserves.
- 25.4 The General Meeting, may resolve to pay interim-dividend, taking into account the relevant statutory provisions.  
The Agreement contains certain provisions with respect to the (distribution of) interim-dividend.
- 25.5 Any resolution of the General Meeting to make a distribution, as referred to in the previous paragraphs of this article, shall be without any effect until the Management Board has granted its approval to such resolution.
- 25.6 The Management Board shall only withhold the approval as referred to in paragraph 5 of this article, if the Management Board is aware or reasonable should be aware of any circumstances by virtue of which the Company cannot continue to meet its obligations in the foreseeable future after the relevant distribution.

## **CHAPTER IX.**

### **General Meetings.**

#### **26. General Meetings**

Each fiscal year, either one General Meeting shall be held, or the Shareholders shall resolve in accordance with article 29 of the Articles.

#### **27. Convocation. Place of the meeting**

- 27.1 Authorised Persons are called to attend a General Meeting by the Management Board, by the Supervisory Board or by any Shareholder holding at least ten per cent (10%) of the issued share capital of the Company, under the obligation to notify the Management Board of such convocation.
- 27.2 General Meetings shall be convened in writing to the addresses of the Authorised Persons as set out in the shareholders' register or, with the consent of the Authorised Persons, by means of a legible and reproducible notice sent by electronic means of communication to the address provided for this purpose.
- 27.3 The convocation shall specify the subjects to be addressed in the General Meeting.
- 27.4 As to subjects brought up for discussion which were not included in the convocation, no valid resolutions can be adopted unless all Authorised Persons agree with the decision-making on these subjects and all managing directors and all supervisory directors have had the opportunity to give their advice to the General Meeting.
- 27.5 The convocation shall take place no later than on the eighth (8th) day prior to the date of the General Meeting.  
If the meeting has been convened less than eight (8) days before the date of the General Meeting, or if there was no convocation at all, valid resolutions may still be adopted provided that all Authorised Persons consent with the decision-making on the subjects to discuss and all managing directors and all supervisory directors have had the opportunity to give their advice to the General Meeting.
- 27.6 General Meetings shall be held in the municipality in which the Company has its registered seat according to the Articles and in Amsterdam, Rotterdam, Schiphol (municipality Haarlemmermeer) and 's-Hertogenbosch.
- 27.7 General Meetings can be held elsewhere, provided that all Authorised Persons have consented on this place of the meeting and all managing directors and all supervisory directors have had the opportunity to give their advice to the General Meeting.

**28. Attending the General Meeting. Decision-making of the General Meeting**

- 28.1 Each Authorised Person shall be authorised to attend and address the General Meeting, either in person or by written proxy.
- 28.2 Each Authorised Person with the right to vote, is authorised to exercise his voting right in the General Meeting either in person or by written proxy.
- 28.3 If needed, the Management Board may create the possibility for Authorised Persons to attend, speak, participate in the deliberation and, as far as such Authorised Person has the right to vote, to exercise his voting right in the General Meeting, either in person or by proxy, through electronic means of communication.

The Management Board shall determine the further rules and conditions for the aforesaid use of electronic means of communication, provided that each Authorised Person that wishes to make use of the facility contemplated in this paragraph can provide a valid form of identification to the Management Board.

All further rules and conditions determined by the Management Board must be specified in the convocation notice.

- 28.4 The Management Board may determine that each Authorised Person with the right to vote is authorised to cast his vote via electronic means of communication during a certain period prior to the General Meeting. Such period is to be decided by the Management Board, provided that this period cannot commence earlier than thirty (30) days before the day of the General Meeting.

Votes cast in accordance with the previous sentence are considered equal to votes cast during the General Meeting.

- 28.5 Each Authorised Person or its representative attending the General Meeting, must sign the attendance-list.

In addition the chairman identifies which Authorised Persons or representatives thereof attend and/or vote at the General Meeting through electronic means of communication.

- 28.6 Each share provides for the right to cast one (1) vote in a General Meeting.

- 28.7 Blank and invalid votes are considered not to be cast.

- 28.8 To the extent that the law or the Articles do not require otherwise and with due observance of paragraph 9 of this article, all resolutions of the General Meeting shall be adopted by a simple majority of the votes cast in a meeting in which more than fifty per cent (50%) of the issued capital is present or represented.

When the aforesaid quorum is not represented at such meeting, a second meeting can be convened to be held not less than two (2) weeks and not more than four (4) weeks after the first meeting, upon notice to the Shareholders stating that the meeting has been adjourned due to lack of quorum.

The notice shall also state that the adjourned meeting shall be held the same time and location as the original meeting.

Further, the notice shall state that, and it shall be the case that, at such adjourned meeting any resolutions shall be adopted by a simple majority of the votes cast (unless the law or the Articles prescribe a larger majority in respect of any such resolution), regardless the issued capital that is present or represented at such adjourned meeting.

28.9 A resolution of the General Meeting relating to the following matters:

- (a) any amendments to the Management Board or the Supervisory Board, including but not limited to its size and composition;
- (b) any amendment of the Articles or the Agreement;
- (c) the issuance of shares or to grant the right to subscribe for shares in the Company's capital;
- (d) the exclusion or limitation of pre-emption rights in case of issuance of shares or a grant of rights to subscribe for shares in the Company's capital;
- (e) transfer or revocation of the authority to exclude or limit pre-emption rights to another corporate body;
- (f) the transfer or revocation of the authority to issue shares or to grant the right to subscribe for shares in the Company's capital to another corporate body;
- (g) a reduction of the Company's issued capital (including the redemption of shares);
- (h) statutory merger or statutory demerger;
- (i) the remuneration and further terms and conditions of employment for each of the members of the Management Board and the remuneration of the Supervisory Board;
- U) changing accounting principles and policies;
- (j) the granting of profit rights;
- (k) any declaration or payment of a dividend or any other distribution of profits or reserves;
- (l) the appointing, suspending, (to the extent permitted by law) dismissing or releasing from liability (decharge verlenen) any managing directors or determine or vary any terms of their appointment (including the employment conditions and remuneration of the managing directors);
- (m) determining or amending the terms of appointment (including remuneration) of the Supervisory Board;
- (n) the adoption of schemes or arrangements in relation to the granting of bonuses or profit rights to the members of the Management Board or employees of the Company;
- (o) the appointment, revocation and remuneration of the statutory auditor;
- (p) the adoption of the Company's annual accounts;
- (q) guarantee any indebtedness;
- (r) transfer of the registered office of the Company outside the Netherlands; and
- (s) changing the nature of the Company's business, shall be adopted with a simple majority of votes which majority is to include a Qualified Preferred Majority.

28.10 The General Meeting shall itself appoint a chairman.

Until that moment a managing director shall act as chairman and in the absence of such a member the eldest person present at the meeting shall act as chairman.

The chairman shall appoint the secretary of the General Meeting.

28.11 The chairman determines the voting procedure, provided that if one of the attending persons with the right to vote requests so, the voting on appointment, suspension and dismissal of persons will take place by sealed and unsigned ballots.

28.12 Minutes must be kept of the proceedings of each meeting.

28.13 The managing directors and supervisory directors shall, as such, have the right to attend the General Meeting and give advice in the General Meeting.

### **29. Resolutions outside of meetings. Records**

29.1 Resolutions of Shareholders may also be adopted in writing without recourse to a General Meeting, provided that all Authorised Persons gave their consent to this form of decision-making.

Consent to this form of decision-making can be given by electronic means of communication.

The votes shall be cast in writing.

If the resolution is in writing and mentions the way in which each Shareholder casts its vote, this should be considered as voting in writing as referred to in this article.

29.2 The managing directors and supervisory directors shall be given the opportunity to give prior advice on the resolutions as mentioned in paragraph 1 of this article.

29.3 The Management Board shall keep a record of the resolutions thus made.

Each of the Shareholders must procure that the Management Board is informed in writing of the resolutions made in accordance with paragraph 1 of this article as soon as possible.

The records shall be deposited at the offices of the Company for inspection by the Authorised Persons. Upon request each of them shall be provided with a copy or an extract of such record at not more than the actual costs.

### **30. Meeting of holders of a specific class of shares**

30.1 A meeting of holders of a specific class of shares or a joint meeting shall be held whenever a resolution of such meeting is required.

Furthermore such meeting shall be held in the event either the Management Board or a holder of shares of the class concerned, deems such useful.

30.2 In the event one or more persons mentioned in paragraph 1 of this article request for a meeting of holders of shares of a specific class or a joint meeting to be held, they shall notify the Management Board.

Each of the requesters is authorized to convene the meeting, if none of the managing directors convenes the meeting in such a way that it shall be held within fifteen (15) days after receipt of the request.

30.3 The provisions of article 27 up to and including 29 apply mutatis mutandis to meetings of holders of shares of a specific class or a joint meeting, with the exception of articles 28 paragraph 13 and article 29 paragraph 2.

## **CHAPTER X.**

### **Merger. Demerger. Conversion. Amendment of the Articles. Dissolution. Liquidation.**

#### **31. Resolutions and proposals**

When a proposal to enter into a legal merger or legal demerger, to convert the Company, to amend the Articles or to dissolve the Company is to be made to the General Meeting, this must be mentioned in the notification of the General Meeting. As regards an amendment of the Articles, a copy of the proposal including the text of the proposed amendment must at the same time be deposited and held available at the offices of the Company for inspection by the Authorised Persons until the end of the meeting.

#### **32. Liquidation**

- 32.1 In the event of dissolution of the Company by virtue of a resolution of the General Meeting, the managing directors will be entrusted with the liquidation of the business of the Company, unless the General Meeting appoints one or more other persons. The Supervisory Board shall be charged with the supervision of the liquidation.
- 32.2 During liquidation, the provisions of the Articles shall remain in force as far as possible.
- 32.3 The Agreement contains certain provisions with respect to the distribution of the liquidation surplus.
- 32.4 After the Company has ceased to exist, the books, records and other database of the Company shall remain at the person appointed thereto by the liquidator for seven (7) years.

#### **Final statement**

Finally the appearing person declared upon the current amendment to the articles of association taking effect, the issued and paid-up capital remains unchanged and amounts to two hundred seventy-six euro sixteen cent (EUR 276.16).

#### **Conclusion of the deed**

The person appearing before me, whose identity I, civil-law notary, have established by means of the document referred to in this deed, is known to me, civil-law notary.

#### **THIS DEED**

a concise summary of the contents of which was stated to the person appearing before me, drawn up to be kept in the civil-law notary's custody was executed in Amsterdam on the date first above written.

I, civil-law notary, informed the person appearing before me of the substance and subsequently explained the contents of this deed.

I also informed that person of the consequences which this deed would have on the party to the deed.

The person appearing before me subsequently declared to have taken note of the contents of this deed, to consent thereto and to not require it to be read out in full.

After some clauses of this deed had been read out, it was then signed by the person appearing before me and by me, civil-law notary.

**DEED OF ISSUE  
LAVA THERAPEUTICS N.V.**

**THIS DEED IS ENTERED INTO ON [DATE] BY**

**LAVA Therapeutics N.V.**, a public company with limited liability, having its corporate seat in Utrecht (address: Yalelaan 60, 3584 CM Utrecht, trade register number: 65335740) (the “**Company**”).

**NOW HEREBY AGREES AS FOLLOWS**

**1 DEFINITIONS AND INTERPRETATION**

**1.1 Definitions**

1.1.1 In this Deed the following definitions shall apply:

<b>Deed</b>	This deed of issue.
<b>DTC</b>	Cede & Co., a partnership under the laws of the State of New York, United States of America, as nominee for The Depository Trust Company, a corporation under the laws of the State of New York, United States of America.
<b>Issue Price</b>	The issue price per Offer Share of USD [ <i>issue price</i> ].
<b>Offer Shares</b>	[ <i>number</i> ] Common Shares.
<b>Offering</b>	The initial public offering of Common Shares and the admission to listing and trading of the Common Shares on the Nasdaq Stock Market.
<b>Common Shares</b>	Common shares in the Company’s capital, having a nominal value of EUR [0.12] each.
<b>Resolutions</b>	The written resolutions of the Company’s general meeting and the Company’s pricing committee, each dated [ <i>date</i> ].
<b>Transfer Agent</b>	[American Stock Transfer & Trust Company, LLC], a limited liability company under the laws of the State of New York, United States of America, in its capacity of the Company’s transfer agent.
<b>Underwriters</b>	The underwriters in the Offering, listed in [Schedule 1] to the Underwriting Agreement.
<b>Underwriting Agreement</b>	The underwriting agreement dated [ <i>date</i> ] between the Company and (representatives of) the Underwriters.

## **1.2 Interpretation**

- 1.2.1 Terms that are defined in the singular have a corresponding meaning in the plural and vice versa.
- 1.2.2 Although this Deed has been drafted in the English language, this Deed pertains to Dutch legal concepts. Any consequence of the use of English words and expressions in this Deed under any law other than Dutch law shall be disregarded.
- 1.2.3 The titles and headings in this Deed are for construction purposes as well as for reference. No party may derive any rights from such titles and headings.

## **2 ISSUANCE**

### **2.1 Issuance of Offer Shares**

- 2.1.1 In giving effect to the Resolutions and the Company's obligations under the Underwriting Agreement, the Company issues the Offer Shares to DTC, for further credit to, or as directed by, the several Underwriters in accordance with the terms of the Underwriting Agreement.
- 2.1.2 Upon the Offer Shares being credited to the several Underwriters in the book-entry systems of DTC, DTC shall be considered to have accepted the Offer Shares.

### **2.2 Payment**

- 2.2.1 The aggregate Issue Price for the Offer Shares has been satisfied in accordance with the terms of the Underwriting Agreement and the Company grants a discharge for the payment thereof.
- 2.2.2 The Company approves payment of the Issue Price in a currency other than euro.
- 2.2.3 To the extent that the aggregate Issue Price for the Offer Shares exceeds the aggregate nominal value of the Offer Shares, such excess shall be considered to be share premium and shall be added to the Company's share premium reserve attached to the Common Shares.

### **2.3 Registration**

- 2.3.1 Promptly following the execution of this Deed, the Company shall (i) register the present issuance of the Offer Shares in its register within the meaning of Section 2:85 of the Dutch Civil Code and (ii) cause the Transfer Agent to register the Offer Shares in the register maintained by the Transfer Agent in respect of the Common Shares.

---

**3 MISCELLANEOUS PROVISIONS**

**3.1 No rescission or nullification**

3.1.1 To the extent permitted by law, the Company waives its rights to rescind or nullify or to demand the rescission, nullification or amendment of this Deed, in whole or in part, on any grounds whatsoever.

**3.2 Governing law**

3.2.1 Without prejudice to the relevant provisions of Chapters 4 and 5 of Title 10 of Book 10 of the Dutch Civil Code, this Deed shall be governed by and construed in accordance with the laws of the Netherlands.

**3.3 Jurisdiction**

3.3.1 Any dispute in connection with this Deed shall be submitted to the exclusive jurisdiction of the competent court in Amsterdam, the Netherlands.

*(signature page follows)*



LAVA Therapeutics N.V.

Name :

Title :

## Subsidiaries

<u>Name of Subsidiary</u>	<u>State or Other Jurisdiction of Incorporation</u>
Lava Therapeutics, Inc.	Delaware (United States)